Annex A

PREVENTION OF CONFLICT OF INTEREST IN RESEARCH PROJECTS

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REGULATORY FRAMEWORK

General Law of Administrative Responsibilities. Articles 3 section VI, 7, 46, 47, 48, 55, 56, 58, 59, 60, 60 Bis. 61, 62, 63, 63 Bis.

Law of the National Institutes of Health. Articles 2 section III, 5 section IX, 7 sections I, III, 10, 11, 39 section III, 41 section III, 44 of the Law of the National Institutes of Health.

Organic Statute of the National Institute of Public Health. Articles 3, 4, 33.

Declaration of Helsinki, WMA, paragraph 22, 26, 36

International ethical guidelines for health-related research involving humans. Council for International Organizations of Medical Sciences (CIOMS). Geneve 2016.

National Guide for the Integration and Function of Research Ethics Committees. CONBIOETICA 2018.

Internal Guidelines of the Research Ethics Committee.

Objective

This Annex is of general and mandatory observance for all INSP personnel with research activities, who participate in the planning, development and conclusion of research projects. Its purpose is to prevent the conflict of interest that may arise in said projects.

Definitions

For the purposes of the guidelines of this Annex, it will be understood by:

Conflict of interest: The possible impact on the impartial and objective performance of the functions of Public Servants due to personal, family or financial/business interests, described in an enunciative but non-limiting manner in the General Law of Administrative Responsibilities.

Conflict of Interest Disclosure Form: Instrument through which personnel with research activities declare possible conflicts of interest.

Sub-recipient institutions: Institutions, agencies or associations, collaborators in research projects financed by third parties, who receive resources within the framework of research projects.

Conflict of Interest Report: Written document documenting the status of Conflicts of Interest between the researchers, the INSP and the sub-recipient institutions participating in the project.

Chapter I

Personnel Training

1. Personnel with research activities who are responsible for the design, implementation or presentation of reports, or who participate in their development, must:

a. Know the content and scope of this Annex, as well as the General Law of Administrative Responsibilities and the regulatory bodies that govern, according to the country of origin of the financing institution.

b. Report at all times, the possible Conflict of Interest that may be updated due to personal or blood relationship reasons up to the fourth degree or by marriage up to the second degree.

2. All personnel with research activities must credit –through the presentation of the corresponding certificate– a training regarding conflict of interest, to participate in a funded research, or proposal for funding.

Chapter II

Requirements of disclosure, review and monitoring

1. Personnel with research activities will disclose their possible conflict of interest, through the Conflict of Interest Disclosure Form. The Research Ethics Committee will designate institutional staff to request and review the Investigator's Form, related to their institutional responsibilities.
2. Prior to the exercise of a budget, for a research project financed by third parties, the officials appointed by the Research Ethics Committee must:
    a. Review the Conflict of Interest Disclosure Form of personnel with research activities involved in the research project.
    b. Determine if there is evidence or indication that updates the assumption of a possible conflict of interest and its possible direct or indirect impact on the design, performance or reporting of the research project.
    c. Develop and implement actions that investigators will have to follow if there is evidence or an indication of a possible conflict of interest.
    d. Report to the Institute's Ethics and Conflict of Interest Prevention Committee, in the event that it has evidence or indications of the update of a presumed conflict of interest.
3. In the event that an investigator joins an ongoing investigation, he or she must fill out the Conflict of Interest Disclosure Form for proper review in accordance with Number 1 of this chapter.
4. In the event that a possible conflict of interest is identified, the Research Ethics Committee will document it and inform CEPCI, which is the consultation and

advisory body specialized in matters of observance and application of the Ethics Code, and the Rules of Integrity and Code of Conduct.

Chapter III

Generation of Reports related to Conflicts of Interest

1. Prior to the start of operations of a new research project, a Report on the status of the Conflict of Interest of the participating research staff must be generated.
2. The sub-recipient institutions of the financing led by the INSP, must also generate the corresponding Conflict of Interest Report.
3. The Reports must contain the following elements:
   a. Project number
   b. Principal investigators
   c. Name of the Investigator with the Conflict of Interest
   d. Name of the entity with which the Investigator has the Conflict of Interest
   e. Nature of Financial Interest (for example: equity, consulting expenses, travel reimbursement, fees ...)
   f. Interest Value
   g. Description of how the Conflict of Interest relates to the research and the basis for determining the conflict with the research.
   h. Description of the key elements of the Management Plan for Conflict of Interest.
4. Reports must be generated with the following periodicity:
   a. Prior to the operation of a research project.
   b. Annually, for the duration of the project.
   c. Within 60 calendar days after the identification of a possible Conflict of interest during the development of the project.

Chapter IV

Requirements for enforcement mechanisms and remedies and non-compliance

In the event that any investigator or an investigator of projects financed by third parties fails to comply with what is described in this Annex on Prevention of conflicts of interest in research projects, the Research Ethics Committee will notify the Ethics and Prevention of Conflicts of Interest Committee of the INSP so that, to the extent of its attributions and powers, it will report to the competent authority the indications or evidence that may

update the presumption and update of a conflict of interest, for its due investigation and sanction.

Chapter V

Requirements for Sub-Recipient Institutions

1. The INSP must establish with all the sub-recipient collaborating Institutions a Collaboration Agreement detailing the nature of the collaboration, the activities to be carried out, as well as the economic resources corresponding to the activities of the Research Project.

2. The principal investigator of the research project must request the Reports on the status of the Conflict of Interest, from the research staff of the sub-recipient institution, with the periodicity indicated in Chapter III, number 4.

Chapter VI

Public accessibility requirements for Conflicts of Interest

1. The guidelines of this Annex are publicly accessible, so they will be available in the INSP Normatheque (https://www.insp.mx/normateca-insp.html).
2. Reports on the status of the Conflict of Interest must be accessible to the public, so it will be available in the INSP Normatheque.

Chapter VII

Record Keeping

1. The principal investigator of the research Project will be responsible for keeping the records of all the Conflict of Interest Reports, and the actions taken. This information must be kept for at least 3 years after the date in which the project's final report is sent.