



**FACULTAD LATINOAMERICANA DE CIENCIAS SOCIALES
(FLACSO)**

FINANCIAL CONFLICT OF INTEREST POLICY

Introduction:

The foremost objective of the FACULTAD LATINOAMERICANA DE CIENCIAS SOCIALES (FLACSO) is to train experts in distinct fields of the social sciences, to conduct research in the problems to build democracies in Latin America and to contribute to the implementation of social programs and policies for the development of a more just and pluralistic society. The institution grew independently of any political, institutional, professional or commercial influence. It takes a rigorous scientific and multicultural approach to issues in the fields of the economy, politics, sociology, communication and the media, education, anthropology, globalization and international relations, local development, social policies, agrarian studies, gender equality, youth, law and bioethics.

In general, there exists an international set of policies, regulations and good practices that tend to identify, prevent, mitigate and resolve conflicts of interest that can hinder research and its findings. The research at FLACSO must be objective and free of any kind of bias that can impact its quality so that the results can make a significant contribution to the state of the art of science and technology, and to the generation and transfer of the necessary knowledge to promote solutions to global challenges.

FLACSO upholds a series of basic principles and rules when faced with the problematic that can occur at the most diverse levels of institutional activity. Based on such principles and rules, as well as on the regulations of different counterparts that help finance research projects at FLACSO, we find it necessary to complement this with a policy that regulates the declaration of financial interests so that the institutional regulations on conflicts of interest are aligned with the above international principles and good practices.

This policy will make it possible to determine possible conflicts of interest, enabling us to manage them suitably at the institutional level through good practices whereby we can tackle the conflict and thus eliminate it or reduce risks that can hamper the research and participating institutions, producing due evidence of the actions implemented to that end.

Prior definitions.

Relative of a member of the university community. In this regard, a family member is considered a partner or intimately related person, children, adoptees, and relatives up to the third degree of consanguinity or second degree of affinity inclusive.



Persons related to a member of the university community: Those included in this category:

- a) A legal entity in which the member possesses directly or indirectly 10% or more of the capital or is a member of the Board;
- b) Human or legal entity with whom the member shares business dealings or in whose property or control decision-making is carried out;
- c) The corporation or foundation in which, according to its By-Laws, the member has the power to name at least one member of the Board of Directors or a participant on the Executive Committee; and
- d) Other persons that have a link with the member that influences or can influence decision-making in detriment to the University.

Financial interest, signifies any object, good or right of monetary value received or held by a researcher or a family member, be its value easily determined or not, such as payments or fees for services rendered (such as, consultancy fees, travel expenses, among others); any property value, or that represents a capital and/or interests, (such as, shares, options for shares and any other certificate representative of interests over any class of property); intellectual and industrial property rights (such as, patents, trademarks, designs, copyrights), the payment of royalties or other income vis-à-vis said intellectual or industrial property rights.

Financial conflict of interest signifies the existence of a significant financial interest that can directly and largely affect the design, leadership, findings, and preparation of reports associated with a research project, fully depriving it of its essential elements, such as constituting a scientific contribution to the state of the art and of technology in an objective and unbiased manner.

Committee for the Declaration of Financial Interests (CDIF) is the Committee comprised of the Director, Coordinator, financial administrator, and legal advisor to FLACSO Sede Argentina. The Committee will revise the Declarations of Financial Interests (**DIF**) that are presented for consideration and scrutiny so as to certify the fulfillment of the institutional and contractual norms regarding the prevailing conflict of interest at the time the declaration is made.

From the review of the declarations

The DIFs will be received and reviewed by the Committee, which is to verify them in relation to the documents attached and the manifestations presented by the academic and/or researcher.



Should the Committee identify any situation where a financial conflict of interest exists, said situation will be revised together with the academic and/or researcher, who will be requested to present further information to clarify said circumstances. In the case that the Committee identifies the situation as conflictive, the Committee will report the decision to the researcher and corresponding authority so that they can take fitting actions. Such actions can take the form of an authorization, prohibition or the fulfillment of special conditions that implies establishing a plan to suitably tackle the situation of a possible conflict of interests, as well as clarifying the contractual rules with which FLACSO would have agreed to meet with the financial counterparts of the research at national and international levels.

The researcher or affected person has the right to appeal the decision before an arbitration tribunal composed of members of FLACSO's General Secretary.

The antecedents and documents analyzed in each situation by the CDIF will be upheld, under the requisite confidentiality, as a record of its actions for at least three years starting from the end of the project under the custody of the Board of Directors of FLACSO Sede Argentina.

Presentation of the declaration

The DIF is an obligatory measure for the cases in which the institutions that finance research projects demand that FLACSO certify the fulfillment of a financial conflict of interest policy, be it as a prior step in the application for funds and/or in its development, as well as whether it is necessary that this declaration be fulfilled by the key staff of the research projects. The declaration of the researcher must clearly state the reason for which said research is being conducted, together with the necessary length of time should it last for more than one year. In such case, the first declaration is to include the number assigned to it, for example: Declaration 1 of 3 (in the case that the period must cover declarations made over three years). Likewise, it must be stated in the application whether the period to be covered registers a retroactive period, for example, one year.

Any information that has been withheld, and all contravention to that signaled in relation to the existence of conflicts of interest that can affect the research conducted at the University, in addition to information that must be presented in the DIF in fulfillment of this protocol, may be sanctioned as FLACSO sees fit.



Declaration of Financial Interests (DIF)

Name of the researcher:

CUIT/Fiscal ID number:

Academic Unit:

Objective of the application:

Requesting institution:

Periods of obligation:

Associated project:

(Attach a summary of the budget, income and sources of funding, expenditure items and equipment)

I hereby inform of antecedents for the year _____ the first report of ____ or last report.

Check the corresponding response if any of the situations mentioned below arises.



<input type="checkbox"/> yes <input type="checkbox"/> no	<p>1. Compensation (includes travel expenses). You or any Family Member (as set out in the DIF policy) has received compensation from a for-profit entity for activities as consultant, expert witness, advisory committee member and similar. If you answer yes, include the information on a separate page stating at least the entity, concept, date.</p>
<input type="checkbox"/> yes <input type="checkbox"/> no	<p>2. Shares and rights. You or any Family Member (as set out in the DIF policy) owns shares or options to buy shares from an entity that operates on the stock exchange or not, or has interests in an association. If you answer yes, include the information on a separate page stating at least the entity, the number of shares, percentage of shares out of the total, rights and/or % of shareholding.</p>
<input type="checkbox"/> yes <input type="checkbox"/> no	<p>3. Functions. You or any Family Member (as set out in the DIF policy) serve as member of the Board or is a key employee in a for-profit or not-for-profit corporation, business or another entity outside of FLACSO. If you answer yes, include the information on a separate page stating at least the name of the entity, position, starting date, and whether you earn wages, fees, remuneration or other royalty.</p>
<input type="checkbox"/> yes <input type="checkbox"/> no	<p>4. Intellectual property. You or any Family Member (as set out in the DIF policy) have rights or receive royalties for intellectual property (including patents, copyrights and trademarks; excluding academic papers) licenses and/or ownership of a for-profit entity. This DOES NOT include intellectual property registered by FLACSO. If you answer yes, include the information on a separate page.</p>

I HEREBY CERTIFY:

I have read and understand FLACSO's Financial Conflict of Interest Policy and completed truthfully this declaration according to the best of my knowledge, understanding and good faith. If necessary, I am willing to fulfill any condition or restriction deemed by FLACSO to avoid any conflict of interest perceived or real that could affect the research and its findings. Should my external financial interests or those of my family change substantially during the course of the current research project, such that the responses to this report are modified, I will deliver a new version of said report within 15 days following the occurrence of said substantial change.



Full name and signature (date)

Number of additional pages attached _____



ADDENDUM FOR PUBLIC HEALTH SERVICE (PHS) FUNDED RESEARCH

Purpose:

As an institution involved in Public Health Service (PHS) funded research, FLACSO strives to promote objectivity in research. This Financial Conflict of Interest (FCOI) Policy has been established to prevent bias resulting from financial conflicts of interest in the design, conduct and reporting of research funded under PHS grants. FLACSO's FCOI policy applies to all investigators who participate in PHS funded research. Regulations governing FCOI can be found under 42 CFR Part 50 Subpart F.

This FCOI will be maintained and enforced, to meet the regulatory requirements and has in effect an updated, written and enforced administrative process to identify and manage FCOI. It seeks to promote and enforce Investigator's compliance with the regulation, to manage FCOI and provide initial and ongoing FCOI reports, and to agree to make FCOI and Significant Financial Interest (SFI) information (including related Institutional reviews and determinations) available to Health and Human Services (HHS), promptly, upon request, and will fully comply with the regulation's requirements

The principal investigator(s) and participants who are responsible for the design, conduct and reporting of research funded by the PHS must disclose any financial conflict of interest. A financial conflict of interest may exist if the investigator, or the investigators' spouse and dependents hold a significant financial interest in the following:

- Ownership of stock, equity, or other financial interest in a company/entity which has products that might be used in or benefit from or harmed by the results of the project
- Employment, office or directorship in any company/entity involved or potentially involved
- Personal compensation from any company/entity involved or potentially involved
- Consulting/advisory arrangements with any company/entity involved or potentially involved
- Involvement with grants, contracts, research, training or other support (restricted or unrestricted) from any company/entity involved or potentially involved
- Travel grants to attend educational symposia provided by any company/entity involved or potentially involved
- Intellectual property rights (i.e. copyright, patent, trademark) related to the activities of the project
- Relationship with a company/entity that may affect academic advancement or status



Training Requirements:

Prior to starting work on a PHS funded grant, all participants will be provided a copy of: this policy, the investigator's disclosure responsibilities and the Federal regulation. Each PHS-supported Investigator will have to complete FCOI training prior to engaging in research related to any PHS-funded grant at least once every 4 years. This training will be done immediately, if the Institution revises its FCOI policy that affects requirements of Investigators, if an Investigator is new to an Institution, or if an Investigator is not in compliance with the policy or management plan.

Disclosure, Training, Review and Monitoring:

Investigators (and the investigators' spouse and dependents) must provide the following information in a Disclosure Form, which must be submitted to Ana Lía Gromick, who is the designated Institutional Official (IO) for FCOI policy.

1. Name of the individual(s)
2. Name of the entity with which the investigator(s) has a financial conflict of interest
3. The nature of the significant financial interest
4. The value of the financial interest
5. Description of how the financial interest relates to the research project

This information must be disclosed prior to the funding of a project/grant and should be disclosed prior to beginning funding solicitation.

The IO will review disclosure forms prior to the research start date to determine whether there is a SFI as described in 42 CFR Part 50 Subpart F Section 50.603(1), and whether the SFI is related to the PHS funded research. If the IO determines the existence of an FCOI, the IO will implement appropriate measures to restrict or eliminate the FCOI.

Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

- 1) Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
- 2) For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;



- 3) Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias resulting from the financial conflict of interest;
- 4) Modification of the research plan;
- 5) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- 6) Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
- 7) Severance of relationships that create financial conflicts.

If a new SFI develops during the research period, or if the Investigator did not previously disclose an existing SFI prior to the research start date, the Investigator must submit a disclosure form within 30 days of acquiring or discovering a new SFI. The IO will review the disclosure form and make an FCOI determination within 60 days of receipt of the form.

The IO will periodically monitor investigator compliance under this policy throughout the research period. Questions or concerns regarding this policy should be directed to the IO.

Reporting Requirements:

If an investigator is found to have a financial conflict of interest, the IO will submit an FCOI report to the PHS Awarding Component prior to expending funds for the PHS research. If an FCOI is found during the research period, the IO will submit an FCOI report and a management plan to the PHS Awarding Component within 60 days of identifying the FCOI. The FCOI report will include:

- (i) Project number;
- (ii) PD/PI or Contact PD/PI if a multiple PD/PI model is used;
- (iii) Name of the Investigator with the financial conflict of interest;
- (iv) Name of the entity with which the Investigator has a financial conflict of interest;
- (v) Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);



(vi) Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value; CHEQUEAR MONTOS EN REGLAMENTO

(vii) A description of how the financial interest relates to the PHS-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and

(viii) A description of the key elements of the Institution's management plan, including:

- (A) Role and principal duties of the conflicted Investigator in the research project;
- (B) Conditions of the management plan;
- (C) How the management plan is designed to safeguard objectivity in the research project;
- (D) Confirmation of the Investigator's agreement to the management plan;
- (E) How the management plan will be monitored to ensure Investigator compliance; and
- (F) Other information as needed.

If an FCOI report is submitted, the IO will provide an annual FCOI report to the PHS Awarding Component that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the PHS-funded research project.

If an FCOI is not identified or managed in a timely manner, the IO will complete a retrospective review of the investigator's activities and the PHS funded research within 120 days of the discovery of noncompliance to determine whether the design, conduct, or reporting of the PHS funded research has been tainted by bias during the period of noncompliance.

The review will be documented with the following information:

- 1) Project number;
- (2) Project title;
- (3) PD/PI or contact PD/PI if a multiple PD/PI model is used;
- (4) Name of the Investigator with the FCOI;



- (5) Name of the entity with which the Investigator has a financial conflict of interest;
- (6) Reason(s) for the retrospective review;
- (7) Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
- (8) Findings of the review; and
- (9) Conclusions of the review.

If bias is found, the IO will notify the PHS Awarding Component, will take corrective action for noncompliance and submit a mitigation report that contains the information found during the review.

Maintenance of Records:

FCOI disclosures and reports will be maintained for a period of 3 years after the end of the research period, or from other dates as specified in 45 CFR 75.361 where applicable.

Enforcement, Remedies and Noncompliance:

Violations of this policy will be fully investigated. Individual(s) found in violation of this policy will be removed from the project and will be subject to disciplinary action including but not limited to administrative leave, and/or termination.

SFIs which are not disclosed timely or were previously reviewed, or whenever an FCOI is not identified or managed in a timely manner and to document the reviews consistent with the regulation, will have to be completed and documented in retrospective reviews within 120 days of the Institution's determination of noncompliance.

Under certain circumstances, if the HHS determines that an FCOI resulted in bias in the PHS funded research, the investigator with the financial conflict of interest may be required to disclose the FCOI at each public presentation of the results.

Subrecipient Requirements:



FCOI regulations apply to subcontractors used in any PHS funded research. Subcontractors must have their own FCOI policy or use FLACSO's policy if none exists. The contracting agreement should certify that the subcontractor shall comply with FCOI regulations. The agreement should also specify the time period to submit disclosure forms and FCOI reports to FLACSO.

Public Accessibility:

A copy of this policy can be found on FLACSO's website at <https://www.bioeticaflacso.org/informaci%C3%B3n-institucional>

FCOI requests can be made in writing to FLACSO, Tucumán 1966, Ciudad Autónoma de Buenos Aires, Argentina, or via mail to: agromick@flacso.org.ar.

If an SFI was 1) disclosed and is still held by the Investigator, 2) the SFI is related to PHS funded research, and 3) the SFI is determined to be a financial conflict of interest, FLACSO will issue a written response to your FCOI request within 5 business days of the request.

The information will include the Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

FLACSO will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the identification of a new financial conflict of interest, which should be requested subsequently by the requestor.