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ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Chairman/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARZO 2013

INTRODUCTION

The Procedure Manual is an administrative tool, the importance of which is based on the fact that it describes the logical and chronological sequence of related operations or tasks (procedures) that are carried out in each of the structural and functional areas of the Institute, and that it specifies who, how, when, where and for what purpose said operations or tasks are performed.

The purpose of describing procedures is to standardize and document tasks and to guide the persons who carry them out.

The Research Ethics Committee of the *National Institute of Medical Sciences and Nutrition Salvador Zubirán* (the Salvador Zubiran National Institute of Medical Sciences and Nutrition) is an autonomous, institutional support organization set up in accordance with the standards established in the General Health Act of Mexico, to supervise the safety and protection of the rights of humans that take part in research projects. Its functions are based on a thorough examination of the ethical research requirements established in the Operating Guidelines for Ethics Committees that supervise Biomedical Research, published by the World Health Organization, and as established in Title V, Health Research, of the General Health Act of Mexico.

For the purpose of the manual, biomedical research includes pharmaceutical research, medical, medical radiation and imaging equipment, surgical procedures, clinical records and biological samples, and epidemiological, social and psychological research. The purpose of these Guidelines is to facilitate and assist the tasks of the Research Ethics Committee of the National Institute of Medical Sciences and Nutrition *Salvador Zubirán*.

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I. PURPOSE OF THE MANUAL

The purpose of the manual is to lay down the guidelines for the tasks of the Ethics Committee of the National Institute of Medical Sciences and Nutrition *Salvador Zubirán*, that meets jointly with the Research Committee, in order to specify the logical sequence of the steps of each procedure, and the operating responsibility of the members and staff of each working area, and describes graphically the flow of tasks, and also helps to educate and orientate new employees of the Institute, so as to assist them in the performance of their functions.

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II. - LEGAL FRAMEWORK

The Mexican Political Constitution
Official Gazette of the Federation 05-II-1917 Reforms and Additions.

LEGISLATION

The General Health Act
Official Gazette of the Federation 7-II-1984 Reforms and Additions.

The National Health Institutes Act.
Official Gazette of the Federation 26-V-2000.

The Transparency and Access to Public Government Information Act.
Official Gazette of the Federation 11-VI-2002.

REGULATIONS

The Health Research Regulations of the General Health Act.
Official Gazette of the Federation 6-I-1987.

The Regulations of the Federal Transparency and Access to Public Government Information Act.
Official Gazette of the Federation 11- IV-2003.

OTHER LOCAL LEGISLATION

The Organic Charter of the Institute
Approved by the Board of Governors on 25-III-2009

The National Development Plan 2007-2012.
Official Gazette of the Federation 30-V-2007.

The Sectorial Health Program 2007-2012.
Official Gazette of the Federation 17-I-2008.

INTERNATIONAL REFERENCES

The following international references that the Institute observes must also be included:

- The Helsinki Declaration – Ethical principles for medical research carried out on human beings.
- Good Clinical Practices, of the ICH (E6).
- Operational Guidelines for Ethics Committees that Review Biomedical Research, of the WHO.
- The Universal Declaration on Bioethics and Human Rights.
- International Ethical Guidelines for Biomedical Research that Involves Human Beings, issued by the Council for International Organizations of Medical Sciences (CIOMS).
- The Belmont Report.

III. PROCEDURES

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1. PROCEDURE FOR SELECTING PERMANENT MEMBERS OF THE RESEARCH ETHICS COMMITTEE

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1.0 PURPOSE

To incorporate representatives of all areas of the Institute and persons not connected with the Institute, so as to ensure that the ethical aspects of all research projects received for approval are properly assessed.

2.0 SCOPE

Internal: The scientific and non-scientific committee of the Institute.

External: Those persons recognized on account of their employment, scientific and social background.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. Members of the Research Ethics Committee must always include experts in their areas of knowledge, both scientific and non-scientific, there must be a balance of age and gender, and they must represent the interests and concerns of the community they serve in a plural and multi-disciplinary manner.

2. Those persons proposed to sit on the Research Ethics Committee must have a successful employment, scientific and social background. These members will be considered as **Permanent Members**.

   The career background of permanent members must be sufficiently varied so as to promote the comprehensive and proper assessment of the research activities that the Research Ethics Committee normally deals with.

   Permanent members must include:

   - **Scientific Members:** investigators in medical, biological, social, behavioral and physical sciences, and others, who are members of the Institutional Investigators System and/or the National Investigators System. These members must have proven experience in scientific research. When the Research Ethics Committee has to discuss a protocol the scientific area of which it is not conversant, an advisor may be invited to sit on the committee, although he or she will not be a permanent member.

   - **Non-scientific Members:** so that a Committee is plural and multi-disciplinary, it must incorporate professionals from various areas of knowledge, related or not to medical, social or biological sciences, whose main function is not scientific. These persons may be doctors, nurses and, ideally, philosophers, persons experienced in ethics, attorneys, and others. These members need not necessarily be affiliated to the Institute.

3. The Research Ethics Committee will publish calls to meetings in the T-shirt and on notices that specifies the requirements to be met by potential members of the Committee, plus a profile of the tasks and responsibilities of committee members.

   Requirements for new members:

   - It is desirable that members of the Research Ethics Committee are prepared to:
     - Committee themselves to being trained professionally and to deal with ethics-related disputes.
     - Inform themselves to the extent possible of the situation.
     - Ask any necessary questions to better understand disputes concerning conflicts of principles, if any, and philosophical viewpoints.
     - Conduct any necessary dialogue to this end and to assume the position of those involved in the problem.
     - Not be influenced when taking decisions, but rather to be influenced by "the best possible argument".
     - Not break off the dialogue if it is not possible to reach an agreement, but rather leave it open for the future, even when a consensus is not possible.
     - Contribute to the dialogue only those arguments that other persons involved may understand and accept concerning the basis of the minimum values shared.

4. New Committee members may be proposed as follows:
   - By members of the Technical Administration and Programming Council (made up of the President and Heads of Department).
   - By outgoing Committee members.
   - By recognized members of the Institute.

5. Appointments will be made by consensus or by the majority vote of members during the monthly meeting of the Research Ethics Committee. All cases must be confirmed by the Chairman of the Research Ethics Committee.

6. The Secretary and the Members last three years in office with full right of renewal for an equal period.

7. The position of Secretary will be rotated so as to permit continuity, development and maintenance of experience on the Research Ethics Committee, and the regular contribution of new ideas.

8. Members of the Research Ethics Committee or the Research Committee will not receive any remuneration.

9. All members of the Research Ethics Committee must agree to the following conditions of their appointment in writing:

   - Members must provide their full name and profession;
   - All income and expenses that are solely related to the Research Ethics Committee, if requested;
   - A confidentiality agreement concerning meetings at which projects, applications, information of those involved in research and related matters are discussed. All the administrative staff of the Research Ethics Committee must sign a similar confidentiality agreement.

10. Members of the Research Ethics Committee will be given an induction course and will be entitled to receive ongoing training in relation to biomedical research ethics and science.

11. Members of the Research Ethics Committee will only be given induction training regarding their tasks on the Research Ethics Committee and the Research Committee, plus opportunities to improve their training in ethics.

12. Members of the Research Ethics Committee may appoint an alternate who must be acquainted with those matters to be discussed at the meeting that he or she attends at the request of the permanent member. Alternate members must be formally appointed as alternate members or the C.E.I. Alternate members must follow the same training requirements as regular members. When an alternate member replaces a regular member at a meeting, the alternate assumes all the responsibilities of the regular member, including voting

    Alternates must meet the provisions of policy no. 2 and the requirements for new members, established in policy no. 3 of this procedure.

13. Members of the Research Ethics Committee may review the functions to be performed in the Composition and Operating Manual of the Committee, in Section **IV.3.- Functions and responsibilities of members.**

14. If a member has conflict of interest because he state according to the definition in our manual including if is author in a review project, this members must leave the room and the coordinator assure there is enough quorum to continue the session; all projects with conflict of interest with the member of the committee must leave to discuss at the end of the session.

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ASSESSMENT OF REGULAR MEMBERS OF THE RESEARCH ETHICS COMMITTEE

This section describes the process for assessing members of the Research Ethics Committee.

1. New members to be appointed to the Committee will be assessed by current members.
2. The participation of members of the Research Ethics Committee will be assessed every year by the Chairman, and Secretary of the Committee
3. Then results of assessments will be notified to members of the Research Ethics Committee personally.

4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF TASK
C.E:.I	1	Assesses the need to appoint one or more new members.
C.E:.I	2	Publishes an invitation that establishes the requirements to be met by potential committee members.
C.E:.I	3	Asks the COTAP, members of the Committee and, in some cases, recognizes scientific staff of the Institute, for suggestions.
COTAP, Committee members or scientific staff of the Institute	4	Send proposals to the Committee for assessment.
Staff of the Institute	5	Responds to the invitation and presents itself to be considered as a member of the Committee.
Research Ethics Committee	6	The Committee President interviews potential candidates and asks them for their professional profile to be distributed to the Committee
C.E:.I	7	The Research Ethics Committee convenes and establishes if potential committee members meet the requirements established in the operating policies, standards and procedures of this document. Do potential scientific members belong to the Institutional or National Investigators System? Yes.- Appoints new member. No.- Returns to task 2
C.E..I	8	Sends letter of appointment that describes their position, in accordance with the terms and conditions described in the Committee's composition and operating manual.
New members	9	Receive their letter of appointment to the Committee and sign as confirmation of receipt.
C.E..I	10	Retains a copy of confirmation of appointments in the Committee's file and amends the composition of the Committee.
C.E..I	11	Delivers the Committee Composition and Operating Manual, the institutional protection program for research members and other educational and standards material to new members. END OF PROCEDURE

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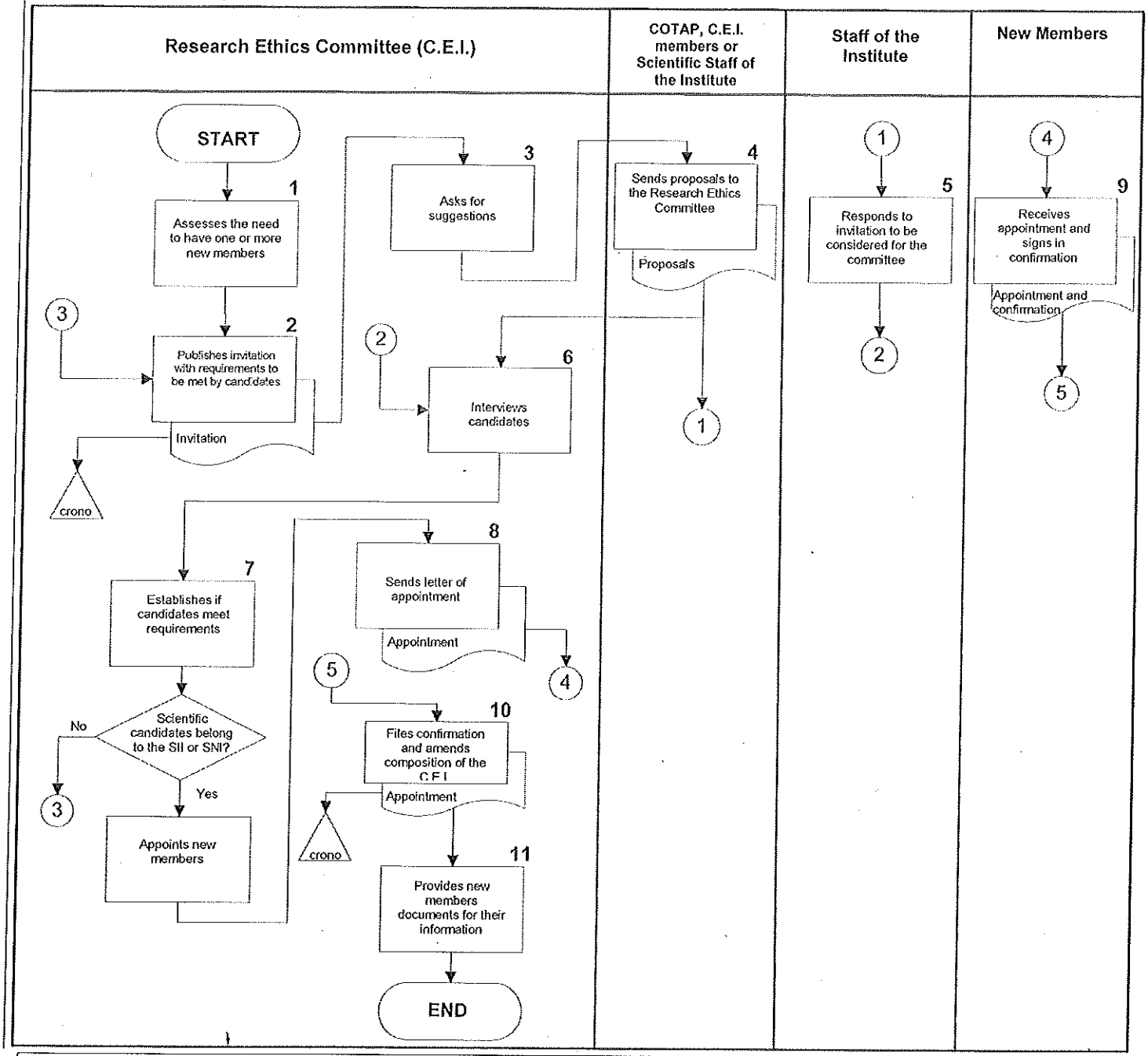
5.0 FLOWCHART

5.1 Selection of permanent members of the Research Ethics Committee



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6.0 RECORDS:

1. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman is needed to review and obtain various documents and files.

2. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the dead files of the Committee.

Records	Time Retained	Person Responsible	Code Number
Invitation	5 years	CEI	FC1102
Letter of appointment	5 years	CEI	FC1102
Profile	5 years	CEI	FC1102
Committee Composition Document	Permanent	CEI	FC1102

7.0 GLOSSARY:

C.E.I.- Research Ethics Committee
COTAP.- Technical Administration and Programming Committee

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9.0 FORMS AND INSTRUCTIONS: Not applicable

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2. PROCEDURE FOR SELECTING ADVISORS INVITED TO SIT ON THE RESEARCH ETHICS COMMITTEE

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1.0 PURPOSE

To have persons who are competent in specific areas to assist in assessing complex matters that require expertise not available on the Research Ethics Committee, or additional expertise and, if applicable, to approve research projects.

2.0 SCOPE

Internal: Staff of the Institute that provides the Research Ethics Committee specific expertise.

External: Persons from outside the Institute who may provide the Research Ethics Committee specific expertise.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. All projects that vulnerable or special populations is required to engage the participation of an external evaluator for discussion of the project and the opinion of the CEI.
2. Persons invited to sit on the Committee will be considered as Temporary Members and will have expertise in a particular field, and may be proposed as follows:
   - By Committee members;
   - By recognized members of the Institute; or
   - By members of the Technical Administration and Programming Council (made up of the President and Heads of Department).
3. Guest advisors may attend meetings of the Research Ethics Committee, and must have proven employment, scientific and social experience. Guest advisors may specialize in ethical or legal matters, in diseases or specific methodologies, or may represent special groups, such as communities, patients or groups of interest.

   Guest advisors may be:

   - **Scientific**: investigators in medical, biological, social, behavioral and physical sciences, and others, who are members of the Institutional Investigators System and/or the National Investigators System.
   - **Non-scientific:** professionals in various areas of expertise, related or not to medical, social or biological sciences, whose main activity is non-scientific. These persons may be doctors, nurses and. ideally, philosophers, specialists in ethics and attorneys.

4. Representatives of special groups: the involvement of members or advisors conversant with the need of specific groups or local context may be required when assessing certain research protocols. For example, if the Research Ethics Committee assesses a protocol that includes the involvement of prisoners, a member representing this group, either a former inmate or a person who specializes in this sector of the community, should be part of the Research Ethics Committee.

5. Guest advisors may not be influenced by members of the Research Ethics Committee.

6. Advisors invited to Committee meetings will have the right to be heard, but not to vote, and may have no influence on the decisions taken by the Committee.

7. Advisors must submit a written report on their involvement to the Committee, which must be filed in the project file.

8. Guest advisors may remain in the meeting room while protocols are being assessed, but must then leave the meeting room.

9. Advisors will be asked to disclose any conflicts of interest by the same process as REC members. In most cases, if the person has a conflict of interest they will not be allowed to be an advisor. If an advisor is used who has a conflict of interest, the REC will be informed of the conflict and the advisor will be allowed to provide information to the REC.

10. It is desirable that guest advisors of the Research Ethics Committee are prepared to:

    - Commit themselves to being given professional training and to deal with ethics-related disputes.
    - Attempt to inform themselves to the extent possible of the details of the situation.
    - Ask and answer questions to better understand a dispute of principles, if any, and various philosophical viewpoints.
    - Conduct any necessary dialogue to this end and to assume the position of those involved in the problem.
    - Not be influenced when taking decisions, but rather to be influenced by "the best possible argument".
    - Not break off the dialogue if it is not possible to reach an agreement, but rather leave it open for the future, even when a consensus is not possible.
    - Contribute to the dialogue only those arguments that other persons involved may understand and accept concerning the basis of the minimum values shared.

11. If questions arise as to who qualifies as a legally authorized representative, guardian, child/minor, or other legal questions, or legal questions concerning research conducted outside the jurisdiction of Institute National de Cenci's Medics y Nutrition Salvador Zubirán, the Research Ethics Committee will seek advice from legal counsel assigned to assist the Research Ethics Committee.

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12. The President of the Research Ethics Committee will ask the advisor invited for additional information, if necessary.

13. The advisor invited must inform the President immediately after he or she has been appointed to review a research protocol, if he or she has any conflict of interests, so that another advisor may be appointed.

    - The advisor must do this by contacting the Committee President before the meeting, on 5487-0900 Exts. 2501 and 2503 or by sending an e-mail to patricio.santilland@quetzal.innsz.mx.

14. The guest advisor excluded for having a conflict of interests may not submit any supporting documents to the Research Ethics Committee to be filed with other documents of the research project.

4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
C.E.I.	1	Identifies the need to invite an expert advisor on specific ethical or legal matters, diseases or specific methodologies.
C.E.I.	2	Asks committee members, recognized members of the Institute or members of the Technical Administration and Programming Council (COTAP) for suggestions.
Committee Members, members of the COTAP, staff of the Institute	3	Send proposals to the Committee for assessment.
C.E.I.	4	Meets and establishes those advisors who may be invited to meetings and establishing the order in which they will be invited. Do the advisors invited have sufficient experience in the relevant area? Yes.- Continues No.- Returns to task 2
C.E.I.	5	The Committee President invites the external advisor by sending him or her a letter.
Guest advisor	6	Receives letter and signs as confirmation of receipt.
Guest advisor	7	Analyzes the option of assisting in assessing the protocol. Accepts? Yes: Sends a letter of acceptance to the Committee President. No: Sends a letter of rejection to the Committee President. Return to task No. 5
C.E.I.	8	Receives the letter concerning the decision of the guest advisor and files it.
C.E.I.	9	Contacts the guest advisor and sends him or her the documents that he or she needs to provide an opinion.
Guest advisor	10	Attends the committee meeting on the date established in order to clarify any doubts and gives his or her opinion.
Guest advisor	11	Submits a written report on his or her involvement at the meeting.
C.E.I.	12	Files report in the project file. END OF PROCEDURE

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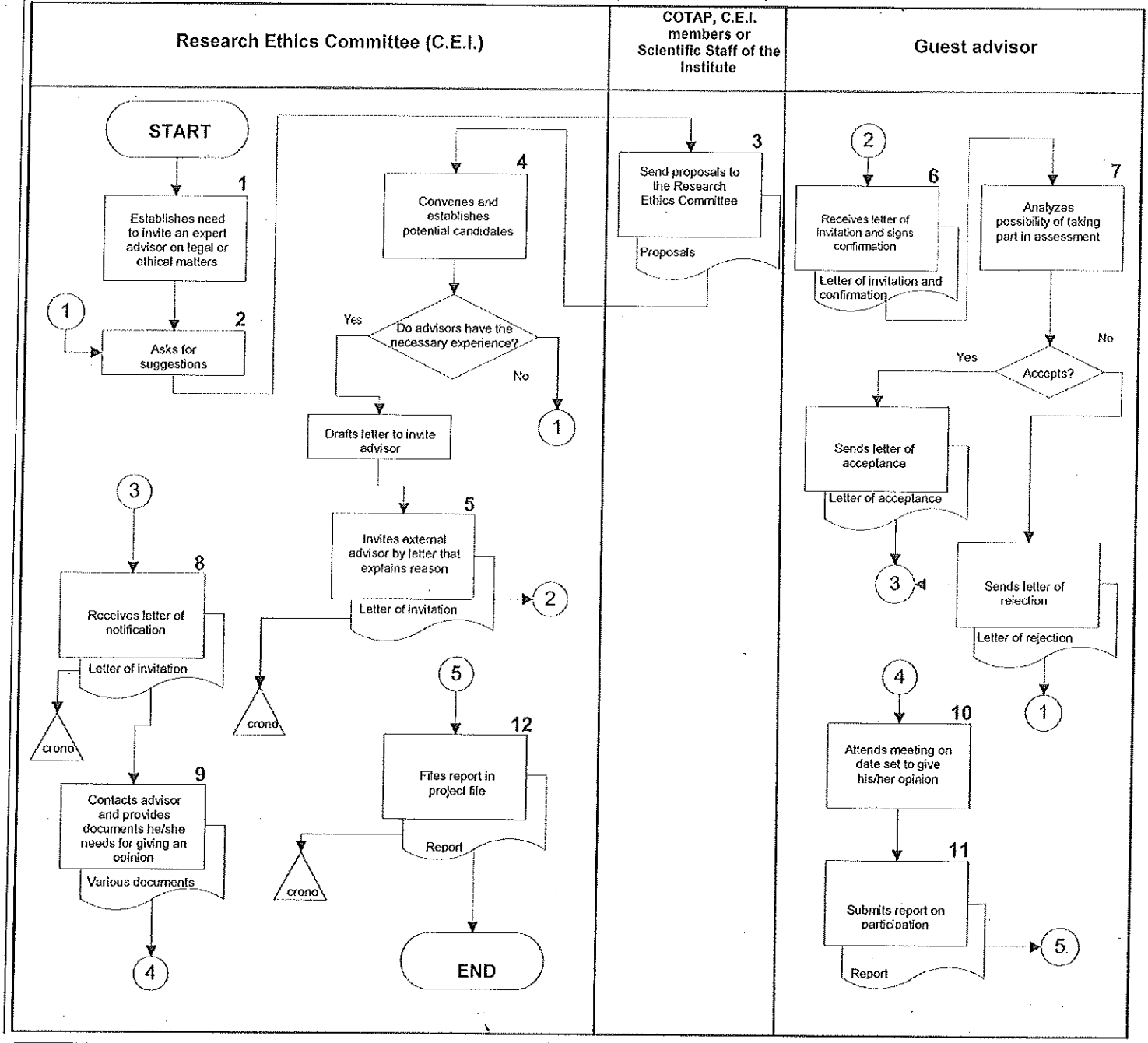
5.0 FLOWCHART

5.1 Selection of advisors invited to the Research Ethics Committee



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6.0 RECORDS

1. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman is needed to review and obtain various documents and files.

2. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee.

Records	Time Retained	Person Responsible	Code Number
Letter of invitation	5 years	CEI	FC1102
Letter of acceptance	5 years	CEI	FC1102
Profile	5 years	CEI	FC1102

7.0 GLOSSARY:

C.E.I. - Research Ethics Committee
COTAP. - Technical Administration and Programming Committee

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9.0 FORMS AND INSTRUCTIONS: Not applicable

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3. PROCEDURE FOR REGISTERING RESEARCH PROJECTS

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1.0 PURPOSE

To register all research projects to be conducted at the Institute, or submitted by other institutes for assessment, for control and supervisory purposes.

2.0 SCOPE

Internal: Investigators and other members of the Institute who conduct research at the Institute or in collaboration with other institutes.

External: Institutes that asks the Research Ethics Committee for support in assessing and, if applicable, approving research projects.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. Research will be conducted by the health professionals referred in Article 14 of the Health Research Regulations of the General Health Act, and they will have sufficient knowledge and experience in protecting the research participant at the responsibility of a health institute that is being supervised by the proper health authorities, and that has the staff and resources needed to protect the well-being of research participants.

2. Members of the Institute may not commence their own research projects or any research project in collaboration with another institute if they are not registered with the SERPI and do not have the authorization needed according to the nature of the research.

3. It is a requirement that all personnel involved in the investigation including the principal investigator, co-investigators, and study President subinvestigators delivered when registering a research project a declaration of conflict of interest signed by each of the participants.

4. That investigational drug are used only in CEI approved research protocols and under the direction of principal investigators.

5. The principal investigator is responsible for recording in a log the use and distribution of medication to the research participants, recording the following data:

   - Name of participant research.
   - Registration number.
   - Name of the drug.
     - Use Date.

- Quantity delivered
- Serial Number
- Expiration Date

6. The sponsor is responsible for ensuring that the pharmaceutical product or products researched and, when applicable, the comparison products provided for clinical trials, are of suitable quality and have been submitted to quality guarantee procedures.

7. When major changes are made to the formula of the product being researched or of the comparison product during the trial, results of additional studies will be required, for example, on stability, comparative dissolution rate or, if applicable, comparative bioavailability, before the new formula is used for the trial. Studies must show that it is not expected that rgw changes will alter the pharmacokinetic profile or other clinical features of the product.

8. The measures that the sponsor takes to supply the investigator the pharmaceutical products needed for the clinical trial must be described in the protocol. The manner in which they will be registered, sent, dispensed and stored must be specified.

9. Good Manufacturing Practices must be applied not only by the supplier of the product or the pharmaceutical product or products, but also by any intermediary responsible for the temporary storage of these products.

10. Records must be kept of information concerning the sending, delivery, receipt, storage, return and destruction of all excess pharmaceutical products. The investigator must not supply the product researched to any person who is not authorized to receive it. Preferably, a local drugstore or the pharmacy department of the local hospital will assume liability for storage, delivery, return and registering of products researched and, when applicable, comparison products. When this happens, these procedures may be documented so an audit may be carried out.

11. All investigators must provide the information requested by the SERPI, clearly and completely, according to the nature of the research.

12. When the researcher is recording a new project should mention if your project is under the HHS regulations or the FDA. These projects usually have special exemptions or different regulations with the use of drugs or devices. For the CIS has to be aware and take care during the evaluation process and the next. All these exceptions are described below and the other in the manuals of pharmacy

13. If the Research Ethics Committee is asked to review a project, the investigator involved must also provide a List of Documents, the documents listed thereupon and the Investigators Declaration Form, signed and completed.

14. All projects must have a project number allocated on the Research Registration Form.

15. All projects registered on the SERPI will be revised for authorization by the Research Director as President of the Research Committee, who will corroborate if it will be necessary for one or more Committees to assess and approve the project.

16. Extensions to approved projects will not be registered as new projects; only information that changes will be adjusted (for example, probable date of completion, funding, etc.), and the system will allocate an additional number at the end of the project version number. These changes must be assessed and approved by the relevant Committees, according to the nature of the study.

17. In all cases, the investigator responsible must be a member of the Institute and must be registered on the SERPI, according to the system's user manual.

18. Contracts with Research Sponsors.

    a. All the contracts will be celebrate in Spanish, The legal advisory department is responsible for ensuring that the appropriate language is included in the contracts

    b. The legal advisory department is responsible for reviewing, amending and authorizing research protocol collaboration agreements.

    c. The legal department is responsible to review, modify and approve the collaboration agreements of research protocols.

    d. The legal department and the Research Ethics Committee will be responsible to review, modify and approve, the specific arrangements to ensure that patients receive care in the event of any research-related injury.

    e. The legal advisory department and the Research Ethics Committee will review, amend and authorize agreements to ensure that they specify the following:

        (1) The National Institute of Medical Sciences and Nutrition follows the procedures for recording and reporting data; allow monitoring, auditing and inspection of research and retains essential clinical documents related to the investigation until the sponsor informs the institution that they are no longer needed.

        (2) A description of who is responsible to pay care when a participant is injured in research. For instance, the contract must indicate whether this is the responsibility of the research sponsor or another entity.

        (3) A statement indicating that the sponsor should promptly inform the National Institute of Medical Sciences and Nutrition study any outcome that monitors and that could affect the safety of participants or alter CIS approval to continue study.

        (4) A statement that the sponsor is required to follow the policies and procedures of the National Institute of Medical Sciences and Nutrition in relation to the publication of sponsored research findings.

        (5) A statement describing the communication of the results of a research study participants when those results directly affect safety or care. For example, the contract should state that the sponsor shall report the results of studies that could affect the health care of the participants to the National

Institute of Medical Sciences and Nutrition.

19. The investigator and the sponsor will be responsible for any injuries caused to patients related to the research project.

20. The Committee President will review agreements to ensure that the sponsor is required to promptly disclose any results of the study monitors that may affect the safety of the participants or alter the approval of the Research Ethics Committee for continuation of the study.

RESEARCH PROJECTS CONDUCTED OUTSIDE THE INSTITUTE:

1. The Institute or the relevant investigator must do what is necessary to have his or her research project registered on the SERPI.

2. The Institute or the relevant investigator must provide all information concerning said research project.

3. Those parties involved must sign an agreement before the project commences.

NOTICES

1. The Committee must check the following:

- The information included in advertisements
- The manner in which they are distributed
- The final copy of printed advertisements
- Recorded video/audio advertisements.

2. The Committee must ensure that advertisements:

- Do not indicate or imply certainty of a favorable result or other advantages beyond those included in the consent document and the protocol.
- Do not include a exculpatory language
- Do not accentuate the sum to be paid using bold type or capital letters.
- Do not promise free treatment when the intent is only say that costs will not be charged to patients
- Restricted to the information prospective participants needed to determine their eligibility and interest, such as:

  - The name and address of the r investigator or research facility.
  - The purpose of the research or condition under study
  - In summary form, the criteria to be used to determine the eligibility for the study.

- Brief list of participation benefits, if any.
- A brief list of participation advantages, if any.
- The time or other commitment required of participants
- Location of the research and the personal office to contact for further information.

For USA's FDA-regulated research advertisements:

- Do not make claims, either explicitly or implicitly, about the drug, biologic or device under investigation that are inconsistent with FDA labeling.
- Do not use terms such as – new treatment - , new medicine or new drug without explaining that the test article is investigational.
- Do not include compensation for participation in a trial offered by a sponsor that implies a coupon for a discount on the purchase price of the product once it has been approved for marketing.

PAYMENTS:

1. The Committee must check the following:
   - That the sum paid, the method proposed and timing of disbursement are neither coercive nor present undue influence.
   - Credit for payment accrues as the study progresses and is not contingent on participants completing the entire study.
   - Any sum paid as a bonus for completion is reasonable and not so large so as to unduly induce participants to remain in the study when they have decided to withdraw.

2. The National Institute of Medical Sciences and Nutrition Salvador Zubirán through the Research Ethics Committee, prohibits the following:
   - Payments to health professionals in exchange for referring possible participants (payment or fee).
   - Payments to participants in exchange for referring possible participants (payment or fee), unless this is considered not to increase the possibility of coercion or undue influence on participants by providing reasonable compensation or unreasonable conditions for distribution of compensation.
   - Payments used to speed up recruitment that are tied to the rate or timing of enrollment (bonus payments), unless considered that it would not interfere with providing possible participants the opportunity to consider the option of participating and that do not increase the possibility of coercion or undue influence on investigators or participants.

4.0 DESCRIPTION OF THE PROCEDURE

4.1 Registering the Institute's research projects

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Investigator	1	Checks current status on the SERPI. Registered? No. Registers. (As per the instructions of the SERPI user manual). Yes. Provides the information required by the SERPI to commence the session.
Investigator	2	Completes all forms provided by the SERPI for registering a new project, as per the user manual.
Investigator	3	The project needs to be assessed and authorized by the Animal Research Committee, the Bio-safety Committee or the Ethics Committee. Authorization required? No. Uses the general project registration module. Yes. Uses the Committee review and authorization module.
Investigator	4	Checks that all information entered on the system is correct and clear, so that the Research Committee President may check it. The SERPI automatically allocates the investigator a protocol number and prints the Registration Form as confirmation of processing.
Investigator	5	Asks the Head of Department, Head of Section or Director (according to the authorized organizational chart) to authorize registration of the research project on the relevant module, for assessment.
Head of Department, Head of Section or Director	6	Checks project information. Agrees with the project? Yes. Procedure continues. No. Project rejected. END OF PROCEDURE

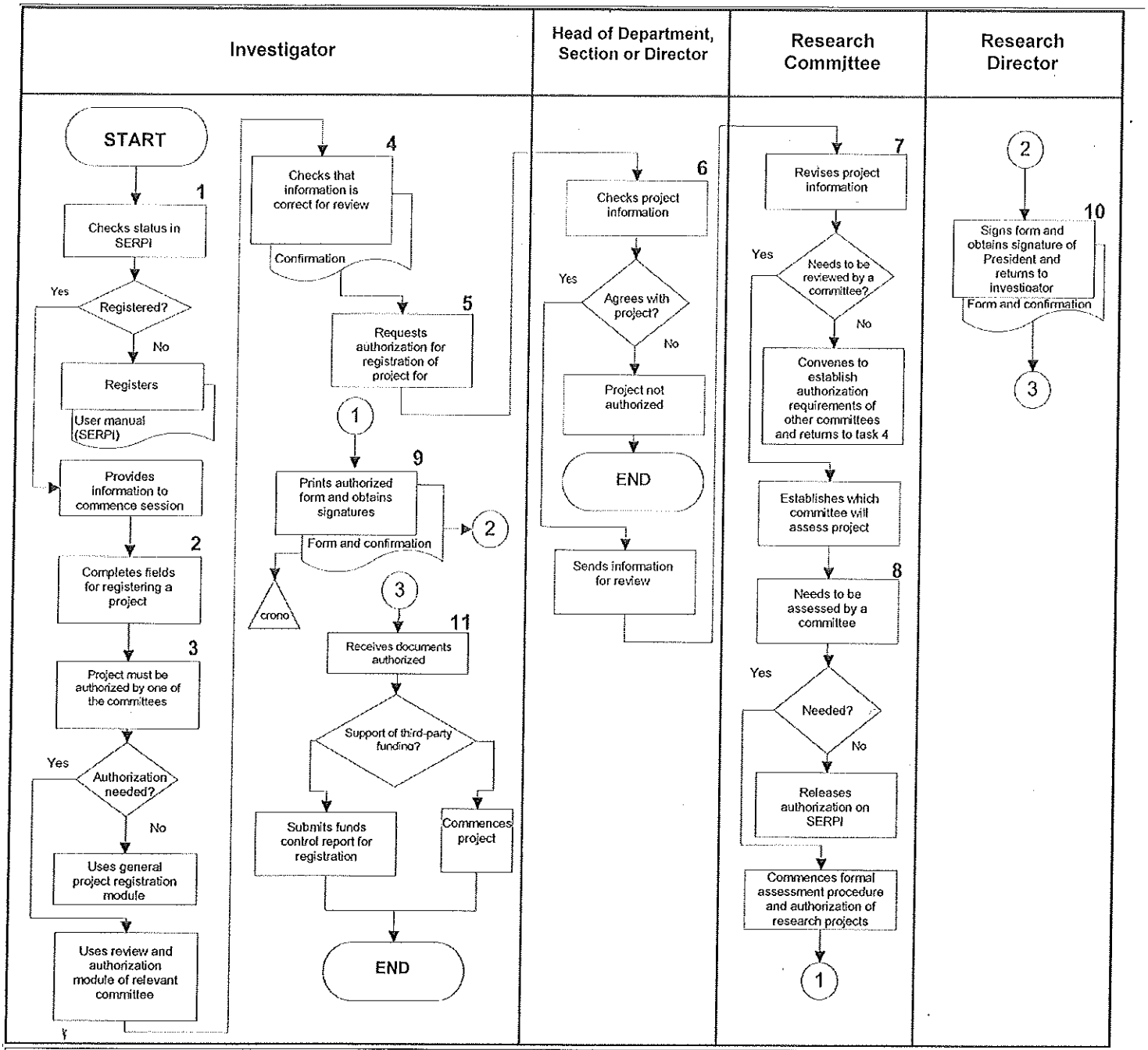
ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

PERSON RESPONSIBLE	TASK	DESCRIPTION OF ASK
Research Committee President	7	The C.I. President checks information of the research project to be commenced. May he establish if the project needs to be assessed by the Animal Research Committee, the Bio-safety Committee or the Ethics Committee? Yes Establishes which committee will assess the project. No Asks for an extraordinary meeting of the Research Committee to establish authorization requirements for other committees and returns to task 4.
Research Committee President	8	Research project needs to be assessed and authorized by the Animal Research Committee, the Bio-safety Committee or the Ethics Committee. Assessment and authorization needed? Yes Connects with formal project assessment and authorization procedure. Once the project is authorized, procedure continues. No Releases authorization on the SERPI and notifies investigator of authorization.
Investigator	9	Prints the authorized Research Registration Form for signing and to obtain signature of the Head of Department, and sends to the Research Division
Research Director	10	Signs as authorized on the Research Registration Form obtains authorization of the President, sends the authorized form to investigator.
Investigator	11	Receives signed registration form a and sends C.E.I. the documents specified on the list of documents form, and the Investigators Declaration Form Project supported by third-party funding? Yes. Submits authorized form to the Special Research Funding Control Department for registration and to open account. Stamped as received, files document. No Files document END OF PROCEDURE

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

5.0 FLOWCHART

5.1 Registering the Institute's research projects



ISSUE CONTROL			
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Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

4.2 Registering research projects involving two or more institutes

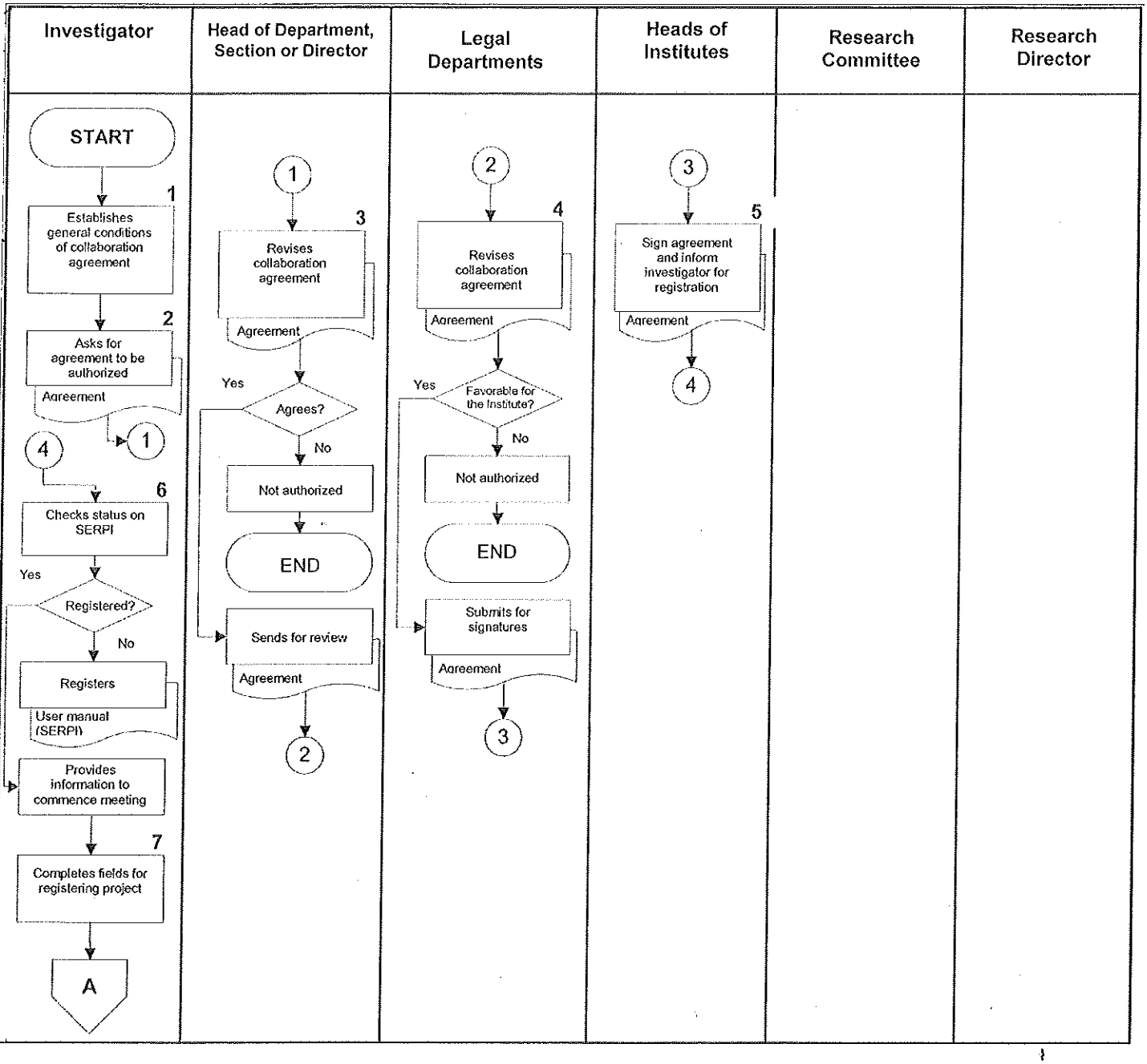
PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Investigator	1	Establishes general conditions of the collaboration agreement with instates involved in research projects.
Investigator	2	Asks Head of Department, Head of Section or Director (according to authorized organizational chart) to authorize the collaboration agreement with instates involved in research projects.
Head of Department, Head of Section or Director	3	Checks the collaboration agreement of the project to be commenced. Agrees with agreement? Yes Sends it to legal department for analysis. No Participation of institute reject and END OF PROCEDURE
Legal Departments	4	Check collaboration agreement with institutes involved for signing by the person responsible of each institute. Do the agreement's terms favor the Institute? Si Sent to institutes for signing. No Participation of institute reject and END OF PROCEDURE
Persons Responsible of Institutes	5	Sign collaboration agreement and inform investigator for registering with the C.E.I.
Investigator	6	Checks current status on SERPI. Registered? No Registers. (Follows instructions in SERPI user manual). Yes Provides information required by SERPI to commence session.

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Investigator	7	Completes all SERPI forms to register a new project, as per the user manual.
Investigator	8	Does the project need to be assessed and authorized by the Animal Research Committee, the Bio-safety Committee or the Ethics Committee? No. Uses the general project registration module. Yes. Uses the review and authorization module of the Committees.
Investigator	9	Checks that all information entered on the system is correct and sufficiently clear so that the Research Committee President may check it. The SERPI automatically allocates the protocol number and prints the Registration Form as confirmation of processing.
Investigator	10	Asks the Head of Department, Head of Section or Director (as per the authorized organization chart) to authorize registration of the research project in the corresponding module, for assessment.
Research Committee	11	The Research Committee President checks the information of the research project registered. Does the project require the assessment of the Animal Research Committee, the Bio-safety Committee or the Ethics Committee? Yes. Establishes which committee will assess the project. No. Convenes an extraordinary meeting of the Research Committee to establish the requirements for authorization by other Committees and returns to task 9.

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Research Committee	12	The research project needs to be assessed and authorized by the Animal Research Committee, the Bio-safety Committee or the Ethics Committee. Is assessment and authorization required? Yes. Connects to the procedure for formal research project assessment and authorization. Once the project is authorized, continues with the procedure. No. Issues the corresponding authorization on the SERPI and sends notification of authorization to the investigator.
Investigator	13	Prints the authorized Research Registration Form for signing and for the signature for the Head of Department and sends to the Research Division.
Research Director	14	Signs authorization on the Research Registration Form and obtains authorization of the President and sends the authorized Form to the investigator.
Investigator	15	Receives the Form duly authorized and sends to the Research Ethics Committee all documents specified on the List of Documents Form, and the Investigators Declaration Form. Is the project supported by third-party funding? Yes. Submits the authorized Form to the Special Research Funding Control Department for registration and to open an account. Stamps as received. Files document. No. Files document. END OF PROCEDURE

5.0 FLOWCHART

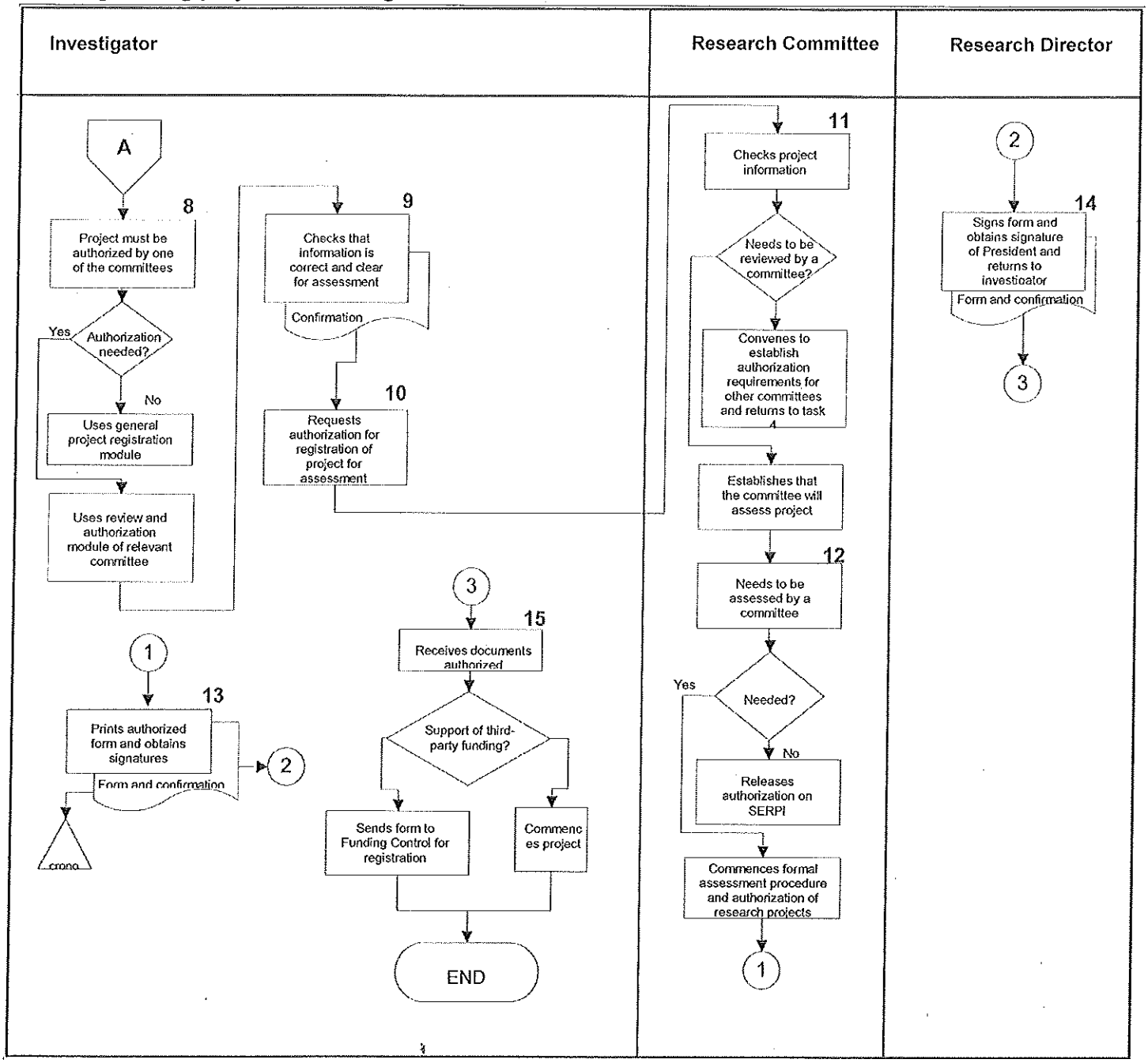
5.1 Registering research projects involving two or more institutes



ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

5.0 FLOWCHART

5.1 Registering projects involving two or more institutes



ISSUE CONTROL			
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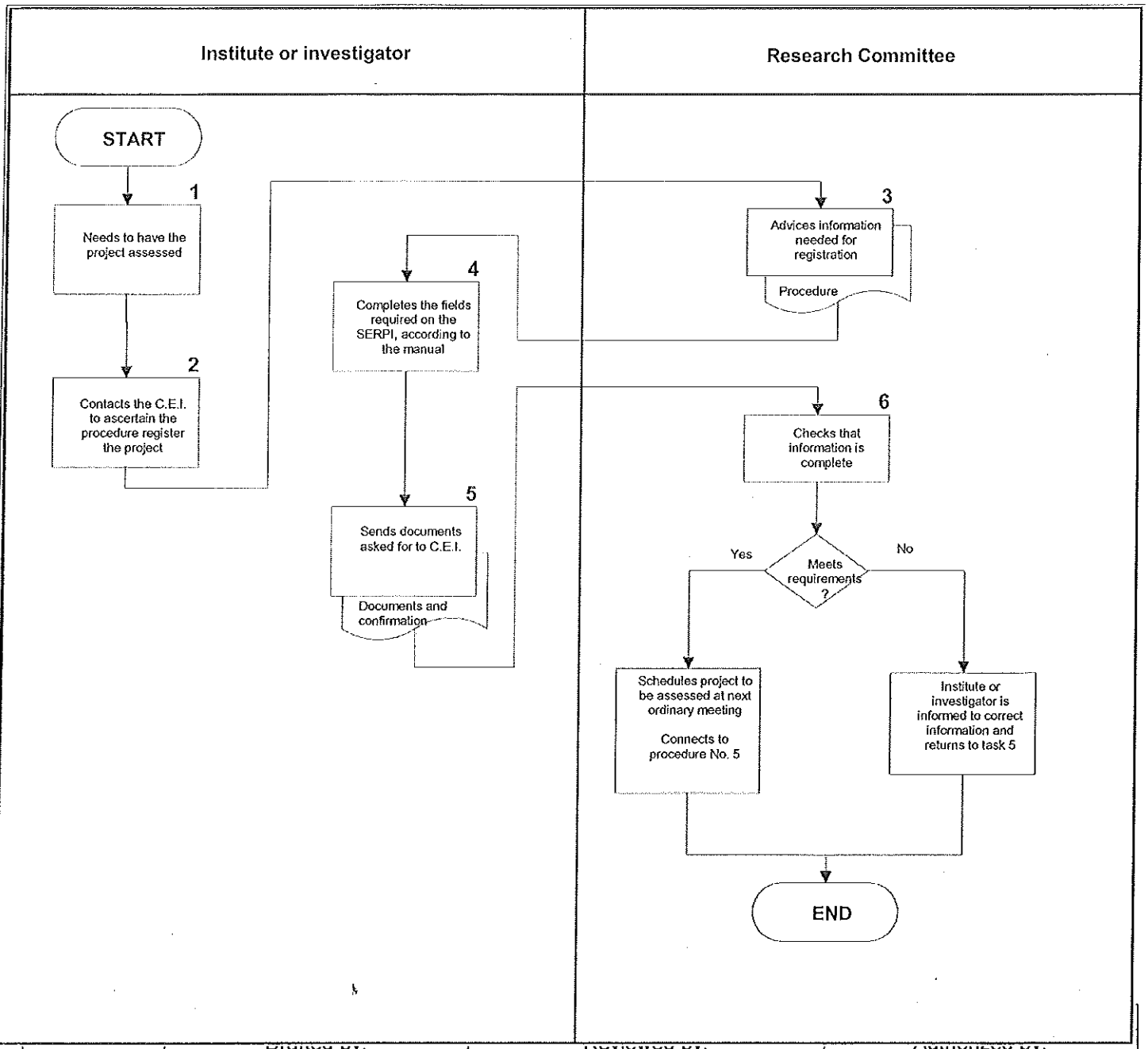
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

4.3 Registering external research projects

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Institute or Investigator	1	Project needs to be revised and assessed by the Research Ethics Committee of the Institute.
Institute or Investigator	2	Contacts the Research Ethics Committee to ascertain the requirements for registering the project.
C.E.I.	3	Provides the information needed so that the Institute or investigator may register the project on the SERPI.
Institute or Investigator	4	Completes all SERPI forms to register the project, as per the user manual. Uses the Research Ethics Committee's review and authorization module.
Institute or Investigator	5	Sends all documents specified on the List of Documents Form and the Investigator Declaration Form to the Research Ethics Committee.
C.E:I.	6	Checks that the information sent by the institute or the investigator is complete and is that to be reviewed at the Committee's next ordinary meeting. Does the information meet minimum requirements? No. The institute or investigator is informed of the situation so that any necessary corrections may be made. Yes. The project is scheduled to be revised by the Committee at its next ordinary meeting. Returns to Task No. 5 for formal assessment and authorization of research projects. END OF PROCEDURE

5.0 FLOWCHART

5.1 Registering external research projects



	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

6.0 RECORDS

1. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman and Committee is required to review and obtain the various documents and files.

2. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee.

Records	Time Retained	Person Responsible	Registration Code
SERPI Database	Indefinite	Research Division	
Collaboration agreement	5 years	Legal Department	
Investigator Declaration	5 years	C.E.I.	FC1102

7.0 GLOSSARY

C.I.- Research Committee

C.E.I.- Research Ethics Committee

INNSZ.- Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán

SERPI.- The Electronic Research Protocol Registration System.

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

9.0 FORMS AND INSTRUCTIONS:

SALVADOR ZUBIRAN NATIONAL INSTITUTE
OF MEDICAL SCIENCES AND NUTRITION

Wednesday, October 20, 2009

INVESTIGATORS' STATEMENT

PROJECT TITLE:
C.E.I. Registration Number:

The investigators participating in the referenced project voluntarily submit to the evaluation of that project by the Research Ethics Committee on in and freely declare:

- *We are familiar with all aspects of the study and we have the capacity to implement it fully and properly.*
- *A thorough review of the scientific background of the project justifies its implementation and we undertake to maintain a high scientific standard that allows us to obtain information useful to society.*
- *We are familiar with the potential risks to which we are exposing the patients invited to participate, which we have discussed with them fully.*
- *We will put the research subjects' well being and safety of above any other objective.*
- *We will conduct ourselves in accordance with nationally and internationally accepted standards of ethical and scientific conduct as established in the General Law on Healthcare and the Regulations in Matters of Healthcare Research of the United Mexican States (Mexico), the International Ethical Guidelines for Biomedical Research and Experimentation in Humans of the World Health Organization, and the Helsinki Declaration*

Name of investigator	Signature

Vasco de Quiroga No. 15
Tlalpan 14000, D.F. México

Complete and print this declaration on a separate sheet. This declaration must be signed by all investigators involved in the project.

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

No.	DESCRIPTION	INFORMATION TO BE PROVIDED
1	Project Title	The full project title.
2	*C.E.I. Registration Number*	The registration number allocated by the Research Ethics Committee.
3	*Investigator's Name*	The full name of the principal investigator and the full name of all associate investigators.
4	*Signature*	To be signed by all investigators on the list.

SALVADOR ZUBIRAN NATIONAL INSTITUTE
OF MEDICAL SCIENCES AND NUTRITION

LISTING OF DOCUMENTS
(Checklist)

PROJECT TITLE:
C.E.I. Registration Number:

DOCUMENT	Hardcopy	File
C.E.I. Research Project Evaluation Form		
Subject Information Sheet for Informed Consent Form		
Letter of Consent Form		
Investigators' Statement (signed)		
Certification issued by one of two courses on ethics for research in humans		
Other documents delivered (specify):		

Date:

Investigator:

Received:

Vasco de Quiroga No. 15
Tlalpan 14000, D.F. México

No.	DESCRIPTION	INFORMATION TO BE PROVIDED
1	Project Title	The full project title.
2	C.E.I. Registration Number	The registration number allocated by the Research Ethics Committee.
3	Printed	Place an X against the document delivered.
4	File	Place an X against the file delivered, except for the investigator's statement that must be on an original document with an original signature.
5	Date	The date on which all documents are received.
6	Investigator	The full name of the investigator submitting the document.
7	Receipt	The full name of the person receiving the documents.

INSTITUTO NACIONAL DE CIENCIAS
MEDICAS Y NUTRICION SALVADOR ZUBIRAN

CONFLICT OF INTEREST

PROJECT TITLE:

Registry Number C.E.I.:

¿The investigator incurs the following Conflict of Interest?

In case of conflict exists or not explain why.

CONFLICT OF INTEREST	YES	NO
The interest is worth more than U.S. $ 10,000 when added to the immediate family.		
Interest is not listed on the stock exchange.		
The interest value will increase or decrease depending on the results of the investigation.		
He owns 5% or more of the company sponsoring the study or the product generated (or 1% if other relatives are involved)		
The interest is related to a patent, trademark, copyright, or licensing agreement.		

Date:

Researcher Name and Signature:

Received:

Vasconcelos Quiroga No. 15
Tlalpan 14000, D.F. Mexico

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

4. PROCEDURE FOR ESTABLISHING IF RESEARCH INVOLVING HUMANS MAY BE ASSESSED QUICKLY (FORMAL ASSESSMENT NOT REQUIRED)

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

1.0 PURPOSE

To establish which research projects do not require a formal and strict assessment by the Research Ethics Committee for authorization and that may be assessed more quickly.

2.0 SCOPE

Internal: All research projects conducted at the Institute on humans that do not require formal assessment.

External: Research projects conducted at other institutions on humans for which a formal assessment is not required.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. All research projects must be reviewed and approved by the Research Ethics Committee.

2. The CEI is aware that some research projects, due to its methodological structure do not affect the participants (if patients) or very little affect. Such projects can be evaluated without requiring a formal evaluation by the Committee. This type of test is known as expedited review and may be requested by the principal investigator. Only the president of the CEI can decide whether the research can be evaluated in the expedited review procedure. In this case, the president and other members of the Committee will review the proposal. If there is unanimity in the decision, the approval shall be issued expeditiously. ERC President shall report to the full Committee expedite the approvals granted since the previous session. For research with risk committee be convened a special meeting and its evaluation will be according to the policies established evaluation.

In accordance with the project classification established in the Regulations, the Committee will assess the project according to the following general guidelines:

I. Research without risk: These are studies that employ retrospective documentary research techniques and methods and those in which no intervention or intended modification is carried out in the physiological, psychological, and social variables of the individuals who participate in the study, among which the following are considered: questionnaires; interviews, and review of clinical files and others, in which behavioral-sensitive aspects are not identified nor treated.

II. Research with minimal risk: Prospective studies that employ data risk through common procedures in physical or pathological examinations of diagnoses or routine treatment, among which the following are considered: weighing of the participant; auditory acuity tests; electrocardiogram; thermography; collection of excrement and external secretions; obtaining of the placenta during delivery; collection of amniotic liquid on membrane rupture; obtaining of saliva, deciduous teeth, and permanent teeth extracted by therapeutic indication; dental plaque and calcifications removed by means of non- invasive prophylactic procedures; hair that has been cut, or the cuttings of nails without causing disfiguration; extraction of blood by venous puncture in adults in a good state of health with a maximum frequency of twice weekly and with a maximum volume of 450 ml in 2 months, except during pregnancy; moderate exercise in healthy volunteers; psychological testing of individuals or groups in which the behavior of the participants is not manipulated; research with drugs of common use, broad therapeutic margin, that are authorized for sale, employing the indications for use, doses, and routes of administration established, and that do not comprise the drugs for research that are defined in Article 65 of the Bylaws.

III. Research with greater-than-minimal risk: Research studies in which the probabilities of affecting the participant are significant, among which the following are considered: radiological studies and those with microwaves; assays with drugs and modalities that are defined in Article 65 of the Bylaws; assays with new devices; studies that include surgical procedures, extraction of 2% of the circulating blood volume of neonates; amniocentesis and other invasive techniques or more extensive procedures; procedures that employ randomized assignment methods to therapeutic schemes and those which include placebo controls, among others.

3. In order to request assessment of a project using the quick assessment procedure, the investigator must submit the same documents referred to in the documents section of Procedure No. 5 for formal assessment and authorization of research projects.

4. For applications without risk research President presented at the next meeting of the committee a list of projects that were evaluated without risk and its opinion; leave available to the committee the record in the case that a member decides to further review and discuss the project in full session, in this case as a body be validated or reverse the decision of the President, if different than originally issued be notified within 24 hours to the researcher.

5. Any project under FDA regulations can not be evaluated by the rapid assessment procedure.

6. The expedited review does not preclude the obligation to declare a conflict of interest by the research team and during the process of registration and evaluation policies should follow the procedure 5 Section B (Conflict of Interest)

7. The investigator must submit to request a review by the expedited review procedure documents in the same paragraph of the documentation of the Procedure No. 5 for the formal evaluation and approval of research projects.

8. All research projects classified as risk free and minimum risk may be assessed using the quick assessment procedure.

ISSUE CONTROL			
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Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

9. For research with minimal risk, the Ethics Commission, for good cause and at the request of the principal investigator, may authorize that informed consent is obtained without written formulated. However, the researcher is obliged to deliver information written leaflet, booklet or case summary and without risk research, the investigator may waive informed consent but if the patient is present, it is the obligation of the researcher give written information, which should present the receipt for your records.

10. The Committee President will receive applications from investigators and establish if the research protocol may be assessed using the quick assessment procedure.

11. All projects not approved by the Quick Assessment Method shall be referred to the Research Ethics Committee for Formal Assessment.

12. To expedite evaluation will only be attended by the Secretary sufficient without a quorum, but shall be subject to confirmation by the full Research Ethics Committee as determined by the President. It will require the affirmative vote of the President and the Secretary to grant expedited approval

13. The Research Ethics Committee President or the member who will conduct the assessment using the quick assessment procedure must give his or her decision in writing and open a file on all considerations concerning standardization using the quick assessment procedure. The person who conducts the assessment using the quick assessment procedure must not have any direct interest in the project in question. If an assessor establishes that he or she has been allocated to assess a research project in which he or she has a conflict of interests, he or she must immediately inform the Committee President who will ensure that the project is allocated to another assessor who does not has a conflict of interests.

14. No member of the CEI can carry out the review of a research protocol using rapid assessment procedure when he or she has a conflict of interest.

15. The Research Ethics Committee, through the President, must give a decision in writing and open a file on all considerations concerning the research project assessed using the quick assessment procedure.

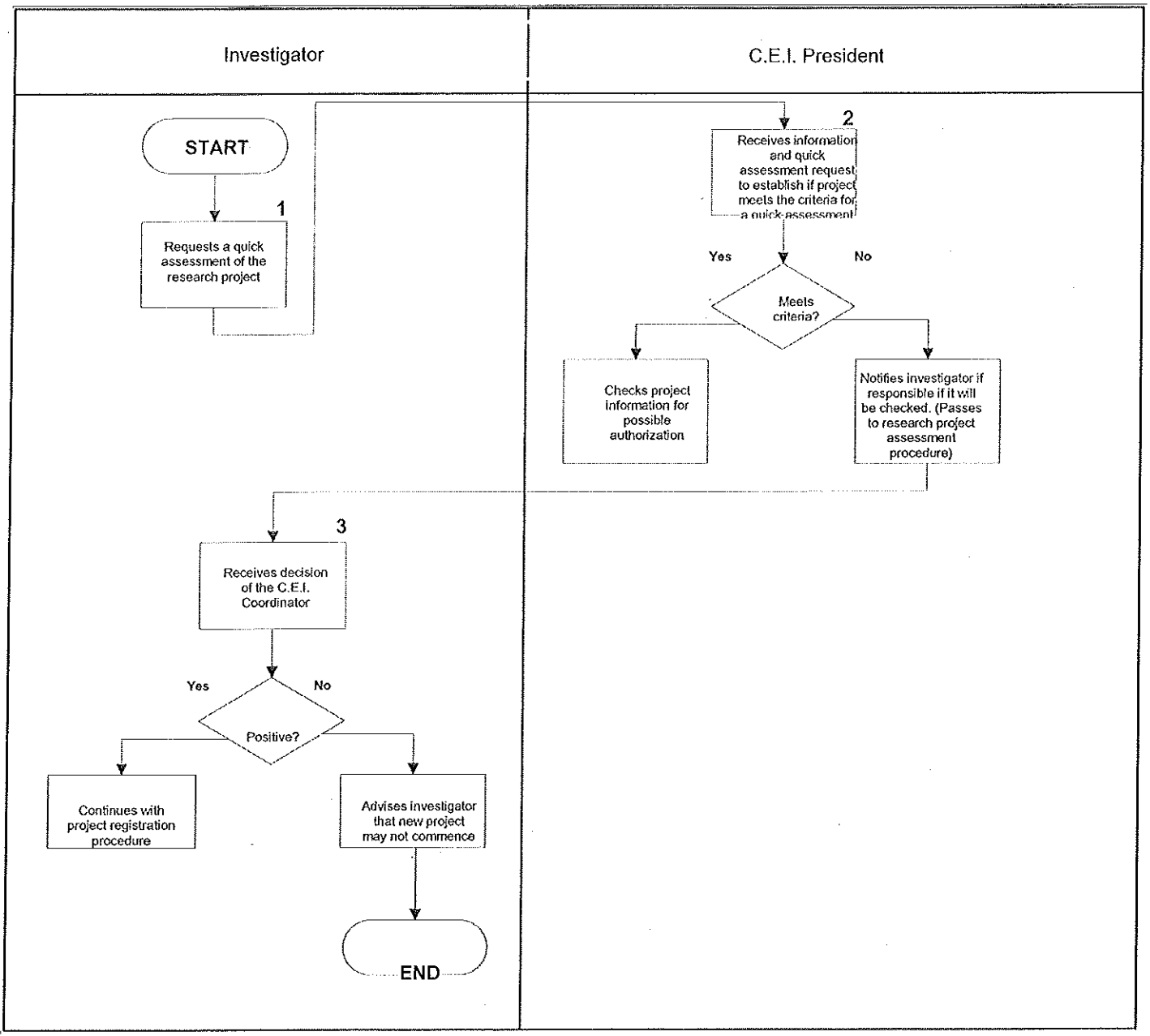
16. The determination of the exemption does not necessarily preclude the need to provide informed consent or other supporting documentation.

4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Investigator	1	Requests a quick assessment of a research project.
C.E.O. President	2	Receives information and the application for quick assessment to establish if the type of project meets the criteria for quick assessment. Does it meet criteria? No. Notifies the investigator that the project will be assessed formally by the Research Ethics Committee at its next meeting (linked to the formal assessment procedure for research projects). Yes. Reviews project information for authorization.
Investigator	3	Receives the decision of the President of the Research Ethics Committee. Has the quick assessment method been approved? Yes. Continues with the project registration procedure. No. Notifies the investigator (sic) that the new project may not be commence. END OF PROCEDURE

5.0 FLOWCHART

5.1 Registering external research projects



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Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

6.0 RECORDS

a. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman and the President is needed to review and obtain various documents and files.

b. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee.

Records	Time Retained	Person Responsible	Registration Code
Application for quick assessment	5 years	C.E.I	FC1102
Notification of authorization on research project	5 years	C.E.I	FC1102

7.0 GLOSSARY

C.E.I.- Research Ethics Committee

Quick Assessment.- An alternative manner in which the C.E.I. reviews research projects proposed.

Investigator: a qualified scientist who takes on the scientific and ethical responsibility, on his or her own behalf or on behalf of an organization/company, of the ethical and scientific integrity of a research project conducted on a specific site or group of sites.

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9.0 FORMS AND INSTRUCTIONS: Not applicable

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

5. PROCEDURE FOR FORMALLY ASSESSING AND AUTHORIZING RESEARCH PROJECTS

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

1.0 PURPOSE

All projects to be conducted in the Institute by staff that conducts research on humans, will be submitted to a consistent ethical and quality assessment and, if approved, according to the internal criteria of the manual and the Institutional Research Participant Protection Program.

All research projects conducted on humans at the Institute that involve investigators of at least two institutes, one of which is the Institute, must be assessed consistently in terms of ethics and quality and, if approved, according to the internal criteria of the manual and the Institutional Research Participant Protection Program.

Projects that are not of the Institute must be conducted ethically and professionally and risks to patients must be kept to a minimum, by means of a consistent ethical and quality assessment and, if approved, according to the internal criteria of the manual and the Institutional Research Participant Protection Program.

2.0 SCOPE

Internal: All research projects conducted on humans at the Institute.

External: Research projects conducted on humans at other institutes and for which an assessment is required.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. The Research Committee and the Research Ethics Committees will meet jointly so as to improve the efficiency of procedures and to contribute to the quality and consistency of the methodological and ethical assessment of research projects to be authorized or rejected.

2. Any research project that is conducted at the National Institute of Medical Sciences and Nutrition must meet the definition of research, in accordance with the Regulations of the General Health Law in the Field of Health Research, defines research (health research) and must be reviewed by the CER before you start.

3. All actions that contribute to the following:

   - The knowledge of biological and psychological process in humans.

- The knowledge of logical implications between causes of disease, medical practice and social structure.
- Prevent and control health problems.
- The knowledge and evaluation of the harmful effects of the environment on health.
- The study of techniques and methods that are recommended or employed.
- Providing health services and for the production of health products

4. Before a research project may commence at the Institute, all projects must be authorized according to their nature.

a).- All projects must be authorized by the Head of Department, Head of Section or Director, and by the Research Director and the President.

b). - Projects involving humans must also be authorized by the Research Ethics Committee

c) Projects that involve the organs, tissue and the products of human corpses must be reviewed and authorized by the Research Ethics Committee, in accordance with the definition of health research.

d). - Research involving animals must also be authorized by the Animal Research Commission.

e).- Research projects that involve the use of radioactive isotopes, the use of nucleic recombining acid and pathogenic agents that need to handle at security levels III and IV, must also be authorized by the Bio-safety Committee.

f).- Pharmacological research through Stage I, II, III and IV clinical tests must be authorized by the COFEPRIS (Federal Commission for Protection against Health Risks).

The following documents must be submitted so that this authorization may be given:

- Research protocol that includes a complete and objective analysis of all possible risks, in comparison with the risks of established diagnosis and treatment methods, and the expectations for the living standards of the participant, with or without the proposed procedure or treatment;
- Letter from the head of the institute that accepts that the research will be conducted;
- Approval of the REC and, if applicable, of the Bio-safety Committee.
- Description of resources available, including the areas, equipment and/or auxiliary services of laboratories and doctor's offices.
- The curriculum vitae of the principal investigator, including his or her qualifications, representative scientific production and clinical practice or experience in the field of research proposed.

- The qualifications and experience of medical and paramedical staff and of other experts involved in the research study.
- The authorization of the Federal Commission for Protection against Sanitary Risks is needed to assess the medicine used for research involving humans during stages I to IV of the pharmacological research.
- Authorization of the Federal Commission for Protection against Sanitary Risks must be obtained after the REC has given its authorization.
- The investigator will ensure that the medicine to be used is registered with the Ministry of Health and other relevant authorities.

5. The secretary of the research ethics committee is the responsible and will validate the identification number given by the Ministry of Health for a product in research as well for research drugs or devices regulated by the US FDA, will review the protocol submitted by the sponsor to determine that the IND (for drugs) or IDE number (for devices) is valid.

6. The application for the review of research project must be made on the SERPI by the investigator responsible for the ethical and scientific aspects of the project.

7. With regard to projects conducted at the Institute or in collaboration with other institutes, the Investigator of the INNSZ must be a base member and be registered with the SERPI according to the SERPI user manual.

8. All research involving human subjects that is conducted on the premises owned by the National Institute of Medical Sciences and Nutrition must be reviewed by the Research Ethics Committee.

9. There must be an authorized agreement for projects conducted with other institutes (see Procedure 3, Registration of research projects).

10. For projects that involve humans, both the investigator who asks for the review of a research project, and all assistant investigators, must submit the certificate issued from one of the two human research ethics courses of the INNSZ (see Institutional Research Participant Protection Program).

11. The investigator responsible for each health research project must comply with the authorized project proposal, in observance of ethics and taking into account the wellbeing of subjects.

12. The Committee must make a consistent and quality assessment and, if the project is approved, according to the criteria in the manual and in the Institutional Research Participant Protection Program.

13. All research conducted at the National Institute of Medical Sciences and Nutrition will be held in accordance with the Regulations of the General Health Law in the Field of Health Research and ICH-GCP (E6).

14. When the National Institute of Medical Sciences and Nutrition conducts research that is supported by the U.S. Government (NIH, for example), the following applies:

    a. 45 CFR 46 Subpart A (Common Rule) or equivalent protections as defined in the Bylaws of the General Health Law in the Matters of Health Research.

    b. 45 CFR 46 Subpart B for research involving pregnant women or equivalent protections as defined in

the Bylaws of the General Health Law in the Matters of Health Research.

15. The Investigator must submit all detailed project information.

16. If necessary, the Committee will ask the investigator to make changes, so as to guarantee protection of participants.

17. The information submitted to the Research Ethics Committee must include a section that describes possible solutions to research risks, in order to prevent participants from being exposed to greater risks.

18. The Institute's REC will examine unexpected problems that create risks for participants or third parties, as described in: http://aahrpp.org/Documents/D000148.PDF

19. The Research Ethics Committee of the Institute will keep in touch with the committees of the parties involved, with the external institute or the investigator heading the project, in order to guarantee the proper conducting and functioning of the project.

20. When a research project of another institute that has already been authorized by the Research Ethics Committee of the INNSZ is altered, all changes must be assessed and approved by the Committee of the Institute and not by another Committee.

21. With regard to research projects funded by the pharmaceutical industry or those that do not involve the Institute for which assessment is requested, the Research Ethics Committee will charge a fixed fee for reviewing applications. This fee will not be refundable if projects are rejected. Income will be used to fund the Committee and the administrative tasks and training of its permanent members.

22. The Committee may appoint or authorize a person, from inside or outside the institute, to observe the informed consent process, particularly in the following cases:

    - When the research requires a legal representative.
    - When an investigator has a record of failure to obtain the informed consent of research patients.
    - When the investigator conducts his or her first research project.
    - When a study is particularly risky.
    - When the project is regulated by the FDA

23. When the principal investigator is a member of the Institute and takes part in a multi-center study, the Committed must determine if patient protection is suitable

24. A section with the following information will be published on the website of the institute:

    - Name of the protocol:

- Name of the principal investigator:
- Telephone:
- e-mail:
- In order to discuss, deal with and ask about aspects concerning the research

DOCUMENTS:

1. The investigator must submit all documents required for a thorough and full review of the ethical aspects of the project proposed. Said documents must include, but not be limited to:

- Application form, signed and dated;
- The research project proposed, together with all supporting documents and annexes, in Spanish or English;
- A summary in Spanish of the protocol (form to be decided upon);
- A proposal of consent documents.
- Recruitment material
- The complete protocol
- Any application for funding
- The investigator's brochure (if applicable).

2. Documents are to be sent to the President of the Research Ethics Committee.

- One copy of all documents on the document list (comparison) is required.
- The deadline for receiving applications will be the last day of each month.
- Investigators will be notified of the receipt and acceptance of applications, and if an application is incomplete, by a stamped confirmation of receipt.

ASSESSMENT PROCESS:

1. All applications for the assessment of research projects correctly registered will be processed according to the assessment scheme established in this procedure and in the Institutional Research Participant Protection Program.

2. All research projects put to the Research Ethics Committee must be submitted using the Research Project Assessment Form, irrespective of whether the assessment will be Quick or Formal.

- This form is a summarized version of the research project proposed, however, substantial information is needed so it may be assessed thoroughly, which the investigator is responsible for providing.

- There are occasions on which the complete project may be included on the form, however, some projects, such as those of the pharmaceutical industry (commonly known as brochures) include information, information annexes and operating documents that need not be included on the form of the Committee, but should be duly referenced to it. In these cases, the Committee must be provided a copy of the doc or pdf file of the original project and its annexes.

3. The Committee will assess and, if applicable, approve the new research project.

4. Each member of the Research Ethics Committee must receive information on the project to be assessed so it may be properly assessed. This includes the informed consent document proposed, recruitment subjects (sic), the complete protocol, the application for funding, the investigator's brochure (when applicable) plus the research project, the assessment form, which include the content of policies 1 to 6 included in the project review section of this procedure.

5. The research project will be submitted to all members of the Committee fifteen days before its monthly meeting. The Research Ethics Committee will discuss each study in sufficient depth in order to establish if all criteria, general principles and policies for research on humans are met.

6. Any amendment to the research project that the Research Ethics Committee requires concerning general principles and research policies must be put to a new vote of the Research Ethics Committee.

7. If any problems arise, the Committee will recommend to the principal researcher any improvements and changes to be made for the project to be authorized

- The investigator may submit changes to the Research Ethics Committee in order to clarify any doubts, either in writing or personally at the next meeting of the Committee. The Research Ethics Committee must review the reply of the investigator to establish if it meets the requirements of the Research Ethics Committee and approval criteria, as defined in General Principles and Research Policies.

8. If the project contravenes the ethical principles of the Institute, it will not be authorized

9. The Research Ethics Committee will notify the investigator in writing, if the application is approved, still to be approved or rejected. For those applications that are rejected or still to be approved, the Research Ethics Committee must explain its decision and give the investigator an opportunity to respond personally or in writing.

10. The maximum time in which the decision is given after the protocol is assessed will be 15 business days. The research conclusion date is the same as the time established by the investigator, less one day after the date on which the project is approved.

11. The Committee will guarantee that at least one person who is conversant with the project subject will attend the monthly meeting at which the project is assessed.

12. If any member of the Committee is not conversant with the project subject, another person who is not a member of the Committee will be asked to assess the project (see procedure 2, Selection of guest advisors).

13. When an external advisor is invited to attend the Committee's monthly meeting, said person will be entitled to be heard, but not to vote on the final decision. The guest advisor must submit a written report to the Committee on his or her participation, which must be filed in the project file.

14. Members will assess each protocol before the Committee meets formally, in order to guarantee that when the research protocol involves vulnerable members of the community, at least one member who is experienced with working with these types of people will be present at the Committee meeting

15. The National Institute of Medical Sciences and Nutrition conducts no research with prisoners, or children.

16. Members will assess each protocol before the Committee meets formally, in order to guarantee that when the research protocol involves vulnerable members of the community; at least one member who is experienced with working with these types of people will be present at the Committee meeting.

17. The Committee must postpone approval of a project if it has any doubts and an expert in the area of research proposed is not present at the time.

18. When a Committee member has a conflict of interests concerning a project, he or she will not be allowed to vote on it.

ASSESSMENT OF PROJECTS

The main task of the Research Ethics Committee is to assess research projects proposed and their supporting documents, paying particular attention to the informed consent process, documents, and the viability and suitability of the protocol. The Research Ethics Committee will always take into account previous scientific reviews, if any, plus the requirements of applicable laws and regulations.

All applications for approval of research projects registered will be processed according to the following assessment procedure:

1. Scientific design and conducting of the study.

1.1 The suitability of the design of the study in relation to its objectives, the statistical methodology (including calculation of the size of sample) and the potential to arrive at solid conclusions with the least number of participants in the research;

1.2 The weight of the justification of predictable and inconvenient risks against foreseen benefits for participants and communities involved in the research;

1.3 Justification of the use of a control group;

1.4 Justification of the use of the placebo;

1.5 Justification of the washout period;

1.6 Criteria for the premature withdrawal of research participants;

1.7 Criteria for suspending or terminating the research project;

1.8 Provisions to monitor and audit the research project, including setting up a data security monitoring panel;

1.9 The suitability of the research site, including the support team, facilities available and emergency procedures;

1.10 The manner in which research results will be reported and published.

2. Recruitment of Research Project Participants.

2.1 Characteristics of the population from which participants will be taken (including sex, age, education, economic level and ethnic origin);

2.2 The means by which first contact will be made and by which patients will be recruited;

2.3 The means by which all information will be notified to potential research participants, or their representatives;

2.4 Inclusion criteria for research project participants;

2.5 Exclusion criteria for research project participants.

2.6 There will be no distinction with regard to social class, economic status or religion with regard to the recruitment of participants, and all persons who wish to participate and qualify will be treated on an equal basis.

3. Care and Protection of Research Project Participants.

3.1 Suitability of the investigator with regard to his or her professional training and the experience of the investigator or investigators of the study proposed;

3.2 Specifying the plan for interrupting or refusing conventional therapy for the project proposed and the justification for this action;

3.3 Medical attention that participants will be provided during and after the research project;

3.4 The suitability of medical supervision and psychosocial support for project participants;

3.5 The procedures to be followed should project participants withdraw voluntarily during the project;

3.6 The criteria for increasing access to the emergency use of and/or for the use prior to sale and regulation of the project's products;

3.7 Description of the plans to make project products available to participants, once the project has concluded;

3.8 Description of any cost that project participants may have to pay;

3.9 Compensation for project participants (including cash, services and/or gifts);

3.10 Measures for compensation/treatment in the event of the injury/disability/death of the participant attributable to his or her involvement in the project;

3.11 Insurance and indemnity agreements.

4. Protection of the Confidentiality of Project Participants.

4.1 List of persons who will have access to data;

4.2 Measures to ensure the confidentiality and security of the personal information of project participants, including clinical records and biological samples;

5. Informed Consent Procedure.

5.1 The information to be communicated to the participant or the representative during the consent process does not include exculpatory language through which the participant or the legally authorized representative is made to waive or appear to waive any of the participant's legal rights.

5.2 The information to be communicated to the participant or the legally authorized representative during the consent process does not include exculpatory language through which the participant or the legally authorized representative releases or appears to release the investigator, the sponsor, or its agents from liability for negligence.

5.3 Complete description of the procedure for obtaining an informed consent, including identification of persons responsible;

5.4 The correct, complete and comprehensible information that will be given to project participants, both orally and in writing and, when necessary, to their legal representatives; in accordance with Art. 100 of the General Health Act

5.5 Clear justification of including persons in the project who may not give their consent, and a full description of arrangements to obtain the consent or authorization for the participation of said persons;

5.6 Guarantee that project participants will receive information, as it becomes available, concerning their participation during the project (including their rights, safety and wellbeing);

5.7 The arrangements made for receiving and answering questions and complaints of participants or their representatives during the course of the project;

5.8 A non-therapeutic clinical trial (i.e. a trial in which there is no anticipate clinical benefit for the participant) should be conducted on participants who personally give consent and who sign and date the written consent document.

5.9 Non-therapeutic clinical trials may be conducted with the informed consent accepted by participants or by a legal representative will be satisfactory, if the following conditions are met: a) The objectives of the trial can not be met by means of a trial on participants who can give consent personally. B) The foreseeable risks to participants are low. The negative impact of the participants well being is minimized and low. d) The trial is not prohibited by law. e) The opinion of the Research Ethics Committee is expressed and sought on the inclusion of such participants and the written opinion covers its aspects. Such trials, unless an exception is justified, should be conducted on patients having a disease or a condition for which the product researched is intended. Participants in these trials should be particularly closely monitored and must be withdrawn if they appear to be unduly distressed

5.10 When the research protocol so requires, the investigator must have the following statements:

- A statement that the particular treatment or procedure might involve risks to the participant, which are currently unforeseeable.
- A statement that if the participant is or becomes pregnant the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
- The consequences of a participant's decision to withdraw from the research project.
- Procedures for orderly termination of a participant's involvement.
- A statement that significant findings developed during the course of the research which may be related to the participant's willingness to continue participation will be provided to the participant.
- Any additional cost for participants related to research will be covered by the budget allocated for the research.

- A statement that in the event of a research-related injury, the institute will provide medical care and medical treatment at no cost to the patient.

5.11 To cover the provisions of the regulations code in the Good Clinical Practices Section of the ICH (E6), the investigator must include the following statements:

- The alternative procedures or treatment that may be available for participants, including their advantages and major potential risks.
- That the monitor, the auditor, the REC, and the regulatory authority will be granted direct access to the participant's original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the participant, to the extent permitted by applicable laws and regulations and that, by signing a written consent form, the participant or the participant's legally acceptable representative is authorizing such access.

5.12 The Research Ethics Committee considers that investigators must take into account the following in order to obtain the consent of patients who do not speak Spanish or who are illiterate:

- The informed consent must specify that the grounds required for access have been explained orally to the patient or the legal representative.
- There will be a person who will witness this.
- For patients who do not speak Spanish, the witness will speak both Spanish and the language of the patient.
- The patient or the legal representative will sign (or place their thumbprint) the informed consent document.
- The patient or the legal representative will sign and date the informed consent document.
- The witness will sign the form and a copy of the summary.
- The person who obtains the informed consent will sign a copy of the summary.
- A copy of the form will be given to the patient or the legal representative.
- A copy of the summary will be given to the patient or the legal representative.

5.13 When research involves minimum risk and no risk, the Research Ethics Committee may not authorize the documents of the informed consent process.

For research with minimal risk, the Ethics Commission, for good cause and at the request of the principal investigator, may be authorized to obtain informed consent without written formulated. However, the researcher is obliged to provide information related to the project objectives and benefits, written in leaflet, booklet or case summary and without risk research, the investigator may waive informed consent but if present

the patient should also delivered information written.

When the Research Ethics Committee does not authorize the documents of the informed consent process, it must recommend that the investigator proceeds as follows:

- Reviews the written description of the information that will be given to patients.
- Considers having a written declaration of patients with regard to the research,

If the Research Ethics Committee considers that the informed consent process may not be authorized, it must establish the following:

- The research may not be conducted without authorization or changes to the informed consent.

6. Community Considerations.

6.1 Effect and relevance of the research on the communities from which project participants will be chosen, and for those who are concerned about the research;

6.2 Procedures followed to consult the communities involved during design of the research project;

6.3 Influence of the community on the consent of individuals;

6.4 Consultations with the community during the course of the research project;

6.5 Extent to which the research contributes to the training of human resources and material resources, including improvement of the health system, research and the option of responding to public health needs;

6.6 Description of the availability and accessibility of any successful product of the study that may be used by the communities involved, after the project has concluded;

6.7 The manner in which the results of the research project will be made available to participants and to the communities involved.

6.8 When research is conducted on communities, the investigator must obtain the written approval of the Federal Commission for Protection against Sanitary Risks and other civil authorities

GENERAL PRINCIPLES AND POLICIES FOR RESEARCH INVOLVING HUMANS

1. Risks to participants are reduced to a minimum by using procedures that are compatible with the design of research projects and that do not unnecessarily expose participants to these risks.

2. Risks to participants are reduced to a minimum by using procedures carried out on participants for diagnosis or treatment purposes.

3. The Committee will ask principal investigators to monitor data so as to guarantee the safety of participants

4. So that a research protocol may be approved, the Committee must establish that said research protocol has a monitoring plan in order to guarantee safety of participants

5. The Committee must ensure that research protocols that involve vulnerable members of the Community include protection measures and the informed consent in accordance with health research requirements and the international guidelines established in the participant protection program, in addition to which they must include the procedures for each category of vulnerable participants identified in the research protocol, which may include

   - Children
   - Disabled participants
   - Women of child-bearing age.
   - Pregnant women.
   - Women giving birth, during puerperium and while breast feeding
   - Embryos, obituses, and fetuses
   - Participants being given artificial insemination
   - Groups dependent on others, such as students, laboratory and hospital workers, employees, members of the armed forces, prisoners, and other special members of the community whose informed consent may be influenced by the authorities
   - Participants who do not have all their faculties

6. The Committee must ensure that recruitment and selection of participants is fair, to which end it must consider the objective of the research and the terms under which research will be conducted, and also ascertain inclusion and exclusion criteria

7. The Committee must establish that there are suitable controls for keeping information secret

8. The Committee must ensure that here are adequate safeguards to protect the privacy of participants.

CONFLICTS OF INTERESTS:

1. All committee members must notify the Committee President of any conflict of interests concerning the research protocol, as established in the disclosure requirement.

Policies concerning conflict of interests must take into account:

- Protection of patients.
- Integrity of the research.
- Maintaining ethics in the practice of medicine.
- Promoting compliance with professional obligations for the institute they work with.
- Explaining clearly the obligation to bring into the open the possible existence of a conflict of interests.
- Ensuring that the relationship of doctors and institutes with industry is conducted on an ethical basis.

The purpose of this policy is to ensure the objectivity of research involving humans, and to avoid possible conflicts of interests in the conducting of these research projects.

This policy applies to research projects carried out on humans and assessed by the Research Ethics Committee, under any of the following circumstances:

- Studies sponsored by business organizations.
- Studies of registered medication, devices or technology or products being studied that are not registered.

2. Committee members may achieve this by contacting any other member of the Committee before the meeting is called or when the conflict is declared at a meeting called to discuss a permanent subject of the program.

3. In all cases, the President will notify committee members at the meeting held before a research protocol is reviewed, that because there is a conflict of interests, the member of the Research Ethics Committee involved must leave the room and may not be present at the meeting or vote on said project, and will be excluded from the quorum to review a specific protocol.

4. When a member of the Research Ethics Committee does not vote on a project due to having a conflict of interests, a note must be made accordingly in the minutes of the meeting.

5. If a committee member has a conflict of interests regarding a project, but his or her experience and knowledge on the subject is required to assess the project, the committee member will be allowed to provide additional information to assess the project.

6. No member of the Research Ethics Committee may review a research protocol using the quick assessment procedure when he or she has a conflict of interests. Members must inform the President immediately if they are appointed to review a research protocol in which they have a conflict of interests, so that another member of the Research Ethics Committee may be appointed.

TAKING DECISIONS

The Research Ethics Committee will take the following into account when taking a decision concerning the ethical review of a biomedical research project:

1. Withdrawal of a committee member from the meeting when a decision is taken in the eventuality that an application may create a conflict of interests with said member. Any such conflict will be notified to the President before the application is assessed and a note will be made in the minutes of the meeting;
2. A decision may only be taken when sufficient time is available to assess and discuss the application;
3. The application will only be discussed by members of the Research Ethics Committee and non-committee members may not attend these meetings (e.g.: the investigator, representative of the sponsor, independent consultants);
4. Decisions may only be taken when there is a quorum (refer to the Composition and Operating Manual of the Research Ethics Committee);
5. Before a decision is taken, all documents required for assessing the project must be complete, plus all other items referred to above;
6. Only members who review the application may be involved in taking the decision;
7. When possible, it is recommendable that decisions be taken by consensus, when a consensus is unlikely, will lead to a majority vote;
8. Decision taking may include suggestions that are not obligatory;
9. The Research Ethics Committee may give the following types of decisions: rejected, pending (subject to the review of the full Committee or not) or approved.
10. With regard to pending decisions, a list of observations or objections must be made for review, and the procedure for reviewing the application again must be specified;
11. Rejection of an application must be properly justified.

NOTIFYING THE DECISION

The Research Ethics Committee will notify applicants in writing according to its procedures, preferably within two weeks of the meeting at which the decision is taken. It will also provide a document on its resolutions that will include the project title, the Committee code, the name of the principal investigator, the department to which he or she belongs and the resolution of the assessment, which will be sent to the relevant authorities.

Notification of the decision must include, but not be limited to, the following:

1. Clear identification of the research protocol proposed, or the amendment, plus the date and version number (if applicable) on which the decision was based;
2. The names and, when possible, the specific identification numbers (version number/dates) of documents reviewed, including information concerning potential participants and the type of informed consent;
3. The name and title of the applicant;
4. The name of the institute and place at which the research will be conducted;
5. The date and place of the decision;
6. A clear statement concerning the decision taken;
7. The observations and objections of the Research Ethics Committee;
8. With regard to conditioned decisions, the requirements of the Research Ethics Committee, including suggestions for review and the procedure for re-reviewing the application;
9. If an application is approved, a declaration of the responsibilities of the applicant, for example, confirmation of acceptance of any of the requirements established by the Research Ethics Committee; submitting progress reports, the need to notify the Research Ethics Committee with regard to members of the protocol (but not amendments that only involve logistical or administrative aspects of the study); the need to notify the Research Ethics Committee if amendments are made to recruiting material, or to information for potential project participants, or to the informed consent form; the need to report serious and unexpected adverse events related to the conducting of the study; the need to report unexpected circumstances, termination of the study or significant decisions taken by other Committees; the information that the Research Ethics Committee expects to receive to put into practice the review, the summary or final report;
10. If an application is rejected, the reasons must be clearly stated;
11. Date and signature of the President (or another authorized person) of the Research Ethics Committee.

12. The Research Ethics Committee will notify the result of its assessment of health research projects observing the confidentiality of the application and the assessment.

13. The Research Ethics Committee will ensure that the institute's web page includes the following text: "If you have any comments concerning any protocol or monitoring any protocol, please send them to the e-mail address of the Committee.

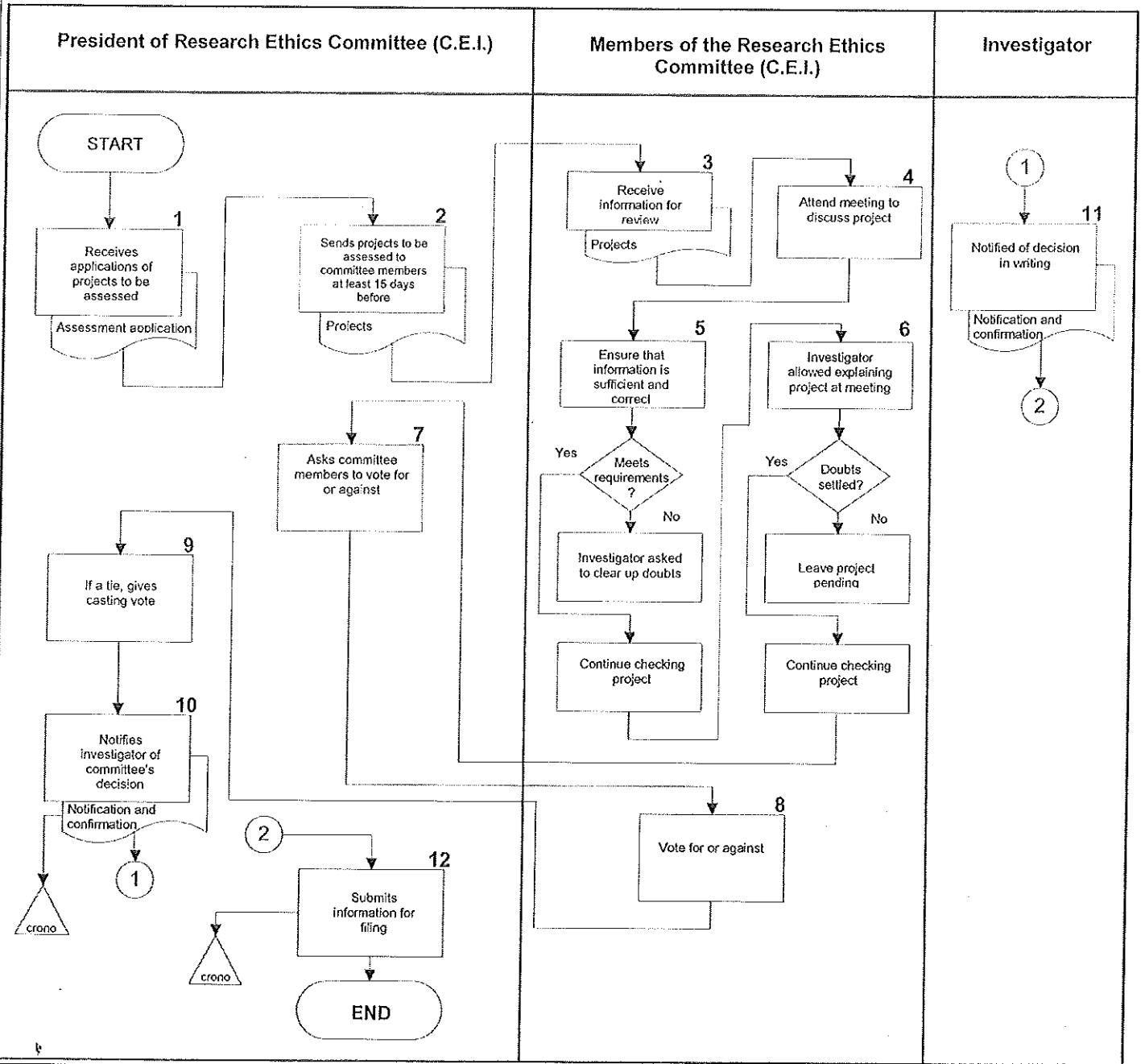
4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
C.E.I. President	1	Receives all applications of projects to be assessed at the next ordinary meeting of the Committee.
C.E.I. President	2	Sends the research projects to be assessed to all members of the Committee at least 15 days before the meeting.
Members of the C.E.I.	3	Receive information of projects to be assessed.
Members of the C.E.I.	4	Discuss research projects in technical and ethical terms.
Members of the C.E.I.	5	Ensure that all information provided on the Research Project Assessment Form and documents submitted is sufficient to decide whether to authorize the research project or not. Has sufficient information been provided? Yes. Continue with the review of the project and of all documents in order to reach a decision. No. Ask the investigator to clarify any doubts that arise from the first assessment.
Members of the C.E.I.	6	Allow the investigator to explain the project at the meeting. Did the investigator clarify doubts? Yes. Continue with assessment of the project and of all documents so as to take a decision. No. Members of the Committee may choose to leave the assessment pending (go to Task 10).

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
C.E.I. President	7	Asks members of the Committee to vote for or against the project assessed.
Members of the C.E.I.	8	Cast their vote for or against.
C.E.I. President	9	In the event of a tie, gives his or her casting vote for or against.
C.E.I. President	10	Notifies the investigator of the Committee's decision by written notification and through the SERPI.
Investigator	11	Receives written notification and through the system, so that he or she may conduct the procedures necessary to ask for the project to be assessed again or to commence the protocol.
		Submits all documents for filing. END OF PROCEDURE

5.0 FLOWCHART

5.1 Registration of external research projects



ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

6.0 RECORDS

1. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman is needed to review and obtain various documents and files.

2. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee.

Records	Time Retained	Person Responsible	Registration Code
Scheduling of meetings	5 years	CEI	FC1102
Minutes of meetings	5 years	CEI	FC1102
File of the project assessed (with all material sent by the applicant)	5 years	CEI	FC1102
Declaration of investigators	5 years	CEI	FC1102
Correspondence of members of the C.E.I. with applicants or with those involved with the application, decision and follow through	5 years	CEI	FC1102
Copy of the decision and of any suggestions or requirements sent to the applicant	5 years	CEI	FC1102

7.0 GLOSSARY

The definitions in this glossary indicate the sense in which the terms in this Manual are used. These terms may have different meanings in other contexts.

C.E.I.- Research Ethics Committee.

Community: a community is a group of persons who have a certain identity as they share common interests or are close to each other. A community may be identified as a group of persons that live in the same village, town or country, and who share geographically close to each other. A community may be identified as a group of persons that shares values, interests or illnesses.

Conflict of interests: a conflict of interests arises when a member or members of the Research Ethics Committee has an interest with regard to a specific assessment application that may compromise him or her meeting his or her obligation to provide a free and independent assessment of the research project, focused on protection of project participants. Conflict of interests may arise when a member of the Research Ethics Committee has a financial, material, institutional or social involvement with the research project.

Decision: a conditioned answer with or without assessment, rejection or approval of the Research Ethics Committee of an application after it has been assessed, in which the position of the Research Ethics Committee concerning the ethical validity of the study is expounded.

Amendment to protocol: written description of a formal change or clarification to the protocol.

Investigator: a qualified scientist who assumes scientific and ethical responsibility, either on his or her own behalf or on behalf of an organization/company, of the ethical and scientific integrity of a research project conducted on a specific site or several sites.

Clinical research "any experiment that consists of a test article on one or more human participants and that or should meet requirements for subsequent presentation to the REC and

Human Participant: A live individual who is registered as a subject in the research study. This definition considers the use of existing data, including identification details. May be healthy individuals or patients. A human participant includes an individual for whose sample a device is used.

Project participant: a person who participates in a biomedical research project, either as a direct receiver (e.g.: study product or invasive procedure) as a control or by observation. The individual may be a healthy person who volunteers for the research project, a person with a disease that is not related to the research, who volunteers, or a person (generally a patient) whose disease is relevant to the use of the product being studied or the questions being investigated.

Sponsor: an individual, company, institution or organization that funds a research project.

Protocol: a document that specifies the background, reasons and objectives of a research project, describes its design, methodology and organization, including ethical and statistical considerations. Some of these considerations may be specified on other documents that refer to the protocol.

Requirements: in the context of decisions, requirements express and contemplate ethical considerations, the implementation of which is considered as indispensable and obligatory by ethics committees in order to conduct research.

Applicant: a qualified investigator who takes on the scientific and ethical responsibility of a research project, either on his or her own behalf or on behalf of an organization/company, and who request the approval of the Ethics Committee's by submitting a formal application.

Suggestion: a non-obligatory consideration linked to the decision, the purpose of which is to provide ethical assistance to those persons involved in the research project.

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

9.0 FORMS AND INSTRUCTIONS

FORM 9.1: RESEARCH PROJECT EVALUATION FORM

RESEARCH ETHICS COMMITTEE
RESEARCH PROJECT EVALUATION FORM

Place cursor in the white space to enter information (Do NOT use shaded areas) CEI registration no.:

1. Project title

2. Investigators

2a. Identification

Name, signature, and institutional affiliation of each of the participating investigators. The principal investigator must be a professional affiliated with the Institution (staff physician or researcher) and not a course student, resident, intern, etc.).

INVESTIGATOR	Institutional Position	Position on the project	Telephone no. (ext.)	Email

2b. Involvement with the group of investigators in relation to the project

Briefly describe the qualifications of the research group in relation to the process of scientific research in general and in relation to the project presented (e.g.: academic degree, work experience, member of the INS researchers' system, SNI, etc).

Will research are conducted at another institute not owned by Institute National de Ceneí's Medicals y Nutrition Salvador Zubirán?

YES NO

If the answer is YES

Does the institute or which he/she work have a research ethics committee? YES NO

Is he/she authorized by the institute to conduct the research? YES NO

Note: Attach the letter of authorization of the institute he/she works for.

If No, does the other institute plan to rely on Institute National de Ceneí's Medicals y Nutrition Salvador Zubirán's REC to review the research?

2c. Is the principal investigator a member of the Institute? YES NO

If the answer is NO

Does the institute where you work have a Research Ethics Committee? YES NO

Are you authorized by the institute to conduct the research? YES NO

Note: Attach the letter of authorization of the institute where you work for.

3. Participating Institutions

Names and addresses of the participating institution or institutions and brief description of what their participation entails. For multicenter studies add the particulars of the coordinating center.

3a. Type of monitoring to identify and deal with unexpected events that may place participants or others at risk.

3b. Manner of providing provisional results for monitoring.

3c. Changes to the protocol.

4. Sponsorship

4a. Sponsoring organizations

Names, addresses, and telephone numbers of the organizations, institutions, or laboratories that will contribute funds.

4b. Specify whether or not the investigators are to receive payment (monetary or in kind) for their specific participation in the investigation.

If so, describe.

5. Vulnerable participants

Are any or all patients that take part in the study considered as vulnerable?

Place an 'X' Yes No

If 'Yes', identify which of the following vulnerable participants will be enrolled in the research protocol?

Children	
Disabled participants	
Women of child-bearing age	
Pregnant women	
Women giving birth, during puerperium and while breast feeding	
Embryos, dead fetuses and fetuses	
Participants being given artificial insemination	
Groups dependent on others, such as students, laboratory and hospital workers, employees, members of the armed forces, prisoners, and other special members of the community whose informed consent may be influenced by the authorities	
Participants who do not have all their faculties	

Please also provide a brief description of the additional guarantees that the protocol includes to protect the rights and well being of participants.

7. Theoretical framework

Explain in detail the information available to date on which the proposal study is based (biological meaning, data from experiments in animals or in humans):
a) background,
b) definition of the problem,
c) justification

7a. Hypothesis

Defined as a verifiable affirmation regarding the relationship between a dependent variable and an independent variable.
Remember that the concepts "null hypothesis", "alternative hypotheses", etc., are related to statistical analysis, and therefore are NOT to be included under this heading)

7b. Objectives.

Those the investigator specifically expects to obtain from the study and specified as general objective and specific objectives

8. Methodology: General design.

Describe the general design of the study and, if pertinent, specify the following points:
a) Design of the study: describe if it is random/non-random, controlled, cohort, type of blind (double blind, single blind), type of controls (placebo, active substance), washout period.
b) Description of maneuver or intervention
c) Sample size (# of subjects to be included; justify the calculation)
d) Patient recruitment and enrollment procedure
e) Mechanism for assignment to treatment (random/open)
f) Treatment groups and
g) Duration of individual follow up

9. Methodology: Screening criteria

a) Criteria for inclusion (consider non-participation in other investigations and contraception if necessary)

b) Criteria for exclusion

c) Criteria for elimination (consider pregnancy if necessary)

10. Methodology: Outcomes and variables

a) Primary variables/outcomes to be measured
b) Secondary variables/outcomes to be measured
b) Frequency of measurements,
c) Criteria of success and failure, if necessary and
d) Strategy for statistical analysis.
When pertinent, specify and justify techniques, devices, and/or instruments (including special mechanical/electronic/cybernetic equipment, evaluation forms, questionnaires, tables of comparison, etc.) to be used for measurement, indicating criteria of validity, reproducibility, and quality controls applied to them.

11. Risks and benefits of the study

a) Discomfort produced by the study (in case of blood samples, indicate total number of punctures, quantity of blood per puncture, and or total and frequency of punctures.)
b) Potential risks (presence of complications or adverse effects, consider medicamentous interactions, consider psychological effects of evaluation methods, e.g.: surveys on sensitive issues),
c) Means of detecting the anticipated risks.
d) Safety measures for opportune diagnosis and prevention of risk.
e) Procedures to follow to resolve risks if they arise.
f) Direct benefits expected.
g) Indirect benefits expected.
h) General weighting of risks against benefits for the proposed study.
i) Other kinds of risk (e.g.: the possibility of breach of confidentiality of the data generated; social effects from participation in certain projects – stigmatization for participating in HIV studies, birth control, others).)

12. Costs

a) Specify costs (direct/indirect, monetary, in time of participation, visits/travel) the investigation will entail for participating subjects (Specify whether or not doctor visits, laboratory/cabinet tests, and medical/surgical treatments related to the study will be covered by the patient/research subject). Statement on who will cover such costs.
b) Specify compensations to be offered (reimbursement of expenses incurred for participating in the study; e.g.: payment for transportation, meals, lodging, etc).
c) Specify incentives to be offered if applicable (an incentive is understood as an offer or influence that compels a subject to take an action without its implying a substantial deviation from their general plan; e.g.: giving subjects a book for having participated)
d) If there is any compensation, specify when and how participants will receive it.
Note: A disproportionate compensation/incentive is considered a coercive attitude.

13. Bibliographical references.

14. Informed Consent

Informed Consent is understood as all *actions that promote a process of communication and dialog that helps a person make decisions regarding an action, practice, or product that affects his or her body, privacy, or other vital spaces.* Information is made available to the research subject to allow him or her to make an autonomous decision regarding whether or not to participate in a clinical research project. This process is implemented through dialog with the subject and is documented by means of an institutionalized document (on the Institute's letterhead) and taking into account the accepted guidelines for the purpose.

Name and telephone number of the investigator in charge.
Name and telephone number of the person who can answer questions or provide subsequent information on ethical issues.
Name of the person who will conduct the consent interview.

14a. <u>Subject Information Sheet</u> to participate in the study (attach on a separate page).

This document must be prepared in writing by the principal investigator, using second-person language understandable to the research subject, (e.g.: *You have... and for that reason we are inviting you to participate... etc.*). Use of multi-level language is recommended, understood as phrases that explain the same thing one level above and one level below the expected level of comprehension of the subject to be included. A copy must be given to the subject. This Information Sheet should include, but is not limited to:

A clear description of the justification and objectives of the investigation, procedures to be used, aspects of the study that are experimental, expected discomforts or risks, and benefits that may be obtained.
Alternative treatments or procedures.
Responsibilities of the subject and the doctor, including a guarantee to respond to any question and/or enquiry regarding the research protocol.
Compensations in terms of health, drugs, money (should not be treated as remuneration for donating an organ or tissue, but as compensation for participating as a research subject), etc., incurred in participating in the study and in case of an adverse effect.
Costs of participation, availability of medical treatment in case of damages that warrant it, directly caused by the investigation.
The guarantee of confidentiality, voluntary participation, and the option to decline to participate or withdraw at any time, without losing benefits as a patient of the Institute and without penalization.
The reasons for which the study may be terminated.
Name of the person who will give consent or permission.
Any time between patient information and obtaining the informed consent.
Measures taken to reduce the possibility of coercion or undue influence to a minimum.
The language that will be used by those who obtain the informed consent.
The language understood by the patient or his or her legal representative.
The information that will be given to the patient or legal representative.
Please provide a description of the following:

Who will conduct the consent interview?

- Who will provide consent or permission? For instance, will the participants themselves provide consent or will consent be provided by the participants' legally authorized representative when participants are incapable of providing consent?)
- Will there be any waiting period between informing the prospective participant and obtaining consent?
- What steps will be taken to minimize the possibility of coercion or undue influence? (For instance, will participants be allowed to take the consent document home in order to consider whether they wish to participate? Following the consent interview, will there be an assessment of participants understanding of the study? If illiterate participants are to be enrolled in the research, how will you ensure that these participants are fully informed of the information that is included in the consent document?
- What language will be used by those obtaining consent?
- Do you plan to enroll subjects who speak languages different from those obtaining consent?

11b. Informed Consent Letter (attach on a separate page).

This file contains the subject's statement regarding his/her participation in the project, and therefore is worded in the first person (e.g.: I, John/Jane Doe, am aware of the project.... etc.). It will be extended in duplicate, on INCMNSZ letterhead, with one copy for the research subject or his/her legal representative and the other for the investigator. This letter must state, without limitation:

That the subject has received clear, written information.

That all the subject's questions about participating in the protocol have been answered (include title; it is essential to include the correct title for each protocol).

That the subject is aware of the risks, benefits, and responsibilities resulting from his/her participation.

That the subject has voluntarily agreed to participate and that the confidentiality of the investigation will be guaranteed.

That the subject may withdraw at any time, without forfeiting his/her benefits as a patient of the Institute and without penalization.

The name and signature of the research subject or his/her legal representative.

The names and signatures of TWO witnesses and their relationship with the research subject.

The name and signature of the investigator who obtains the consent.

Date on which the informed consent is obtained.

An explanation of the expected duration of the participant's participation.

A statement that notes the possibility that other entities might inspect the records (representatives from the ministry of Health, for example).

An explanation as to whether compensation is available if injury occurs.

If compensation is available when injury occurs, an explanation as to what it consists of or where further information can be obtained.

An explanation of whom to contact for answers to pertinent questions about the research participants' rights.

An explanation of whom to contact in the event of a research-related injury to the participant.

When appropriate, have the investigator add the following statements:

A statement that the particular treatment or procedure might involve risks to the participant, which are currently unforeseeable.

A statement that if the participant is or becomes pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which are currently unforeseeable. =o:p>

The consequences of a participant's decision to withdraw from the research.

Procedures for the orderly termination of participation by the participant.

A statement that significant new findings developed during the course of the research which might relate to the participant's willingness to continue participation will be provided to the participant.

Any additional expenses for participants related to the research, will be borne by the budget allocated for the research.

A statement that in the event of a research-related injury the healthcare institution will provide medical treatment at no expense to the participant.

Open files **CEI 02 HOJA DE INFORME.DOC** and **CEI 03 CARTA DE CONSENTIMIENTO.DOC** to generate the informed consent form. When it is ready, save by prefixing the file name with the project registration number so that the new file is saved as ####CEI 02 HOJA DE INFORME.DOC and ####CEI 03 CARTA DE CONSENTIMIENTO.DOC (where #### = CEI registration number), and attach a separate sheet.

15. Confidentiality Declaration

Describe the action, strategy and precautions that will be taken to protect the confidentiality of patient information.

Specify the following:

- Where this information will be kept.
- How it will be kept.
- Security measures.

Describe safeguards for protecting the privacy interests of participants. This includes a description of the following:

- Describe the setting in which the consent process will take place?
- Where will interviews about the research take place?
- Describe the setting in which research interventions will take place?
- When approaching prospective participants about their interest to participate in a research study, in what setting will his occur?

Describe the measures to be taken when there are indirect identifiers of the population, in order to protect this type of population, for example, when they are populations with specific characteristics.

16. Investigators' statement

Copy and print this statement on the Institute's letterhead.

Open file **CEI 04 DECLARACION DE INVESTIGADORES** to PRINT IT and have it signed by each and every one of the participants in the proposed project. Attach the sheet to the printed Evaluation Form provided.

17. Committee Ruling

This section is only for the information of the investigators: Projects will be reviewed by all the Committee members. The formal evaluation and its resolution will be made by the Committee in a plenary session. The ensuing discussion may give rise to Observations and/or Objections which will influence the Opinion, which may be Approved, Not Approved, or Pending.

17a. Observations

Points detected in the project that raise doubts or warrant clarification but are considered NOT to affect its scientific/ethical structure.

17b. Objections

Points detected in the project that raise doubts or warrant clarification and are considered to affect its scientific/ethical structure and warrant explanation, reply, clarification, amendment, and/or justification to continue the evaluation and reach a resolution.

17c. Opinion

Approved A Project Approval Letter is issued, with which the project's institutional registration will end and its implementation may begin. If there are Observations they must be answered by the principal investigator.		
Not approved The project presents formal Objections of a scientific or ethical nature that prevent its approval. It may be amended and resubmitted by means of a new Request for Review.		
Pending or in progress The Committee has not reached a definite opinion as the project presents Observations/Objections that warrant explanation, reply, clarification, amendment, and/or justification to continue the evaluation and reach a final resolution. A letter with the Observations/Objections will be issued and the evaluation will continue when they are answered.		

General Instructions for Completing the Form:
The investigator must open the **C.E.I. 01 FORMATO DE EVALUACION.DOC** file and fill in the blank spaces with the details of the project (do not use shaded areas).
The form has fifteen sections

FORM 9.2: REPORT SHEET FOR PARTICIPATING IN RESEARCH PROJECTS

No.	BOX	INFORMATION TO BE COMPLETED
	CEI Registration No.:	The registration number allocated by the Research Ethics Committee
1	Project Title:	Note the official project title (in later sections, reference will only be made to the "project", so there is no need to repeat the title.
2	Investigators:	This section has two parts
2a	Identification	(Name, affiliation and position in the project of each investigator. The principal investigator must be a professional affiliated to the Institute, a house doctor, or investigator, not a student, resident, internee, etc.); and
2b	Membership of investigator's group regarding the project	Briefly describe the qualifications of the investigating group with regard to the scientific research projects in general and with regard to the project submitted (academic qualifications, working experience, member of the Investigators System of the INS, SNI, etc.)
2c	Investigator Affiliation	The principal investigator will have to answer the questions on this point.
3	Participating institutes:	Name and address of participating institutes and a brief description of their participation. For multi-center studies, add the details of each coordinating center.
4	Sponsorship:	
4a	Sponsors:	Name, address and telephone number of organizations, institutes or laboratories who will contribute funds.
4b	Specify if investigators are paid (in cash or in kind) for their specific involvement in the research project.	If yes, please specify.

No.	BOX	INFORMATION TO BE COMPLETED
5	Vulnerable Population	Describe if the project involved vulnerable populations.
6	Theoretical framework:	Explain in detail the grounds available to date on which the study proposed will be based (biological sense, information concerning experiments on animals or humans): a) Background b) Definition of problem c) Justification
7a	Hypothesis	Defined as a probable statement regarding the relationship between a dependent variable and an independent variable. (Remember that the concepts of "null hypothesis", "alternate hypothesis" are related to the statistical analysis, so they must NOT be included in this section).
7b	Objectives.	Those expected to be achieved from the study and specified as a general objective and specific objectives.
8	Methodology: general design	Describe the general design of the study and, if relevant, specify the following points: a) Design of the study: describe if it is random/non-random, controlled, cohort, type of blinding (double blind, single), type of controls (placebo, active medicine), washout period. b) Description of maneuver or intervention. c) Size of sample (number of patients to be included, justify calculation) d) Procedure for allocating treatment (random/open) e) Treatment groups, and f) Duration of individual monitoring
9	Methodology: screening criteria	a) Inclusion criteria (take into account that they do not participate in other research projects and anti-conception, if necessary) b) Exclusion criteria c) Rejection criteria (consider pregnancy, if necessary)
10	Methodology: outcomes and variables	a) Main variables/outcomes to be measured b) Secondary variables/outcomes to be measured b) Frequency of measurements c) Success or failure criteria, and d) Statistical analysis strategy.

No.	BOX	INFORMATION TO BE COMPLETED
10	Methodology: outcomes and variables (Continued)	When applicable, the techniques, apparatus and/or instruments to be used for measuring must be specified and justified (this includes mechanical/electronic/special cybernetic equipment, assessment forms, questionnaires, comparison tables, etc.), and specify the validity, reproduction and their quality control criteria.
11	Risks and benefits of the study	a) General problems produced by the study (with regard to blood samples, note the total number of samples, the amount of blood per sample and/or total and frequency of samples). b) Potential risks (presence of complications or adverse effects, consider medical interactions, consider psychological effects of assessment methods, surveys on sensitive subjects). c) Method of detecting foreseen risks. d) Safety measures for opportune diagnosis and risk prevention. e) Procedures to follow to deal with risks, if present. f) Direct benefits expected. g) Indirect benefits expected. h) General weighting of risks against benefits of the study proposed.
12	Costs	a) Specify costs (direct/indirect, monetary, in time of participation, visits/transfer) of the investigation for study patients. Specify if appointments, laboratory examinations and medical/surgical treatment required on account of the study will be paid by research study patients or not. A statement as to who will cover these costs. b) Specify the compensation offered (refunding of expenses incurred for taking part in the study, payment of transport, food, accommodation, etc.). c) Specify incentives offered if applicable (incentive is understood as the offering or influence that compels the taking of an action without implying a major deviation from our general way of life, e.g. giving away a book) Note: any compensation/incentive out of proportion will be considered as a coercive attitude.

No.	BOX	INFORMATION TO BE COMPLETED
13	Bibliographical references	Note the bibliographical references on which the project is based.
14	Informed consent	This section comprises two extra files that must be downloaded and opened: CEI 02 PAGE DE INFORME.DOC and CEI 03 CARTA DE CONSENTIMIENTO.DOC, to prepare the informed consent. Once done, save with the project registration number so that the new file may be saved as ####CEI 02 PAGE DE INFORME.DOC and ####CEI 03 CARTA DE CONSENTIMIENTO.DOC (where #### = CEI registration number); and attach separate sheet.
14a	Patient Report Sheet for participating in the study (include on a separate sheet).	File: CEI 02 PAGE DE INFORME.DOC
14b	Informed Consent Letter (attach on a separate sheet).	File: CEI 03 PAGE DE CONSENTIMIENTO INFORMADO.DOC
15	Confidentiality Declaration	Describe the action, strategy and precautions that will be taken to protect the confidentiality of patient information

SALVADOR ZUBIRAN NATIONAL INSTITUTE
OF MEDICAL SCIENCES AND NUTRITION

INFORMATION SHEET TO PARTICIPATE IN RESEARCH PROJECT

Vasco de Quiroga No. 15
Tlalpan 14000, D.F. Mexico

No.	BOX	INFORMATION TO BE COMPLETED
1	Report Sheet for participating in research projects	To be drafted by the principal investigator, using the second person, understandable for the research patient (e.g. *You suffer… therefore we are inviting you to participate… etc.*). The use of multi-level language is recommended, this being understood as phrases that explain the same for a high level or low level of comprehension expected for the subject to be included. Provide the patient a copy. This Report Sheet must include, but not be limited to: A clear description of the justification and objectives of the research, procedures to be used, aspects of the study that are experimental, troublesome, or the expected risks and benefits that may arise. Alternative treatment or procedures. The responsibility of the patient and the doctor, including the guarantee of answering all questions and/or doubts concerning the research protocol. An explanation of whom to contact for questions and answers concerning the rights of research participants An explanation of what participants must do if they suffer a research-related injury The estimated time that the patient's participation will last Compensation under health terms, drugs, economic terms for their participation in the study (should not be handled as remuneration, but as reward for effort and expenses incurred as a research subject-travel expenses, transport, food, etc.). The costs of their participation, availability of medical treatment if any damage arises that needs such treatment, directly caused by the research. Possible indemnity and action to be taken if any adverse effect appears during the study.

An explanation as to if compensation is available if injury occurs

If compensation when injury occurs, an explanation as to what the patient must do or where further information can be obtained

The guarantee of confidentiality, voluntary participation and of being able to refuse to participate or withdraw at any time, without losing any benefits as a patient of the Institute, or being penalized.

The reasons for termination of the study.

A statement that declares the possibility that other authorities may inspect the records (representatives of the Ministry of Health, the Federal Commission for Protection against Sanitary Risks)

The name and telephone number of the principal investigator.

The name and telephone number of a Committee member who may contact patients to answer questions concerning ethical aspects of the research study, concerns regarding the research study and to receive complaints

The informed consent must include information on participants and the principal investigator so as to clarify problems, answer questions and allay the concerns of study patients

When the research protocol so requires, the investigator must have the following statements:

- A statement that the particular treatment or procedure might involve risks to the participant, which are currently unforeseeable.
- A statement that if the participant is or becomes pregnant the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.
- The consequences of a participant's decision to withdraw from the research project.

		• Procedures for orderly termination of a participant's involvement. • A statement that significant findings developed during the course of the research which may be related to the participant's willingness to continue participation will be provided to the participant. • Any additional cost for participants related to research will be covered by the budget allocated for the research. • A statement that in the event of a research-related injury, the institute will provide medical care and medical treatment at no cost to the patient. To cover the provisions of the regulations code in the Good Clinical Practices Section of the ICH (E6), the investigator must include the following statements: • The alternative procedures or treatment that may be available for participants, including their advantages and major potential risks. • That the monitor, the auditor, the REC, and the regulatory authority will be granted direct access to the participant's original medical records for verification of clinical trial procedures or data, without violating the confidentiality of the participant, to the extent permitted by applicable laws and regulations and that, by signing a written consent form, the participant or the participant's legally acceptable representative is authorizing such access.

FORM 9.3: LETTER OF INFORMED CONSENT

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"Salvador Zubiran"

LETTER OF INFORMED CONSENT TO PARTICIPATE IN THE PROJECT:

(INCLUDE DATE OF PREPARATION AND PROTOCOL VERSION)

Principal Investigator:_____
Researcher address:_____
Telephone contact the researcher (including one emergency):_____
Researchers participating:_____
Study sponsor name:_____
Address of sponsor:_____
Version of informed consent and date of preparation:_____

INTRODUCTION:

Please take all the time it takes to read this document, ask the researcher any questions you have. This consent complies with the guidelines established in the Regulation of the General Law of Health research in health, the Declaration of Helsinki and Good Clinical Practice issued by the National Bioethics Committee.
In deciding whether or not to participate in this study, you should have enough knowledge about the risks and benefits to make an informed decision. The informed consent form will give detailed information about the research study that may discuss with your physician or a member of the research team. Eventually you will be asked to serve on the project and if so, under any pressure or intimidation, will be invited to sign the informed consent.

INVITATION TO PARTICIPATE AND PROJECT DESCRIPTION

Dear Mr.(Ms.)_____

The National Institute of Medical Sciences and Nutrition invite you to participate in this research study that aims:_____.
The study duration is:_____.
The approximate number of participants will be:_____.
You were invited to the study because it has the following features:
_____

STUDY PROCEDURES
The treatment is to be evaluated:_____.
Will be compared against_____.
Your chance to be assigned to one of the aforementioned groups is:_____.

Your participation in the study is:_____***(describe number, frequency and timing of visits, length of the interview, you must attend conditions, taking medications, changes in diet***

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

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NATIONAL INSTITUTE OF MEDICAL SCIENCES AND NUTRITION
"Salvador Zubiran"

or physical activity questionnaires filled or any other action that the patient must make).

The study procedures included conducting:_____ *(describe type and number of tests, test logistics).*
Proposed interventions that are experimental:_____
The interventions included in the study are part of standard treatment are:_____
The responsibilities of the participants included:_____ *(Examples: report address changes or health status, report changes in treatment or other action to alter the results of the study).*

Risks and inconveniences
It should describe in detail the risks and inconvenience to the participant, making specific comments to the embryo, fetus, infant or sexual partner when applicable. You need to describe the procedures followed by the researcher to ensure the privacy of participants
Example:
Regulation of the General Law of Health in Research for Health, said that obtaining biological samples represents a minimal risk in research. The risks of blood sampling are: possibility of light bleeding or bruising at the puncture site, dizziness or lightheadedness may occur rarely and arterial puncture. Staff who draw the blood sample is trained for it, which will minimize the risk of complications.
There is no risk whatsoever in obtaining the urine sample.
Data about their identity and medical information will not be disclosed at any time as required by law, therefore, in the collection of clinical data you do not face greater risks relating to the protection of the confidentiality which will be protected by coding of samples and information.

POTENTIAL BENEFITS
It should explain the potential benefits. If there are no benefits to the participant, should be mentioned.
example:
This study was not designed to benefit you directly. However, the search for _____ could allow development of new therapeutic targets and thereby make more personalized treatment of this disease. Also by participating altruistic, community can benefit significantly by finding new ways to address this medical complication.
ECONOMIC CONSIDERATIONS
It should explain the anticipated expenses for participating in the study, the compensation that the patient can receive for their participation, the procedures to be followed to obtain compensation.
Example:
There shall be no fee for participating in the study, nor will it pay. The researcher may cover the costs of transportation to the Institute up to an amount of ____ dollars per visit. You'll need to submit receipts or invoices (if applicable).
COMPENSATION
It should be explained in detail to get attention if adverse events responsible for the costs and conditions that would exempt the investigator from liability in the event of an adverse event
Example:
If you are injured as a result of participating in this study, we will provide immediate treatment and will refer you, if warranted, to requiring medical specialist. We have no budget to fund compensation for

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

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"Salvador Zubiran"

injuries. The National Institute of Medical Sciences and Nutrition Salvador Zubirán not provide any additional compensation to cover the damage.

ALTERNATIVES TO PARTICIPATION:
It should be noted that participation in the study is voluntary. It must specify the standard treatment for their condition and the alternatives that may follow if not participate in the study
Example:
Your participation is voluntary. However, you can choose not to participate in the study. Being a healthy subject, does not require additional studies or therapeutic actions

Potential commercial products derivable STUDY:
Should describe the property of biological materials and products resulting from the study, citing the benefits they could get the patient
example:
Materials will be owned by the National Institute of Medical Sciences and Nutrition Salvador Zubirán (INCMNSZ). If a commercial product is developed as a result of the study, such input will be owned by the National Institute of Medical Sciences and Nutrition Salvador Zubirán (INCMNSZ) or their designees. In that case, you will not receive a financial benefit.

ACTIONS TO BE TAKEN AFTER THE END OF THE STUDY:
It should describe the actions to care for the participant after the study is over. It should be mentioned if the possibility exists that the patient be contacted after completion of the study example:
You can apply the results of clinical tests and the conclusions of the study Dr._____ of INCMNSZ (tel_____). Research is a long and complex process. The get the final results of the project can take several months.

PARTICIPATION AND WITHDRAWAL OF STUDY:
Your participation is voluntary. If you decide not to participate, it will not affect his relationship with the National Institute of Medical Sciences and Nutrition Salvador Zubirán (INCMNSZ) or your right to receive medical care or any service for which you qualify. If you participate, you are free to withdraw your consent and discontinue participation at any time without affecting your care at the National Institute of Medical Sciences and Nutrition Salvador Zubirán (INCMNSZ.) Will be informed in time if new information is obtained that can affect your decision to continue in the study.
The investigator or the study sponsor may exclude si_____ study.
The study can be terminated prematurely si_____. The procedures that will be necessary if you terminate your participation in the study are_____.

PRIVACY AND INFORMATION MANAGEMENT
Your name will not be used in any of the studies. Biological samples obtained do not contain any personal information and is coded with a serial number to avoid any possibility of identification. By law

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

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"Salvador Zubiran"

the biological samples, including blood, are classified as hazardous waste biological-infectious and therefore during the course of his investigation shows no publicity may be returned. It is possible that their biological samples and medical information and / or genetics can be used for other similar research projects related to the disease under study. It may be used for research unrelated to conditions other than those studied in this project. Your samples may be stored for up por_____ researchers (time).

The codes that identify your sample will only be available to holders researchers, who are bound by law not to disclose their identity. These codes will be stored in a locked filing cabinet. Only the researchers will have access. There is a possibility that your privacy is affected as a result of their participation in the study. Your confidentiality will be protected as required by the law. It will be maintained by assigning codes to your information. The code is an identification number that does not include personal data. No information about you will be shared with others without your authorization, except:

- If necessary to protect their rights and welfare (for example, if you have been injured and requires emergency treatment), or
- It is requested by law.

Studio monitors or auditors may have access to information of the participants.

If you decide to withdraw from the study, it may request the withdrawal and destruction of biological material and information. All data collection sheets will be saved with the same degree of confidentiality, and only holders researchers have access to data that have names.

The Research Ethics Committee of the National Institute of Medical Sciences and Nutrition approved the conduct of this study. This committee is who reviews, approves and monitors human research studies at the Institute. In the future, if we identify information that we consider important for your health, consult with the Ethics Commission that oversees this study to decide the best way of providing this information to you and your doctor. In addition, we request that you authorize us recontactarlo, if necessary, to ask for information that may be relevant to the development of this project.

Scientific data collected as part of this study could be used in medical publications or presentations. Your name and other personal information will be removed before using the data.

If you ask your GP will be informed about their participation in the study

For genetic studies (if applicable):

For their participation in the study, it may be necessary to family members (if applicable). Your family will not be contacted without your permission.

Their genetic material will not be used for purposes other than those listed in this document. If the researcher wants to use it for different purposes must notify and request your signature on a document similar to the one you are reading.

The results of genetic studies will not be included in your file at the Institute, unless they have implications for treatment.

The results of genetic studies could lead to discrimination for people with an abnormality that predisposes them to suffer a disease. We will take the necessary actions to prevent their information from being known by others that may take discriminatory action against you.

IDENTIFICATION OF INVESTIGATORS:

If you suffer an injury related to the study, please contact _____ in INCMNSZ (phone:_____).

Vasco de Quiroga No. 15
Tlalpan 14000, D.F. México

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Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

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"Salvador Zubiran"

If you have questions about the study, please contact the INCMNSZ _____ (phone: _____).
If you have questions about your rights as a study participant, you can talk to the coordinator of the Research Ethics Committee of INCMNSZ (Dr. Carlos A. Aguilar Salinas. Tel. 54870900 ext. 6101).

STATEMENT OF INFORMED CONSENT

I have carefully read this informed consent, I asked all the questions I've had and all have been answered satisfactorily. To participate in the study, I agree with all of the following points:
I agree to participate in the study described above. The global, specific recruitment and possible damage and inconveniences have been explained to my satisfaction.
I agree to voluntarily donate my biological samples (which_____?) For use in this study. Also, my biological and medical information may be used for the same purposes.
I agree, if necessary, to contact me in the future if the project requires collecting additional information or find information relevant to my health.
My signature also indicates that I have received a duplicate of this informed consent.
Please answer the following questions

		YES (please check)	NO (please check)
a.	¿ You have read and understood the informed consent form in their native language?	☐	☐
b.	¿ He has had the opportunity to ask questions and discuss this study?	☐	☐
c.	¿ Have you received satisfactory answers to all your questions?	☐	☐
d.	¿ Have you received enough information about the study and has had enough time to make the decision?	☐	☐
e.	¿ You understand that your participation is voluntary and you are free to discontinue participation in this study at any time without having to justify its decision and without affecting your care or without loss of benefits to which they would otherwise be entitled?	☐	☐
f.	***applying:¿*** Authorizes be given access to their medical records for research and study for regulatory purposes to _____, their representatives, auditors, regulatory offices of the study, other government agencies health in Mexico and possibly other government health agencies in other countries in which to consider the study drug for marketing approval?	☐	☐
g.	¿ Understand the risks, some of which are still unknown, to participate in this study?	☐	☐
h.	¿ Understand that you may not receive any direct benefit from participating in this study?	☐	☐
i.	¿ Have you discussed treatment options with a doctor involved in the study and you understand that other treatment options are available?	☐	☐

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Signature:			
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"Salvador Zubiran"

		YES (please check)	NO (please check)
j	¿ Understand that you are not waiving any of your legal rights to the creditor that is otherwise as a subject in a research study?	☐	☐
k.	¿ Understands the medical study participant can withdraw from it without its consent, either because you did not follow the requirements of the study or if the study participant physician considers medically retirement is in your best interest?	☐	☐
l.	***applying***¿ Understands that the study may be suspended by the sponsor of the study at any time?	☐	☐
m.	¿ Understand that you will receive an original of this signed and dated consent form for your records?	☐	☐

Patient Declaration: I, _____ I declare that my decision to participate in the study. My participation is voluntary. I have been informed that I can refuse to participate or terminate my participation at any time during the study without suffering any penalty or loss of benefits. If I suspend my participation, I will receive standard medical treatment to which I have a right in the National Institute of Medical Sciences and Nutrition Salvador Zubirán (INCMNSZ) and suffer no prejudice in my care or in future research studies. I can I request additional information about the risks and potential benefits of my participation in the study. I can get the results of my clinical examinations if requested. If you have questions about the study, please contact_____. If you have questions about your rights as a study participant, you can talk to the coordinator of the Research Ethics Committee of INCMNSZ (Dr. Carlos A. Aguilar Salinas. Tel: 54870900 ext. 6101). I must inform researchers of any change in my health (eg, use of new drugs, changes in consumption of snuff) or in the city where I live, as soon as possible. I have read and understood all of the information given to me about my participation in the study. I had the opportunity to discuss and ask questions. All questions have been answered to my satisfaction. I understand that I will receive a signed copy of this informed consent.

_____ _____ _____
Name of Participant Signature of Participant date

_____
Place your fingerprint if you can not write

_____ _____ _____

Vasco de Quiroga No. 15
Tlalpan 14000, D.F. México

ISSUE CONTROL			
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"Salvador Zubiran"

Name of legal representative legal (if applicable) | representative Signature | Date

Name of Researcher explained that the document | Signature of Investigator | Date

Name of Witness 1 | Signature of Witness 1 | Date

Relationship to participant: _____

Dirección: _____

_____

Name of Witness 2 | Signature of Witness 2 | Date

Address: _____

_____

Interrelationship with the participant: _____

Place and Date: _____

(This document is original and has _____ pages)

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Date:	MARCH 2013	MARCH 2013	MARCH 2013

No.	BOX	INFORMATION TO BE COMPLETED
1	Letter of Informed Consent	Informed Consent is understood as all those *actions that promote a process of communication and dialogue that help people to take decisions regarding a certain action, practice or product that affects their body or life.* Information will be provided to patients so that they may take an independent decision as to whether they should participate in a clinical research project or not. This process is implemented through dialogue with the patient and is documented on an institutional document (on the letterhead of the Institute) and taking into account the accepted guidelines to do so. The Informed Consent consists of two main sections, the details of which are described below. In general, it is expected that both documents will be available, although these two sections may be combined in a single document, provided that the specific details of each section are retained. See Procedure for Preparing, Compiling and Obtaining the Informed Consent.

INSTITUTO NACIONAL DE CIENCIAS MEDICAS Y NUTRICIÓN
SALVADOR ZUBIRAN

CONFLICT OF INTEREST

PROJECT TITLE:

C.E.I. Registration Number:

The investigator engages in any of the following Conflict of Interest?

CONFLICT OF INTEREST	Yes	No
Salaries, profits or any other remuneration of the sponsor.		
Income earned from seminars, classes or teaching sponsored by public bodies or non-profit making organizations.		
Income earned from services provided as a consultant or review bodies of public institutions or non-profit making organizations		
Shares the value of which does not exceed US$10,000, or 5% of property, when added to the income of the investigator, his or her spouse, children, etc.		
Salaries, profits or any other remuneration, that, together with the income of the investigator, his or her spouse, children, etc. is not expected to exceed US$10,000 in the following year.		

Date:

Investigator Name and Signature:

Received:

Vasco de Quiroga No. 15
Tlalpan 14000, D.F. México

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

FORM 9.3: NOTIFICATION OF APPROVAL LETTER

Mexico City, Federal District, ..., 2009

DR.
PRINCIPAL INVESTIGATOR
DEPARTMENT OF

I hereby wish to advise you that the Research Ethics Committee of the National Institute of Medical Sciences and Nutrition Salvador Zubirán has revised and approved the clinical Research Protocol entitled:

"Title of Protocol"

The following documents have also been assessed and approved:

- Clinical study protocol, version No. .....
- Patient Information

Upon completion of the study, please send the results, together with a summary of all outstanding details and conclusions, an annual report (if the study lasts more than a year) that includes progress made and the partial results of your project.

Your project has been registered by the Institute under number **REF.** ..... This number is required for research support services.

Yours sincerely

DR. CARLOS A. AGUILAR SALINAS
PRESIDENT
RESEARCH ETHICS COMMITTEE

cc Dr. Ruben Lisker Y. Research Division.
Martha Arredondo Urzua. Head of Department. C.F.E.I.

No.	DESCRIPTION	INFORMATION TO BE PROVIDED
1	Date	The date of the letter.
2	Dr.	Name of Investigator responsible for the protocol.
3	Department of	Name of department in which the investigator responsible is assigned.
4	Title of protocol	Full name of the protocol approved.
5	Technical study protocol version No.	Protocol review number.
6	Ref.	Reference number allocated to the research protocol.
7	Signature	Original signature of the president of the Research Ethics Committee

6. PROCEDURE FOR MONITORING RESEARCH PROJECTS

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

1.0 PURPOSE

Give the right track to completion of the research projects that are carried out at the National Institute of Medical Sciences and Nutrition (INNSZ) and were approved by the Research Ethics Committee

2.0 SCOPE

Internal: All research projects conducted on humans at the Institute that are assessed and approved by the Research Ethics Committee.

External: Research projects conducted on humans at other institutes that are assessed and approved by the Research Ethics Committee of the Institute.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. The Research Ethics Committee will monitor the progress of all research studies it approves, as from the time of approval until conclusion of the project.
2. The Research Ethics Committee will ensure that health research projects meet local and international ethics requirements for studies carried out on humans, in order to guarantee the dignity, rights, safety and wellbeing of all research subjects.
3. At least one member of the Committee must review the complete protocol, including any previous change to the protocol already approved by the Research Ethics Committee
4. The quorum convened by the Research Ethics Committee and the assessment is not necessary to continue the assessment when the following quick assessment criteria are met:
   - When the research project is initially approved using the quick assessment procedure;
   - If (i) the research is permanently closed to enrollment of new participants, (ii) all participants have completed all research related to interventions and (iii) the research remains active only for the long-term monitoring of participants;

- When participants have not been enrolled and there are no additional risks or risks that have not been identified, or
- When remaining research tasks only involve analysis of data.

5. Occurrences or events that require unscheduled monitoring (see procedures):

   5.1 Any change to the protocol that affects or may affect the rights, safety and/or wellbeing of participants in the project or the conducting of the study;

   5.2 Serious and unexpected adverse events related to the study or the product being studied and the ensuing response of investigators, sponsors and regulatory agencies;

   5.3 Any event or new information that may affect the benefit/risk ratio of the study;

6. Members of the Committee must observe the following for the ongoing review and monitoring of research projects using the quick assessment procedure.
   - If the research still meets approval criteria as described in the general principles and the policies for research conducted on humans
   - If no major changes have been made to the protocol since the last review of the Research Ethics Committee
   - If the current consent document is still accurate and complete
7. Applicants must be notified of the decision to monitor the project and if the original decision of the Research Ethics Committee is either altered, suspended or canceled, or of confirmation to the effect that the approval given is still effective;
8. If the study is suspended or terminated prematurely, applicants must notify the Research Ethics Committee the reasons and must provide the Research Ethics Committee a summary of the results obtained during the study suspended or terminated prematurely;
9. The Research Ethics Committee must receive the notification of the investigator when a study is concluded;
10. The Research Ethics Committee must receive a copy of the following documents for the ongoing review and monitoring of research projects:
    - The current consent document.
    - Any newly proposed consent document.

- A report on the progress of the research project.
- Any changes recently proposed.

11. The Research Ethics Committee will provide the Institutes' investigators who conduct research projects at the institute or in conjunction with other institutes, advice and support with regard to meeting standards and ethics.

12. The Research Ethics Committee will assist in applying and publicizing the provisions concerning the monitoring and modification of research projects conducted at the Institute.

13. The ongoing review and monitoring of research projects will only be interrupted when:

    - Research is permanently closed to the enrollment of new participants;
    - All participants have completed research related to interventions, and
    - All information has been compiled and analyzed.

14. When the principal investigator does not anticipate the ongoing review and/or monitoring of research projects by the Research Ethics Committee or if a protocol is not approved as of the date of termination:

    - All tasks must be suspended, including contracting, publicity, selection, enrollment, consent, interventions, interaction and generation of information.
    - Interventions and interactions on current participants continue only when the REC finds an over-riding safety concern or ethical issue involves such that it is in the best interests of individual participants
    - When new participants are not recruited.

15. The REC as the authority at any time, to call the principal investigator to review and audit the advance of the project and present information and results and this can be to often as the committee and could be every month 3 or 6 months.

16. If the REC decides to stop or suspend a protocol president ethics committee should have clear communication of decisions to officials of the organization of the Institute, the sponsor or the organization as a regulator of the FDA of a case applying.

17. The principal investigator must notify the progress of research projects in a report that must include the following information:

    Research project progress reports must include:

    - Number of participants assessed

- A summary since the last review of the Research Ethics Committee:
  - Adverse events, unexpected adverse events or results experienced by participants.
  - Unexpected problems that create risks for participants or others
  - Participants withdrawing from the project
  - Reasons for withdrawing from the project.
  - Complaints about the research project
  - Any changes or alterations
- All recent literature that is relevant:
- Any provisional conclusions, including data security control reports
- Any relevant multi-center research reports.
- The investigator's current risk-potential benefit assessment based on study results.

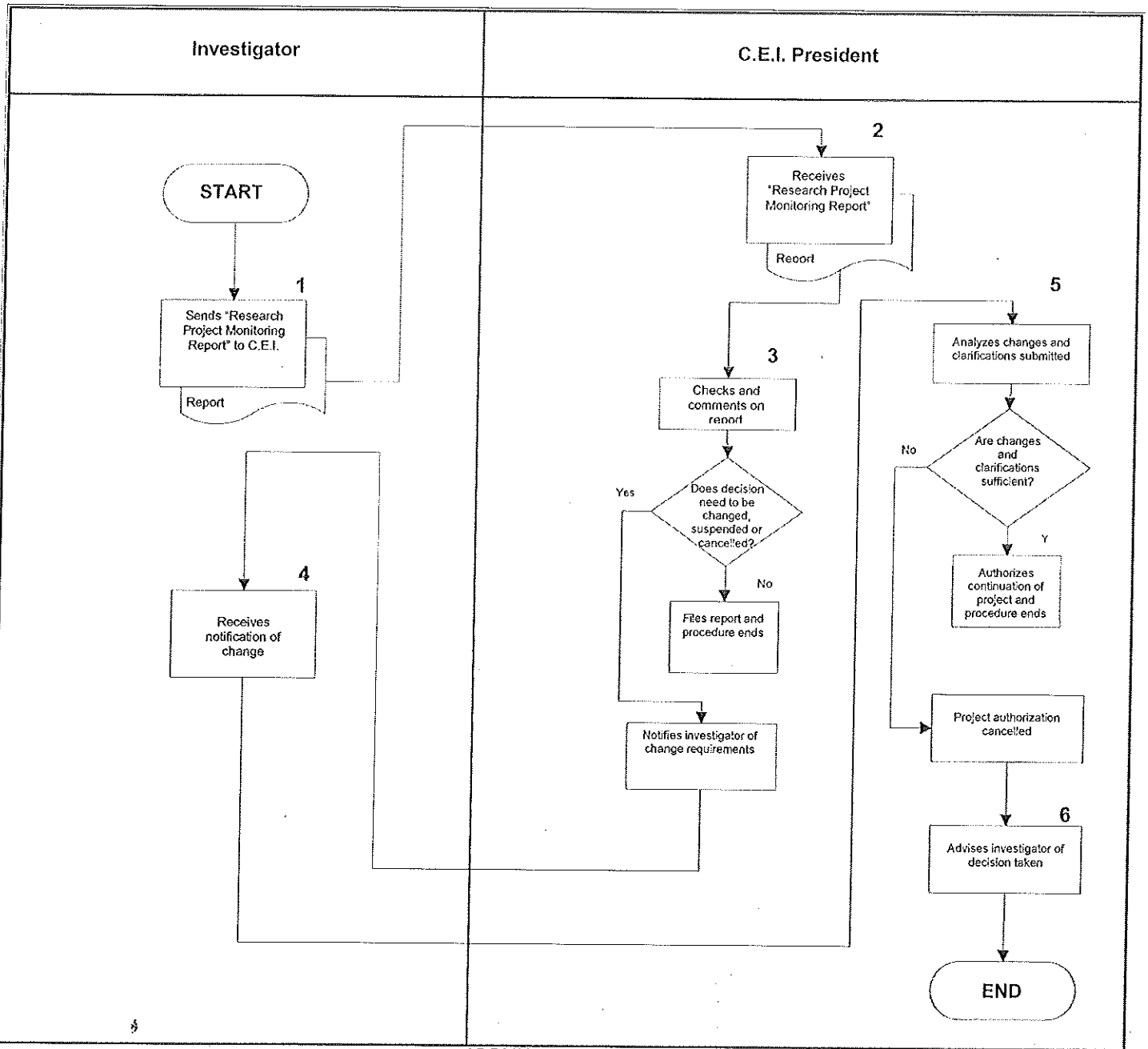
4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Investigator	1	Sends the "Research Project Monitoring Report" to the C.E.I.
C.E.I. president	2	Receives the "Research Project Monitoring Report".
C.E.I. president	3	Revises the "Research Project Monitoring Report" and, if applicable, provides observations. Is it necessary to alter, suspend or cancel the original approval of the C.E.I.? No. Files the report and END OF PROCEDURE. Yes. Notifies the investigator that the project needs to be modified or that the original approval of the C.E.I. is suspended or cancelled.
Investigator	4	Receives the notification of modification, suspension or cancellation and, if applicable, makes any necessary changes and notifies the C.E.I. president r
C.E.I. president	5	Analyzes changes made. Are the changes sufficient and do they meet ethical and methodological standards? Yes. Authorizes continuation of the project. No. Project authorization is cancelled.
C.E.I. president	6	Notifies the investigator of the decision taken. END OF PROCEDURE

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

5. FLOWCHART

5.1 Monitoring research projects



ISSUE CONTROL

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Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

6. Records

a. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman and the president is needed to review and obtain various documents and files.

b. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee.

Records	Time Retained	Person Responsible	Registration Code
Research Project Monitoring Report	5 years	C.E.I	FC1102
Notification of modification, suspension or cancellation of the authorization of the research project.	5 years	C.E.I	FC1102

7.0 GLOSSARY

C.E.I.- Research Ethics Committee

Investigator: a qualified scientist who takes on the scientific and ethical responsibility, either on his or own behalf or on behalf of an organization/company, of the ethical and scientific integrity of a research project conducted on a specific or group of sites.

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9.0 FORMS AND INSTRUCTIONS: Not applicable

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

7. PROCEDURE FOR ASSESSING AND AUTHORIZING CHANGES OR ALTERATIONS TO A RESEARCH PROJECT ALREADY APPROVED

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/Presiden
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

1.0 PURPOSE

To establish if changes or alterations to research projects already approved by the Research Ethics Committee meet ethical and methodological standards.

2.0 SCOPE

Internal: All research projects conducted at the Institute, authorized by the Research Ethics Committee and that are subject to change or alteration.

External: Research projects conducted at other institutes, authorized by the Research Ethics Committee and that are subject to alteration or change.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. The Research Ethics Committee will assess any change to the research project registered or the annexes thereto, proposed by the investigator and signed in agreement by all investigators, in observance of local and international research, ethics and bio-safety provisions for studies carried out on humans.

2. Any change to protocols that may affect the rights, safety and/or well-being of research participants, or the conducting of the study, will be subject to review for authorization purposes, including the informed consent . Changes to research projects already approved may only go ahead without assessment and without the approval of the Research Ethics Committee when the investigator establishes that said changes are necessary in order to do away with an immediate and evident risk to participants. These changes must be notified immediately to the Research Ethics Committee. The Committee will examine changes to ensure that they are compatible with protection of participants and the maintaining of their rights and well-being.

3. Changes or alterations will be assessed using the quick assessment procedure (an alternative method of the Research Ethics Committee assessing research projects or related documents) only if the change is qualified as a minor alteration to the research project. The change proposed will be considered as minor when the following criteria are met:

   - The change proposed does not substantially alter the purpose, design, implementation or risk/benefit assessment of the research project.

- Other procedures that are added and are considered as part of categories 1 and 2, as described in the procedure to establish if research involving humans may be subject to quick assessment

4. When an investigator ask for authorization to amend a research protocol, he or she must submit all amended documents for a thorough and full review of the ethical aspects of the project. The assessor must examine all amended documents thoroughly to establish if the change proposed may or may not be approved. These documents must include, but not limited to:

   - Application form signed and dated;
   - The research protocol, together with the change proposed and any supporting documents and attachments in Spanish or English;
   - A summary in Spanish of the alterations or changes made to the protocol;
   - A proposal of the amended informed consent document;
   - Recruitment material.
   - The full protocol together with any necessary alterations or changes.

5. The Committee President may assess changes without the need of a quorum when the changes proposed are considered as minor changes to the research project, as defined in Point 3 above. Any change approved by the quick assessment procedure, of minor alterations to the research project shall be notified to the Research Ethics Committee at the next meeting for confirmation.

6. The president of the Research Ethics Committee must give his or her decision in writing and keep a file of all decisions taken. The person taking the decision concerning changes or alterations must have no direct interest in the project in question.

7. Changes to research projects not considered as minor will be checked by the Committee using the formal assessment and authorization procedure for research projects.

8. All Committee members must receive a copy of the documents referred to in Policy No. 4 of this procedure, together with the alterations or changes to the research project.

9. The Committee will assure itself that the criteria of general principles and research policies are not affected by the change proposed, before said change to the project is approved.

10. In the case of research projects funded by the pharmaceutical industry or those outside the Institute is requested in the evaluation of research projects, the Research Ethics Committee charged a fixed fee for the review of an application. This fee is not refundable in case of negative decisions. The appeal will go to the fund to support the Committee and will be used to support the business activities and the training of the regular members of it.

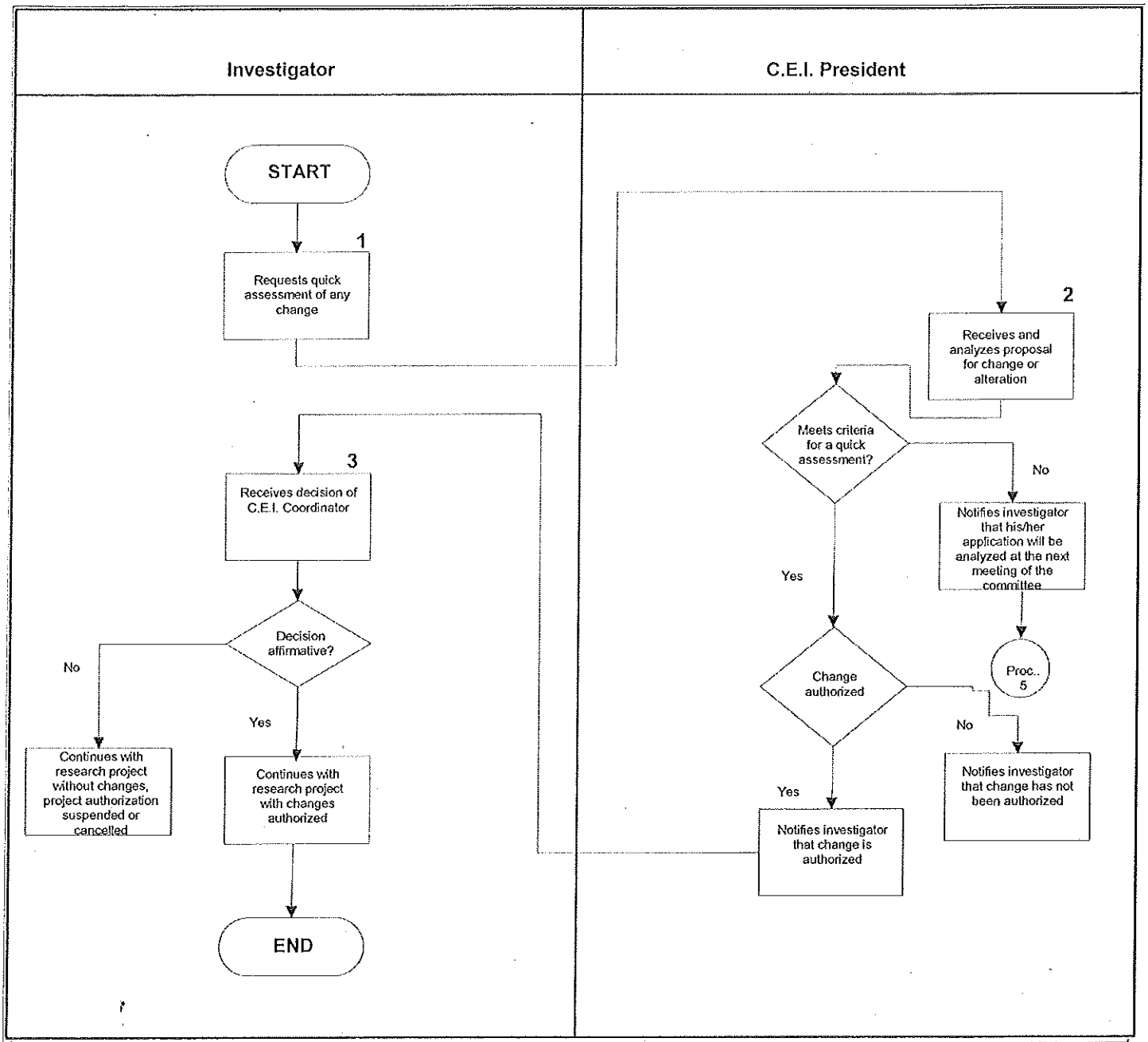
4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Investigator	1	Requests a quick assessment of any change to a research project already authorized by the C.E.I.
C.E.I. president	2	Receives and analyzes the request to alter or change the research project. Does the change or alteration meet the criteria for a quick assessment? No. Notifies the investigator that the application will be assessed formally by the C.E.I. at its next meeting (refer to procedure No. 5). Yes. Continues with the procedure. Is the change or alteration to an authorized project approved? No. Notifies the investigator for writing that the change or alteration of the project is not authorized, so the project must continue without changes, or the authorization will be suspended or cancelled. Yes. Notifies the investigator for writing that the change or alteration has been authorized and that the research project may continue.
Investigator	3	Receives the decision of the C.E.I. president. Is it affirmative? Yes. Continues with the research project with the changes authorized. No. Continues with the research project without changes, project suspended or project authorization canceled. END OF PROCEDURE

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

5.0 FLOWCHART

5.1 Procedure for Assessing and Authorizing Alterations or Changes to a Research Project Already Approved



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Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

6. RECORDS

a. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman and the president is needed to review and obtain various documents and files..

b. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee..

Records	Time Retained	Person Responsible	Registration Code
Request for quick assessment of changes or alterations.	5 years	C.E.I	FC1102
Notification of authorization of changes, alterations or adverse events.	5 years	C.E.I	FC1102

7.0 GLOSSARY

C.E.I.- Research Ethics Committee.

Change to protocol.- A written description of a change or formal clarification of the research project.

Investigator: a qualified scientist who takes on the scientific and ethical responsibility, on its own behalf or on behalf of an organization/company, of the ethical and scientific integrity of a research project conducted on a specific site or a group of sites

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9.0 FORMS AND INSTRUCTIONS: Not applicable

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

8. PROCEDURE FOR ASSESSING RESEARCH PROJECTS IN THE EVENT OF UNFORESEEN PROBLEMS AND ADVERSE EVENTS

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

1.0 PURPOSE

To guarantee the prompt response of the Research Ethics Committee in the face of any unexpected or adverse event that occurs during an authorized research project.

2.0 SCOPE

Internal: All research projects conducted at the Institute, authorized by the Research Ethics Committee, in which an unexpected or adverse event occurs.

External: Research projects approved by the Research Ethics Committee, conducted at other institutes in which an expected or adverse event occurs or in which the standards or ethical or methodological requirements are not observed.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. The investigator must ensure the safety and wellbeing of research subjects.
2. Investigators are responsible for reporting immediately when problems arise the following:

    a. If a serious or an expected event occurs concerning the conducting of the study or the product of the study and the ensuing response of investigators, sponsors and regulatory agencies;

    b. Any event or new information that may affect the benefit/risk ratio of the study;

    c. Internal adverse events that are unexpected, related to the research, and involve new or increased risks to participants or others.
    d. External adverse events that have been determined to be unanticipated problems involving risks to participants or others.
    e. Changes made to the research without prior IRB or EC approval in order to eliminate apparent immediate harm.
    f. Other unanticipated events, incidents, or problems that is related to the research and that indicate participants or others might be at new or increased risks.

        i. Any event that requires prompt reporting according to the research protocol or plan or the sponsor.

ii. Any accidental or unintentional change to the IRB or EC-approved research protocol or plan that involved risks or has the potential to recur.
iii. Any change to the research protocol or plan taken without prior IRB or EC review to eliminate apparent immediate hazard to a research participant.
iv. Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research.
v. Any complaint of a participant that indicates an unanticipated risk or that cannot be resolved by the research staff.
vi. Any other event appropriate to the local context.

g. The above should be reported regardless of whether they occur during the study, after study completion, or after participant withdrawal or completion.

Also, define immediately with 24 hours.

3. The investigator is authorized to immediately take those measures he or she considers necessary to eliminate or reduce the apparent damage caused to research subjects.

4. The principal investigator is authorized to use a test article in an emergency, in accordance with the following criteria:

- For treating an emergency situation in a life-or-death situation.
- When the use of research medicine or a known medicine is considered necessary, employing indications.
- When the dose and means of administration are other than those established.
- The physician must obtain the approval of the REC of the health institute and a letter of informed consent from research participants or from their legal representative, according to the circumstances, on the following basis:
- The REC will notify the use of the research drug beforehand if the investigator may foresee the need for it to be used in emergency situations, before it is actually used.
- If, while the drug is being used, the indication, dose, means of administration or any unexpected event arises (sic).
- The REC will either approve or reject the use the planned use or repeated unexpected use of the drug, and the head of the medical care institute will be responsible for asking the Ministry to authorize these uses, and
- The letter of informed consent will be obtained from research participants, or from their legal representative, or from their nearest relation, except when the condition of participants means that they are unable to do so, or if the legal representative or relation is unavailable, and use of the drug will be suspended if it represents a risk that may bring about death.

5. The assessment of adverse events or unanticipated problems will be made through an expedited review (which is an alternative form of review by the Research Ethics Committee for research proposals or related documents).

6. Only the President need assess changes, without the need for a quorum, but any change will be subject to the confirmation of the Research Ethics Committee, as established by the President.

7. The President of the Research Ethics Committee is authorized to suspend or cancel approval immediately, in other words, in the event of emergency. Any suspension or cancellation made by the Committee President in an emergency situation will be reported to and reviewed by the Committee.

8. If applicable, investigators or other participants may be invited to the Committee meeting, but they will be asked to leave the room during deliberations and when the Committee votes.

9. The Research Ethics Committee is authorized to authorize, suspend or cancel approval of research projects in which serious or unexpected damage has been caused to research subjects, under the following terms:

    a. **Suspension of approval.-** This is "a temporary withdrawal" of the approval of the Research Ethics Committee for some or all research procedures. Studies suspended need to be assessed until they are cancelled or the authorization is confirmed.

    b. **Cancellation of approval of the Research Ethics Committee.-** This is "a final cancellation of the authorization given by the Research Ethics Committee of research procedures". Protocols will be considered as closed and will require no further assessment.

10. When studying approvals, the Research Ethics Committee must take the following into consideration for the temporary or permanent suspension of research projects:

    a. The action to be taken to protect the rights and wellbeing of subjects recruited up to that time.

    b. Take into account if the withdrawal procedures for participants consider their rights and wellbeing.

    c. Establish if participants must be informed of cancelation or suspension of the project.

    d. The Committee must be notified of any adverse event or the results thereof for review

11. A study suspended may be reopened after the unexpected problem that gave rise to suspension has been dealt with.

12. Suspension or cancellation of the approval of the Research Ethics Committee will be notified immediately to the principal investigator in a letter that clearly describes the action taken and why the Committee is taking this action. The following persons will also be notified:

    - Members of the Research Ethics Committee.

- The senior officers of the organization.
- The Ministry of Health or the Federal Commission for Protection against Sanitary Risks. This report must include details of the decision, the measures taken and the implications of the decision and suspension or termination within 15 days.
- To the FDA when the protocol is regulated by this entity.

13. Any person involved in the investigation may notify incidents of violations CIS project methodology. The IRB will determine whether it warrants the suspension or revocation of the approval. This will be communicated immediately to the investigator.

14. The Research Ethics Committee will keep a file of the decisions taken.

15. Any problems or unanticipated event should be included in informed consent.

16. The principal investigator must notify the research ethics committee, all unanticipated problems are identified immediately. Should not be sent or adverse effects of protocol deviations and unanticipated events. (See glossary)

    a. When there is severe risk to participants must be notified during the first week is identified.
    b. When there is risk to participants must be notified during the first two weeks that is identified.
    c. The research ethics committee notified the authorities of the institution of an unanticipated event in a research project during the first month of being notified by the researcher.

17. The adverse events or protocol deviations should be reported to the commission as established in the methodology of the project or the commission upon request.

18. The protocol deviations must be reviewed to determine if it is unanticipated problems involving risks to participants or others (as well as failure).

19. When the C.E.I. makes a determination that an event is an unanticipated problem involving risks to participants or others, the issue will be reported internally and externally as follows:

- Officials within the organization who must be notified.
- Regulatory officials, if required (by Mexican law or regulations
- OHRP, if required by the Federal Wide Assurance.
- Sponsor

20. The research ethics committee in the case of being informed of an unanticipated event can take any of the following determinations:

a. Inform participants
b. Amend the informed consent
c. Suspend or terminate the study
d. Modify the criteria for inclusion / exclusion
e. Modify the design of the study

21. All resolutions arising under evaluation at the onset of unanticipated problems, adverse events or incidents of violations of the methodology of projects, without exception will be reported to the principal investigator through a letter that clearly describes the action and the reasons for the resolution adopted and simultaneously notify the CIS in a period of less than 15 days, with a report should include details of the decision, the resolutions, the ramifications of the decision and the suspension or termination of the project to the following people:

• Officials of the organization.
• Ministry of Health-COFEPRIS
• Food and Drug Administration (FDA) or if the Office for Human Research Protections (OHRP) | HHS.gov. When the protocol is regulated by these entities.

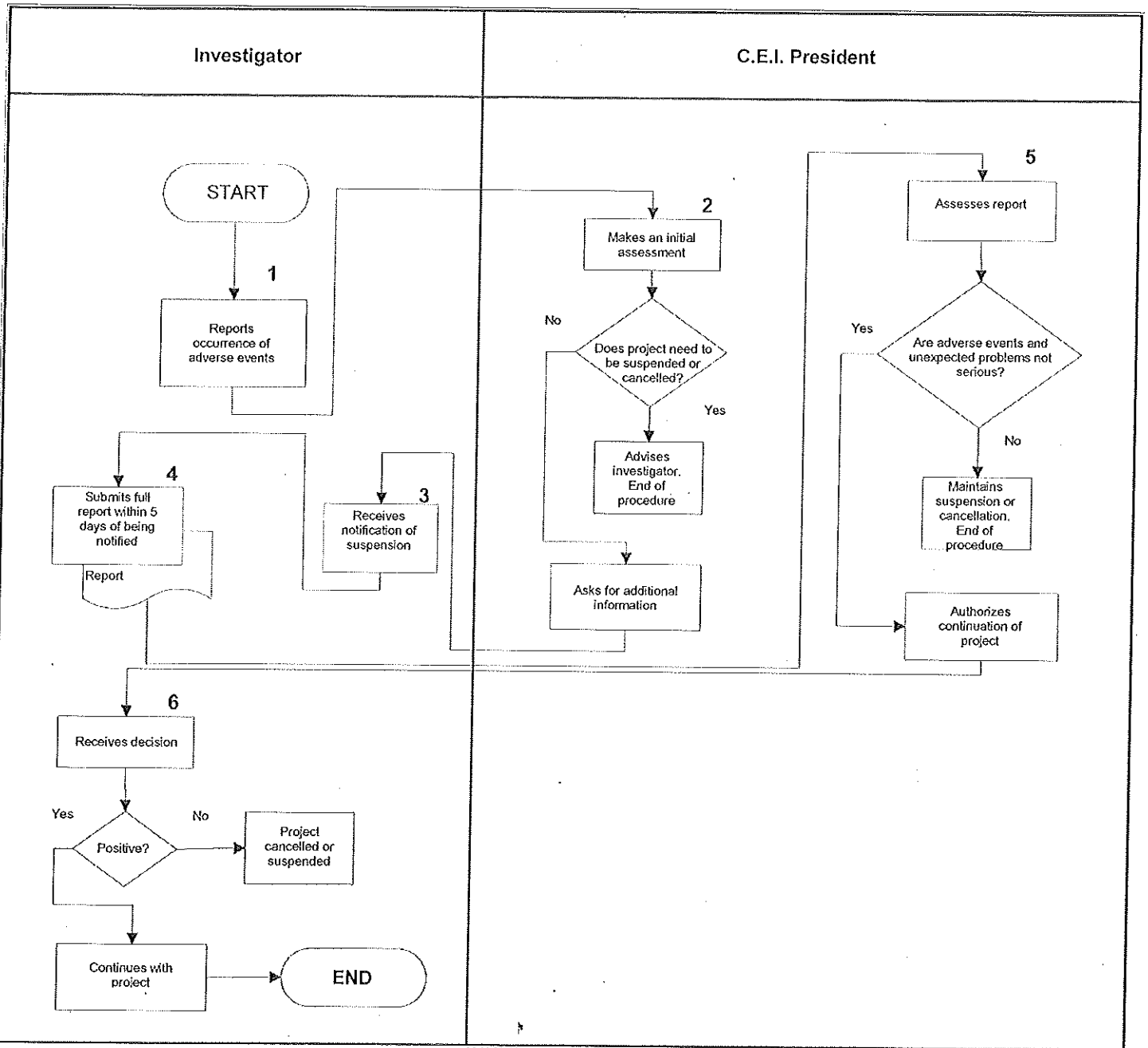
4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Investigator	1	Notifies the president of the research ethics committee on the occurrence of problem or event unanticipated adverse events or the emergence of protocol deviations.
C.E.I. President	2	Makes an initial assessment. Does the situation require the immediate suspension or cancellation of the approval of the C.E.I.? Yes. Informs the investigator of the decision. No. Asks the investigator for additional information so as to make the assessment.
Investigator	3	Notified of the decision of the C.E.I. to suspend or cancel authorization, or receives a request for additional information.
Investigator	4	Submits a full report on the problem and all supporting documents to the C.E.I. within 5 days of the original notification or the request for information.
C.E.I. President	5	Examines the report and documents. Are adverse events and unforeseen problems considered as slight? Yes. Authorizes continuation of the project and informs the investigator. No. Authorization remains suspended or cancelled and informs the investigator.
Investigator	6	Receives the decision of the C.E.I. President. Is the decision affirmative? Yes. Continues with the research project. No. The authorized project is cancelled or suspended. END OF PROCEDURE

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

5.0 FLOWCHART

5.1 Assessment in the face of unexpected problems and adverse events



ISSUE CONTROL

	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

6.0 RECORDS

a. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman is needed to review and obtain various documents and files.

b. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee..

Records	Time Retained	Person Responsible	Registration Code
Application for a quick assessment of unforeseen problems or adverse events.	5 years	C.E.I	FC1102
Notification of authorization concerning unforeseen problems or adverse events.	5 years	C.E.I	FC1102

7.0 GLOSSARY

C.E.I. - Research Ethics Committee.

Investigator: a qualified scientist who takes on the scientific and ethical responsibility, on its own behalf or on behalf of an organization/company, of the ethical and scientific integrity of a research project conducted on a specific site or a group of sites.

Legal Representative.- This term is used to refer to those persons responsible for the subject to be assessed who, for various reasons, do not represent themselves. This applies to:

Children
Disabled participants
Women of child-bearing age
Pregnant women
Women during child birth, pueperium and who are breast feeding
Embryos, obituses, and fetuses
Participants being given artificial insemination Dependent groups, such as students, laboratory and hospital workers, employees, members of the armed forces, prisoners, and other special sectors of the community whose informed consent may be influenced by an authority.

Those persons who are not in possession of all their faculties.

UNANTICIPATED PROBLEM OR EVENT AS FOLLOWS:

Unanticipated problems include any incident, experience or outcome that meets the following criteria:

- Unexpected (in terms of its nature, severity or frequency) is observed in some of the research procedures, or conditioned by the characteristics of the population under study.

- Related or possibly related to participation in research (possibly related means there is a reasonable possibility that the incident, experience or outcome may be caused by participation in research and not necessarily caused by it.

It is suggested when the places where research is conducted, people who perform or are at high risk of damage (including damage, physical, psychological, economic or social) which previously known or recognized.

SERIOUS UNANTICIPATED EVENT

Is considered when a death results, be life threatening, resulting in hospitalization, disability or incapacity, can mask the health of the participant require any medical or surgical intervention.

ADVERSE EVENT

Most adverse events are unanticipated problems involving risks to participants or others.
Adverse events are not related to the investigation are unanticipated problems involving risks to participants or others.
Adverse events are expected in terms of specificity; the severity and frequency (for example, described in the protocol, investigator brochure, literature, or the letter of agreement) are not unanticipated problems.
Adverse events that do not place participants or others at greater risk of injury was considered by the research ethics committee when it approved the investigation are unanticipated problems involving risks to participants or others.

The FDA defines an adverse event as any adverse event that may occur during treatment or administration of a pharmaceutical product and which may or may not have a causal relationship with treatment.

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9.0 FORMS AND INSTRUCTIONS: Not applicable

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

9. PROCEDURE WHEN THE ETHICAL OR METHODOLOGICAL PROCEDURES AUTHORIZED ARE NOT OBSERVED

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

1.0 PURPOSE

To guarantee that the Research Ethics Committee responds promptly in the event of any breach of the standards or ethical or methodological requirements approved.

2.0 SCOPE

Internal: All research projects conducted at the Institute, authorized by the Research Ethics Committee, the standards or ethical or methodological requirements of which have been breached.

External: Research projects conducted at other institutes, authorized by the Research Ethics Committee, the standards or ethical or methodological requirements of which have been breached.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. Breach is the failure to observe regulations, policies and procedures that govern the research project, including the Institutional Participant Protection Program or the requirements and decisions of the Research Ethics Committee, including not conducting the protocol as approved.
2. Investigators, others professionals or officers who are aware or suspect any breach are required to inform the Research Ethics Committee immediately.
3. Reports of breaches will be considered as not proven until the breach has been confirmed.
4. Breaches include medical or procedural errors, the improper use of confidential information or records, loss of confidential documents, application of changes or alterations not authorized.
5. If the initial assessment made by the C.E.I. leads to suspension or cancelation of the project, the investigator will submit a detailed report on the problem, plus all supporting documents, within five days of being notified or receiving a request for information.

6. Breaches may be:

   a. **Serious.-** Any action or omission that compromises the rights and wellbeing of human subjects.

   b. **Ongoing.-** A pattern of actions or omissions that indicates shortcomings in the ability or wish of a person to observe regulations, policies and procedures, or the decisions or requirements of the Research Ethics Committee

7. The Research Ethics Committee will establish the requirements to be met for any serious breach, ongoing breach and a breach that is not serious or permanent, and the action to be taken, depending on the nature and extent of the breach, according to the specifications of Http://aahrpp org/Documents/D000141.PDF

8. The Research Ethics Committee is authorized to suspend or terminate approval of research projects that are not conducted in accordance with the terms and conditions of approval (including assessment requirements).

   a. **Suspension of approval.-** This is "a temporary withdrawal" of the approval of the Research Ethics Committee for some or all research procedures. Studies suspended need to be assessed until they are cancelled or the authorization is confirmed.

   b. **Cancellation of approval of the Research Ethics Committee.-** This is "a final cancellation of the authorization given by the Research Ethics Committee of research procedures". Protocols will be considered as closed and will require no further assessment.

9. When studying approvals, the Research Ethics Committee must take the following into consideration for the temporary or permanent suspension of the research project:

   a. The action to be taken to protect the rights and wellbeing of subjects recruited up to that time.

   b. Take into account if the withdrawal procedures for participants consider their rights and wellbeing.

   c. Establish if participants must be informed of cancelation or suspension of the project.

10. A study suspended may be reopened after the unexpected problem that gave rise to suspension has been dealt with.

11. Suspension or cancellation of the approval of the Research Ethics Committee will be immediately notified to the investigator in a letter that clearly describes the action taken and the reasons of the Research Ethics Committee.

12. The Research Ethics Committee will keep a file of the decisions taken.

13. When the C.E.I. makes a determination of a serious or ongoing breach, the issue will be reported internally and externally as follows:

Officials within the organization who must be notified

Regulatory officials, if required

OHRP, if required by the Federal wide warranty.

Sponsors

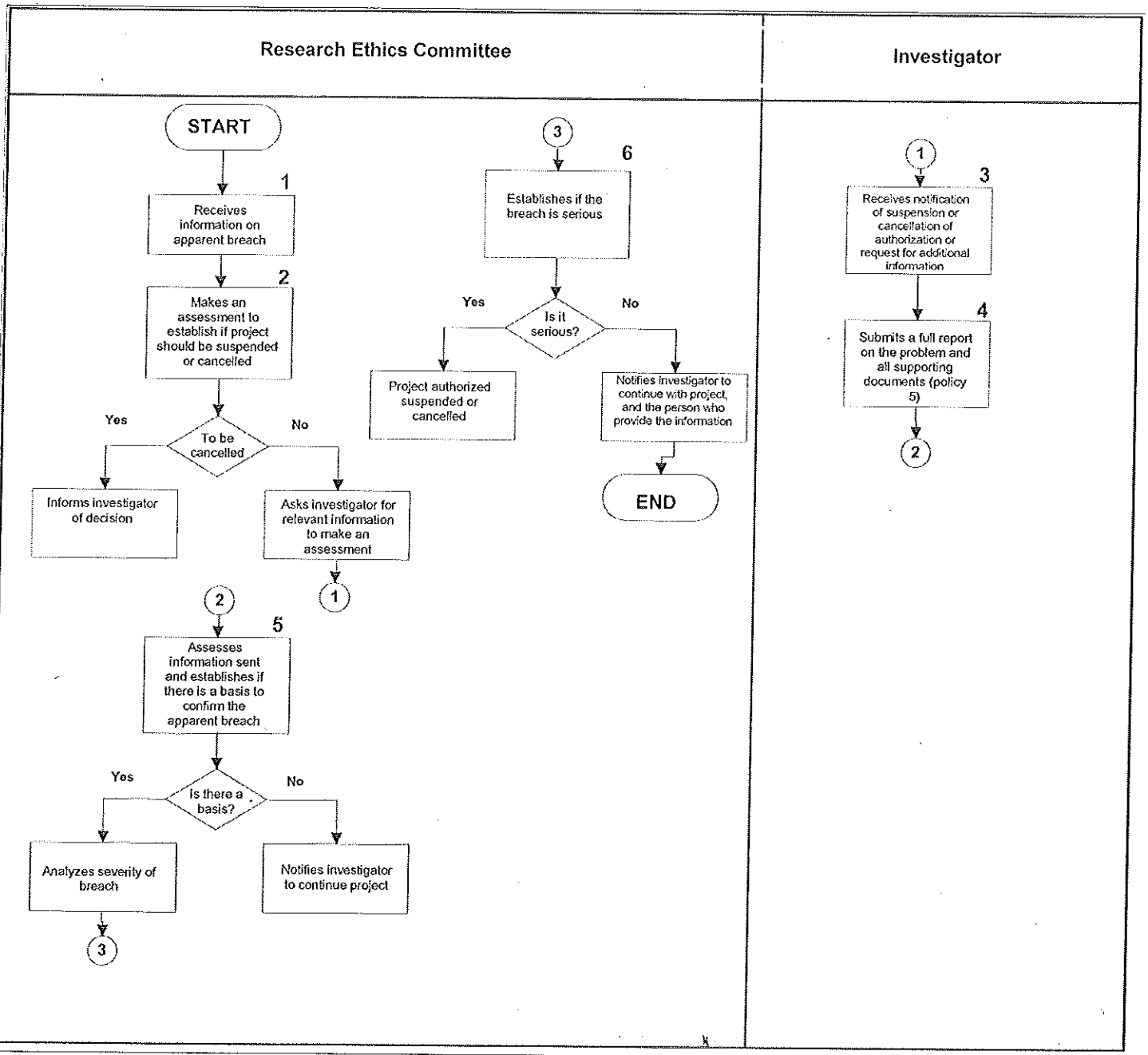
ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
C.E.I.	1	Receives information from investigators, professionals or officials on the assumed breach of standards or of ethical or methodological requirements approved.
C.E.I.	2	Makes an initial assessment to establish if The situation merits immediate suspension or cancellation of the investigator? Yes. Investigator informed of the decision. No. Investigator asked to provide additional information to make the assessment.
Investigator	3	Notified of the decision of the C.E.I. of suspension or cancellation of the authorization or the request for additional information.
Investigator	4	Submits a full report on the problem and all supporting documents to the C.E.I. (policy 5).
C.E.I.	5	Assesses information sent and establishes if there is a basis to confirm the committing of the supposed breach. Is there a basis? No. Notifies the investigator that he or she may continue with the project and the person who provided the information. END OF PROCEDURE. Yes. Analyzes severity of breach.
C.E.I.	6	Establishes if the breach is serious. Is it serious? No. Notifies the investigator that he or she may continue with the project, and the person who provided the information Yes. The project authorized is suspended or cancelled. END OF PROCEDURE

5.0 FLOWCHART

5.1 Action when there is a breach of authorized ethical or medical procedures



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Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

6.0 RECORDS

a. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman and the President is needed to review and obtain various documents and files..

b. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee..

Records	Time Retained	Person Responsible	Registration Code
Report on the breach of standards or approved ethical or methodological requirements.	5 years	C.E.I.	FC1102
Notification of the decision on the breach of standards or approved ethical or methodological requirements.	5 years	C.E.I.	FC1102

7.0 GLOSSARY

C.E.I. - Research Ethics Committee.

Investigator: a qualified scientist who takes on the scientific and ethical responsibility, on its own behalf or on behalf of an organization/company, of the ethical and scientific integrity of a research project conducted on a specific site or a group of sites.

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9.0 FORMS AND INSTRUCTIONS: Not applicable

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

10. PROCEDURE FOR THE FINAL REPORT ON RESEARCH PROJECTS

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

1.0 PURPOSE

To have up-to-date information on completion of research projects approved by the Research Ethics Committee.

2.0 SCOPE

Internal: All research projects conducted at the Institute that are assessed and approved by the Research Ethics Committee.

External: Research projects conducted at other institutes that are assessed and approved by the Research Ethics Committee of the Institute.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

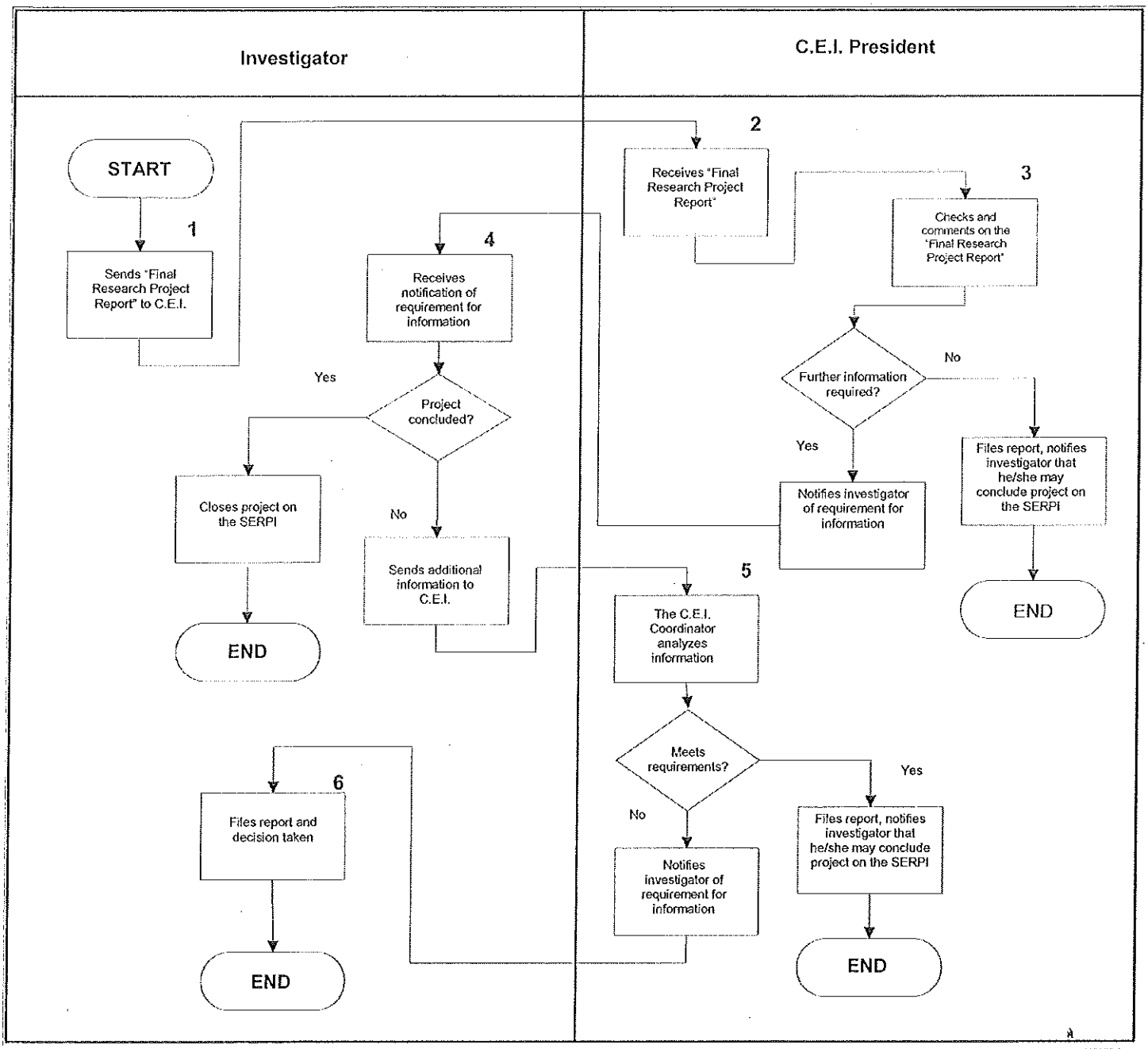
1. The Research Ethics Committee will monitor the progress of all studies it has approved, as from when it takes its decision until the project concludes.
2. The investigator must submit a final report upon conclusion of the research project.
3. If the study is suspended or terminated prematurely, the applicant must notify the Research Ethics Committee of the reasons for suspension/termination and must provide the Research Ethics Committee a summary of the results obtained during the study suspended or terminated prematurely.
4. Only the President need assess the final report, without the need for a quorum.
5. The sponsor must publish the results of the research when it concludes
6. When the sponsor publishes the results of the research, it must notify participants to ensure that their safety or medical care is not affected bny these results

4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF THE TASK
Investigator	1	Sends the "Final Research Project Report" to the C.E.I.
C.E.I. President	2	Receives the "Final Research Project Report".
C.E.I. President	3	Checks and, if applicable, comments on the "Final Research Project Report". Is any further information required? No. Files the report, notifies the investigator that the project may be concluded on the SERPI and END OF PROCEDURE. Yes. Notifies the investigator of the information required.
Investigator	4	Receives notification or information requirements. Project concluded? Yes. Closes the project on the SERPI and END OF PROCEDURE. No. Sends additional information to the C.E.I.
C.E.I. President	5	The C.E.I. President analyzes the information submitted. Has sufficient information been provided and does it meet requirements? Yes. Notifies investigator that the project may be terminated on the SERPI and END OF PROCEDURE. No. Notifies the investigator of the information required (returns to task 4).
C.E.I. President	6	Files report and takes decision. END OF PROCEDURE.

5.0 FLOWCHART

5.1 Final Research Project Report Procedure



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Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

6.0 RECORDS

a. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed as per written procedures. The written authorization of the Chairman and the President is needed to review and obtain various documents and files..

b. Documents will be filed at the offices of the Research Ethics Committee for a minimum of 5 years after the relevant study has been completed, after which documents will form part of the back files of the Committee.

Records	Time Retained	Person Responsible	Registration Code
Final Research Project Report.	5 years	C.E.I	FC1102
Notification of conclusion of research project.	5 years	C.E.I	FC1102

7.0 GLOSSARY

C.E.I. - Research Ethics Committee.

Investigator: a qualified scientist who takes on the scientific and ethical responsibility, on its own behalf or on behalf of an organization/company, of the ethical and scientific integrity of a research project conducted on a specific site or a group of sites.

8.0 CHANGES TO THIS VERSION

Review Number	Date of Change	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9.0 FORMS AND INSTRUCTIONS: Not applicable

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

11. PROCEDURE FOR OPENING FILES OF THE RESEARCH ETHICS COMMITTEE

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

1.0 PURPOSE

To have specific files for keeping up to date information on the research protocols assessed by the Research Ethics Committee.

2.0 SCOPE

Internal: Applies to all research protocols conducted at the Institute and that are assessed and approved by the Research Ethics Committee.

External: Applies to all research protocols conducted at other institutes and that are assessed and approved by the Research Ethics Committee of the INNSZ.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. The files opened for each protocol that the Research Ethics Committee assess must include the following documents:

- Protocols.
- Statements of absence of conflict of interest of researchers
- Applications submitted to the Research Ethics Committee.
- Scientific assessments.
- Reports on injuries to participants.
- Records of ongoing reviews.
- Correspondence between the Research Ethics Committee and the investigator.
- Declarations of new findings that are relevant for participants.
- The following information is required for the initial assessment and follow up of research protocols using the quick assessment procedure:
  - The specific admissible category.

- Description of measures taken by the reviewer.
- A note of any event or those established by regulations.

- Unless noted in the minutes of the Research Ethics Committee, the justification for a specific protocol being exempted from the informed consent procedure or any alteration to the procedure.
- For the initial assessment and follow up of each protocol, the next review date.

2. The Committee must keep all research files for at least five years after the project has ended.
3. The Committee must keep all research protocol files in an accessible place for inspection and retain a copy for the authorized representatives of government departments or agencies for a reasonable time.
4. If a protocol is cancelled, the Committee shall retain the file for at least five years after cancellation.
5. The minutes of Ethics Committee meetings must include a note of the following:
   - The measures taken by the Committee.
   - Separate discussions of each action taken.
   - Votes for and against each protocol, plus any abstentions.
   - The persons who attend the meeting.
   - When an alternate member replaces a proprietary member.
   - The basis for asking for changes to be made to the research protocol.
   - The basis for rejecting a research protocol.
   - A written summary of the discussion of disputed matters and the solution thereof.
   - The approval period, for the initial assessment and follow up.
   - The names of the members of the Committee who leave meetings on account of there being a conflict of interests, and a note to the effect that said member is absent because of a conflict of interests.
   - Justification and the protocol of exemption or amendment specific findings of the consent process.

- The major risk/non determinations of major risk device ratio (sic).

6. The Committee will establish the following:
   - The procedures for recording and reporting data.
   - The review of audits and monitoring research
7. The Committee will retain important documents concerning the clinical study for five years or until the sponsor advises the Institute that these documents are no longer needed.

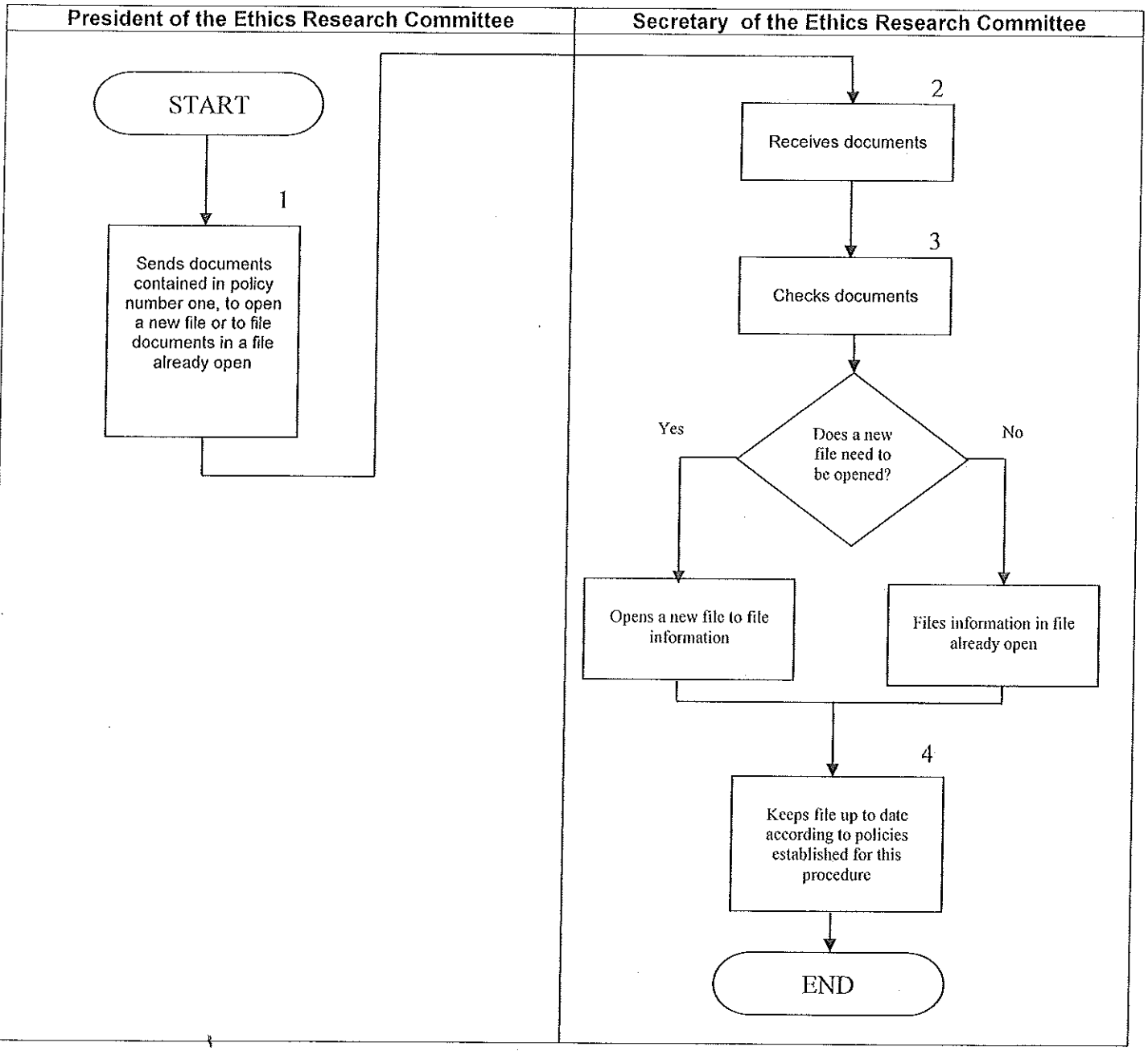
4. DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF TASK
Committee President	1	Sends documents on policy number one to the Committee secretary, to open a new file or to file documents in a file that is already open.
Secretary of the Committee	2	Receives documents.
	3	Checks documents. Does a new file need to be opened? No. Files information in the file already open. Yes Opens new file to file information.
	4	Keeps file up to date according to the policies established in the procedure. END OF PROCEDURE

ISSUE CONTROL			
	Drafted by:	Reviewed by:	Authorized by:
Name:	Dr. José Alberto Ávila Funes		Dr. Carlos A. Aguilar Salinas
Position:	Secretary/ Chief of Geriatrics		Deputy Chief of Endocrinology/President
Signature:			
Date:	MARCH 2013	MARCH 2013	MARCH 2013

5. FLOWCHART

5.1 Procedure for opening files of the Ethics Research Committee



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6. RECORDS

a. All documents and correspondence of the Research Ethics Committee must be dated, numbered and filed according to written procedures. The written authorization of the Chairman and President is required for reviewing and obtaining documents, files and archives.

b. Documents will be filed at the offices of the Research Ethics Committee for a minimum of five years after conclusion of the study, after which documents will be transferred to the Institute's dead files.

c. The written authorization of the Chairman will be needed for reviewing and obtaining protocol files, documents and archives for audits or reviews conducted outside the Institute.

Records	Time Retained	Person Responsible	Registration Code or Unique Identification Code
Protocol files and their archives	5 years	Ethics and Research Committee	FC1102

7. GLOSSARY

C.E.I. - Ethics and Research Committee

8. CHANGES TO THIS VERSION

Review Number	Date Updated	Description of Change
NOT APPLICABLE	NOT APPLICABLE	NOT APPLICABLE

9. FORMS AND INSTRUCTIONS: Not applicable

ISSUE CONTROL			
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12 PROCEDURE FOR OBTAINING INFORMED CONSENT FOR RESEARCH PROTOCOLS

ISSUE CONTROL			
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1.0 PURPOSE

Endorse the research participant or his legal representative has voluntarily expressed their intention to participate in research, having understood the information that has been given about the study objectives, benefits, discomforts, risks and alternatives, their rights and responsibilities

2.0 SCOPE

Internal: The researchers and members of the Research Ethics Committee.

External: Research participants and sponsors.

3.0 OPERATING POLICIES, STANDARDS AND GUIDELINES

GENERAL

1. The principal investigator is responsible for submitting the consent form to the research participants or their legal representative.

2. The principal investigator is responsible for developing and formulating informed consent in writing, stating the information according to the technical standard issued by the Ministry of Health. Obtaining informed consent is a process, in which the patient and / or his representative to obtain the required information the right balance to make the decision to participate in the study. It is the first step of the involucre of the subject in research. No procedure can be performed without informed consent is granted.

3. Members of the Research Ethics Committee are responsible for reviewing and, if appropriate, approve the informed consent.

4. The Research Ethics Committee is responsible for verifying that informed consent principles expressed in the Declaration of Helsinki and the International Ethical Guidelines for Biomedical Research Involving Human Subjects applied in each trial.

5. The Research Ethics Committee placed stamp approved consents. The document presented to the patient includes the seal of approval of the committee.

6. The principal investigator verifies that informed consent is signed by two witnesses and the research subject or his legal representative, if any. If the research subject does not know how to sign, print their fingerprint and sign their name another designee.

7. The principal researcher enough time to consider the information, ask questions, and reflect on the nature of their participation before making a decision to volunteer as a research subject.

8. The principal investigator is responsible for providing a game original signed and dated informed consent to participating in research or their legal representative.

9. The principal investigator is responsible for confirming that the research subjects or their legal representative has read the agreement and can demonstrate a basic understanding of the study and the requirements and responsibilities of their participation.

10. The principal investigator retains an original informed consent on file with the study.

11. The principal investigator is responsible for maintaining the themes about all matters related to their participation in a study, even in some cases after participation is completed.

12. The Research Ethics Committee is responsible for verifying that informed consent contains the basic elements necessary established by federal regulations, which are:

    a) A statement that the study involves research and describing the purpose of the research, the expected duration of participation; description of the procedures to be followed, and identification of procedures that are experimental;

    b) A description of the reasonably foreseeable risks or discomforts;

    c) A description of the benefits to the subject or can be reasonably expected from the research;

    d) Disclosure of alternative procedures or courses of treatment, if any;

    e) A statement describing how and the extent to which confidentiality of records will be maintained;

    f) For research involving more than minimal risk, an explanation as to whether compensation and / or medical treatments are available if injury occurs and, if so, what they consist of, who will pay, and where you can obtain more information;

    g) Contact for technical questions, rights, and research-related injuries;

    h) Statements concerning the voluntariness of the participation and the ability to withdraw consent at any time without penalty or loss of benefits.

    i) A statement that if the subject is or becomes pregnant, particularly the treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.

    j) A statement that the treatment or procedure particular, may involve risks to subjects that are currently

unforeseeable.

k) An explanation of whom to contact in case of an emergency.

13. The research subject or, if applicable, the legal representative must receive clear and complete explanations, so you can understand, at least on the following aspects:

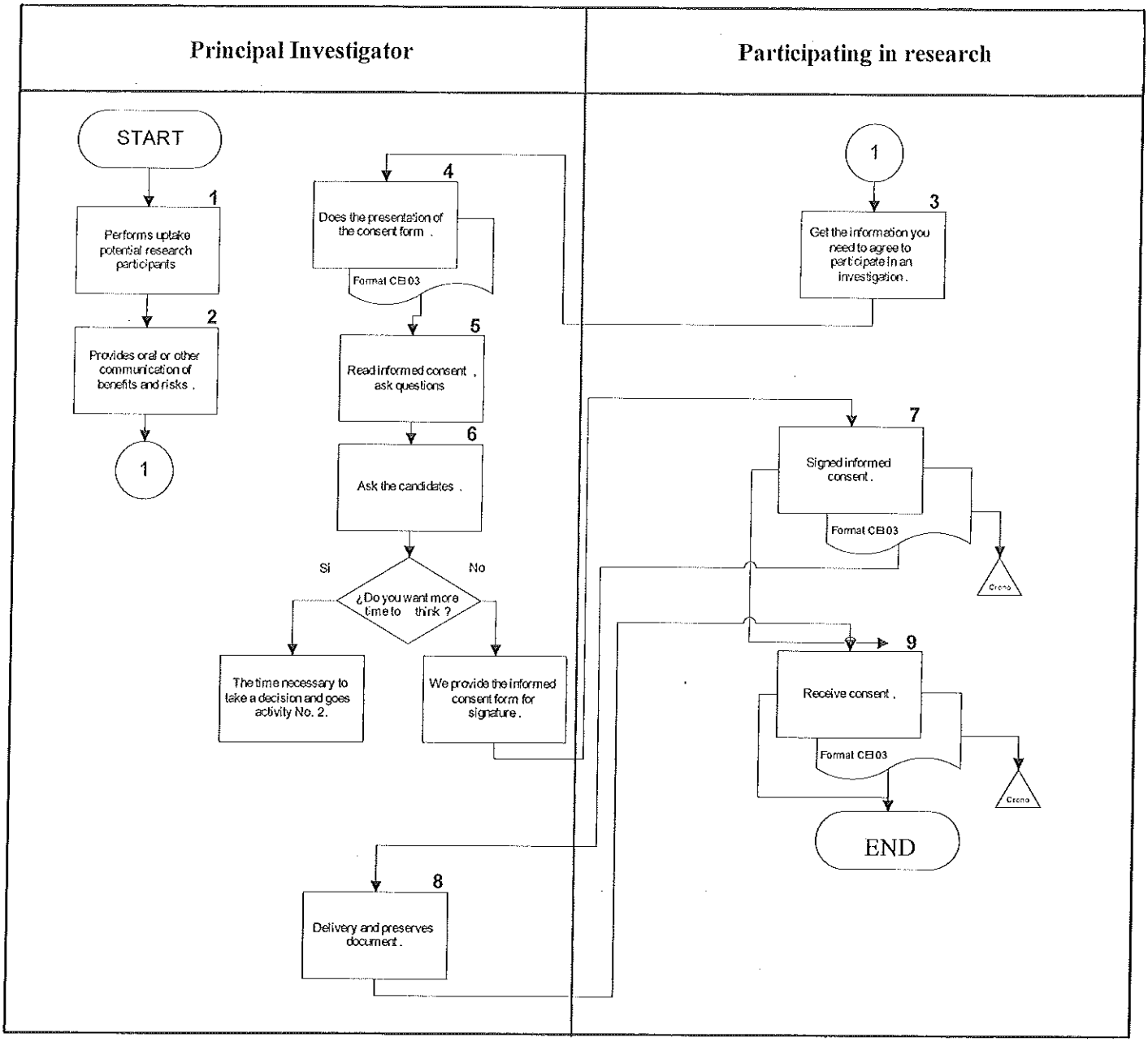
I. I. The rationale and objectives of the research
II. II. The procedures to be used and their purpose, including identifying that are experimental procedures;
III. III. The expected risks or discomforts;
IV. IV. The benefits that can be observed;
V. V. Alternative procedures that might be advantageous to the subject;
VI. VI. Guaranteed to receive answers to any questions and clarify any questions about the procedures, risks, benefits, and other matters relating to the investigation and treatment of the subject;
VII. VII. The freedom to withdraw consent at any time and stop participating in the study, without thereby prejudices are believed to continue care and treatment;
VIII. VIII. The assurance that it will not identify the subject and it will keep the confidentiality of information relating to your privacy;
IX. IX. The commitment to provide updated information obtained during the study although this could affect the subject's willingness to continue participation;
X. The availability of medical treatment and compensation to legally be entitled, by the institution of health care in the event of damage to the warrant, directly caused by the investigation, and

14. The Research Ethics Committee for good cause, if minimal risk research, authorizes that informed consent is obtained without written formulated and safe in the case of research, the researcher obtaining waiver of informed consent. In these cases, the researcher delivered the patient written information about the study. Such information is reviewed and approved by the Research Ethics Committee.

4.0 DESCRIPTION OF THE PROCEDURE

PERSON RESPONSIBLE	TASK	DESCRIPTION OF TASK
Principal Investigator	1	Performs uptake potential research participants.
Principal Investigator	2	Provides oral or other form of communication to the research participant and / or legal representative the benefits and risks of participating in research. (Policy No. 11)
Participating in research	3	Get the information you need to agree to participate in an investigation.
Principal Investigator	4	Ago Filing of consent to the subjects or their legal representative
Principal Investigator	5	Read informed consent with the patient, given sufficient time to consider the information, ask questions, and reflect on the nature of their participation before making a decision to volunteer as a research subject. (Policy No. 6)
Principal Investigator	6	Ask the candidates if Have a question? Did you get the information? Like to think back to another time and date? Want to sign now? Do you reject participate? If given the time needed to make a decision and move on to activity No. 2. No. We provide the informed consent form for signature.
Participating in research	7	Sign the informed consent.
Principal Investigator	8	Delivery an original and retains an original study on the folder
Participating in research	9	Get the original consent. END PROCEDURE

5.0 FLOWCHART



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6.0 RECORDS:

3. All documentation and communication of the Research Ethics Committee should be dated, numbered and filed in accordance with written procedures. It requires written permission of the President and Secretary to review or obtain other documents, records and files.

4. The documents will be filed in the office of the Research Ethics Committee for a minimum period of five years after completion of the study. Following this, the documents will be part of INCMNSZ File dead.

Records	Time Retained	Person Responsible	Registration Code or Unique Identification Code

7.0 GLOSSARY

Informed Consent: The written consent of the Participants in the Project or Research Protocol, you should obtain the investigator or the person designated by the Institute for this purpose, according to NOM-168SSA1-98, the clinical record and ethical principles agreed at the 18th. World Medical Assembly, Helsinki, Finland, June 1964 and amended by the 29th. World Medical Assembly, Tokyo, Japan, in October 1975, 35th. World Medical Assembly, Venice, Italy, October 1983 41st. World Medical Assembly, Hong Kong, September 1989 48th. General Assembly, Somerset West, South Africa, October 1996 and the 52nd. General Assembly, Edinburgh, Scotland, in October 2000, apply in any case, the norm that confers the highest degree of protection for the Participant. - Research Ethics Committee

8.0 CHANGES TO THIS VERSION

Date	Number			Description of Change			Description of Change			De
NOT APPLICABLE				NOT APPLICABLE			NOT APPLICABLE			N

9.0 FORMS AND INSTRUCTIONS: Not applicable

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AUTHORIZATION

DRAFTED BY:

Dr. José Alberto Ávila Funes
Secretary/ Chief of Geriatrics

METHODOLOGICAL REVIEW:

C.P. Miguel Angel Lima Alarcón.
Head of Organization
And administrative modernization.

Pas L.A.P. María de Lourdes Celis Flores
Quality Coordinator

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AUTHORIZED BY:

Dr. Carlos A. Aguilar Salinas
President/ Deputy Chief of Endocrinology.

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