

Logo in Header: **UNIVERSIDAD DE ANTIOQUIA. Office of the Vice-President for Research.**

**REGULATIONS TO THE FINANCIAL CONFLICTS OF INTEREST POLICY]
UNIVERSIDAD DE ANTIOQUIA**

INTRODUCTION:

Colombia has a general constitutional and legal normative framework related to public service (Colombia, Political Constitution arts. 122 & 209) that states: *“No public servant will assume their position without taking an oath to comply with and defend the Constitution and to perform the duties entrusted to them. Before taking office, when leaving it or when requested to do so by the competent authority, they must declare, under oath, the amount of their assets and income... The administrative function is at the service of the general interest and is performed based on principles of equality, morality, efficiency, economy, speed, impartiality, and publicity, through decentralization, delegation and deconcentration of functions.”* Law 1952/2019, article 44, states, regarding conflicts of interest, that all public servants must *“declare themselves impeded from acting in any matter when they or their spouse, partner, or permanent partner, or any relative within the fourth degree of consanguinity, second of affinity, or first civil, or their de jure or de facto partner(s) have a particular and direct interest in its regulation, management, control or decision. Whenever the general interest, inherent to the public function, should come into conflict with a particular and direct interest of the public servant, they must declare themselves impeded.”*

Within the framework of the National System of Science, Technology and Innovation, the ethics, bioethics and scientific integrity policy promotes an active commitment to integrity in the daily actions of public citizens, servants and organizations based on honesty, transparency, rigor, justice, veracity, validity, trust (Colombia. Política de Ética de la Investigación, Bioética e Integridad Científica, Bogotá 2018, p. 309).

Scientific research is a field of human action subject to conflicts of interest between the different actors responsible for its development, including financial conflicts of interest that could potentially arise in research processes in all areas of knowledge, which is an axis of the institution’s mission and cross-cutting to its operations.

Universidad de Antioquia, UdeA, defines and regulates conflicts of interest for public servants and stipulates causes for impediments for “public servants and contractors with a private interest” who may be confused with or sponsored or benefited by any official actions in the public servant’s administrative, academic, contractual, research or extension-related fields, or to the detriment of the general institutional interest that should guide their actions” (Superior Agreement 395/2011, Articles 1 & “). UdeA researchers must comply with rules for public servants.

As regards regulations, a binding regulatory framework exists for financial conflicts of interest in health-related scientific research tied to sponsorships or other forms of compensation that enables the adoption of “necessary measures to prevent these from giving rise to conflicts of interest to the researcher in protecting the rights of research subjects, even if they have consented to preserving the veracity of the results and the allocation of resources” (Colombia, Resolution 8430/1993, Article 51).

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The National Institutes of Health of the United States of America, known by the acronym NIH, and other governmental and nongovernmental entities in other countries that fund scientific research, require that the recipients of their support—grantees and researchers attached to the UdeA—meet certain requirements regarding scientific integrity.

In the case of the NIH, the promotion of objectivity in research requirements are set forth in the Code of Federal Regulations ([42 CFR Parte 50, Subparte F](#)) and the NIH Grant Policy Statement ([Section 4.1.10](#), Financial conflicts of interest). Therefore, all research groups, researchers and, in general, any person carrying out research activities at Universidad de Antioquia with financial resources from national and international entities, in particular from the [National Institute of Health](#)-NIH and/or [the Department of Health and Human Services](#)-HHS, and any other related agencies of the United States of America, thereby assume responsibility for properly managing any financial conflict of interest before the relevant bodies and entities subject to the regulations in force.

As a higher education institution that receives external support for research, UdeA complies with current regulations. Therefore, this policy will be reviewed in an ongoing manner in consideration of future domestic and international regulatory modifications.

JUSTIFICATION:

Research is an essential component of UdeA's mission. As this activity becomes more sophisticated, there are increasingly broad and complex relationships with other domestic and international entities with diverse interests, and this can give rise to potential conflicts of interest for researchers.

UdeA researchers are bound to maintain the objectivity of their research and avoid any, and especially financial, conflicts of interest.

UdeA creates this policy to protect the integrity of research studies funded by external entities—both domestic and international—and, in particular, to comply with federal Public Health Service (PHS) of the United States of America.

POLICY GUIDING PRINCIPLES/VALUES

Certain principles and values related to the public function need to be acknowledged and accounted for in order to apply the policy:

PRINCIPLES:

Administrative due process: Researchers – public servants and contractors with private interests – will have available a due administrative process to manage the declaration of domestic or international financial interests according to the corresponding regulations. This due process also extends to the disciplinary function as provided by the General Statute of the UdeA and the General Disciplinary Code.

Administrative morality: Public servants and private contractors who carry out research at the UdeA in the course of their mission, will declare and duly manage conflicts of

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interest related to national public resources or those arising from international support strictly according to the law, regulations, and ethics.

Equality: All public servants and private contractors that conduct research at UdeA have equal rights and obligations regarding the management of conflicts of interest before the corresponding authorities.

Efficacy: After properly managing conflicts of interest, the use of domestic public resources or resources from international support for research at UdeA must contribute substantively to the achievement of the University Research System's purpose, objectives and goals and contribute to solving the country's main problems and needs with a global perspective.

Economy: The management of financial conflicts of interest must be carried out with as few formalities, processes, and expenses as possible vis-à-vis the relevant authorities.

Celerity: The management of conflicts of interest must be carried out as quickly as possible and without undue delay by public servants.

Impartiality: As regards the management of financial conflicts of interest, the authorities or public officials involved in the proceedings may not use discriminatory practices or treatments of any kind against researchers or private contractors that aspire to access domestic resources or international support for research with institutional support from UdeA.

Publicity: Authorities, public servants, and private contractors obliged to manage financial conflicts of interest shall systematically and permanently inform the public and stakeholders regarding the actions and procedures implemented to manage financial conflicts of interest.

Social control: Citizens have the right and the duty to individually or collectively oversee - through organizations, social networks, and institutions - the management of research-related financial conflicts of interest.

Citizen participation: Citizens may participate through petitions and social control actions related to the provisions of this policy and, in particular, as regards the proactive publication and dissemination of the record of conflicts of interest under Colombian law and foreign regulations issued by funding entities.

VALUES:

Honesty: Always act according to the truth, fulfilling all duties with transparency, rectitude, and in the general interest.

Respect: Acknowledge, value and treat all people with dignity, including their virtues and defects, regardless of their work, origin, titles or any other condition whatsoever.

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Commitment: Awareness of the importance of their role as public servants and ongoing willingness to understand and solve the needs of the people they engage with in their daily work, constantly seeking to improve their well-being.

Diligence: Fulfill their duties, functions, and responsibilities as best as possible, attentively, promptly, and efficiently, to optimize their use of State resources.

Justice: Act with impartiality and guarantee people's rights with equity, equality and without discrimination.

OBJECTIVES AND SCOPE:

The purpose of this policy is to identify, eliminate or control any potential threat to integrity in research funded by external domestic and international entities, including those that could result in unethical treatment of research subjects.

Adoption of this policy implies assuming a commitment to harmonize, apply and disseminate domestic and international requirements related to Financial Conflicts of Interest (FCOI), including those regulated by the Code of Federal Regulations of the United States of America ([42 CFR Part 50 Subpart F](#)).

DEFINITIONS:

Scientific integrity: policies and good practices in and for the generation and appropriation of knowledge aimed at maintaining trust and credibility in science. (Paraphrased from Colombia. Colciencias. Política de Ética de la Investigación, Bioética e Integridad Científica. 2018. page 12. Available at: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://minciencias.gov.co/sites/default/files/pdf_poltica.pdf).

Conflict of Interest: A conflict of interest arises whenever a public servant or an individual performing a public function is affected by a moral or economic situation that prevents them from taking part in regulation, procedure, control, and decision-making processes related to any matter submitted for their consideration, such that the impartiality and independence demanded by the position, job or function would be broken, and that they would - instead - look to their own convenience or personal benefit, or that of their relatives or partners (Superior Agreement 295/2011 by which regulates conflicts of interest of public servants at UdeA).

Financial Conflict of Interest: A financial conflict of interest is that where there is an opportunity to gain any kind of personal financial benefit from the university public servant, their spouse or permanent partner or relatives within the fourth degree of consanguinity, second of affinity or only civil, or their partner or partners in fact or law, which could affect their objectivity and transparency when acting or decision-making and that could directly and significantly affect the design, execution or reporting of a research study.

Financial Interest: Anything that has monetary value, regardless of whether such value is easily verifiable.

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Declaration of Relevant Financial Interests: A declaration made by a researcher of relevant financial interests according to the specific domestic or international precepts that regulate them.

Relevant financial interests in Colombia and Universidad de Antioquia. In Colombia and at Universidad - when dealing with financial resources for research from public sector entities, independently of their nature or amounts - all financial interests are relevant and, therefore, include the obligation for public servants or private contractors to declare themselves impeded for acting in that scientific research, whenever, in the exercise of the public function of carrying out scientific research-they have a specific or direct interest in regulating, managing, controlling or deciding on the destination of those resources, or their spouse, partner, or permanent partner, or any relative within the fourth degree of consanguinity, second of affinity, or first civil, or their de jure or de facto partner(s) have such an interest.

Internationally relevant financial interest. In the case of financial support from international public institutions, public servants and private contractors must adhere to the special requirements on relevant financial interests issued by the relevant regulatory authority.

In the case of the United States of America—pursuant to the Code of Federal Regulations ([42 CFR Part 50, Subpart F](#))— **relevant financial interests exist** when one or more of the following interests of the researcher (and of the researcher's spouse or partner and dependent children) arise, which appear to be reasonably related to the researcher's institutional responsibilities.

1. *With respect to any listed entity, a significant financial interest exists if the value of any remuneration received from the entity over the twelve months prior to the declaration and the value of any equity interest in the entity at the date of declaration exceeds \$5,000 dollars (valued in Colombian pesos at the official exchange rate published by Banco de la República on the day remuneration was received). For the purpose of this definition, remuneration includes salary and any payments for services not identified as salary (e.g., consulting fees, fees, paid authorship); equity interest includes any share, stock option or other ownership interest, as determined by reference to public prices or other reasonable measures of fair market value:*
 - a. *With respect to any unlisted entity, a significant financial interest exists if the value of any remuneration received from the entity over the twelve months prior to the declaration exceeds \$5,000 dollars (valued in Colombian pesos at the official exchange rate published by Banco de la República on the day remuneration was received), or when the researcher (or the researcher's spouse or partner or dependent children) have any share therein (e.g., shares, stock options, or any other kind of shareholding); or*
 - b. *Intellectual property rights and interests (e.g., patents, copyrights), upon receipt of income related to such rights and interests.*
2. *Researchers must also declare any reimbursed or sponsored trips undertaken (e.g., those paid in favor of the researcher, spouse or domestic partner, and dependent*

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children and are not reimbursed to the researcher, such that it may be more difficult to determine their precise monetary value), related to their institutional responsibilities and taking place over the twelve months prior to disclosure.

This reporting requirement does not apply to travel reimbursed or sponsored by a federal, state, or local government agency, institution of higher education, academic teaching hospital, medical center, or research institute associated with an institution of higher education.

This disclosure shall include, at a minimum, the purpose of travel, the identity of the sponsor/organizer, the destination, and the duration.

Institutional officials will determine whether further information, including a determination or disclosure of monetary value, is required to determine whether travel constitutes a financial conflict of interest associated with research projects with different domestic and international funding sources, including research funded by the NIH, PHS, and HHS of the United States of America.

3. *The term relevant financial interest does not include the following types of financial interest: salary, royalties or other remuneration paid by the institution to the researcher, including intellectual property rights and agreements to participate in royalties related to such rights; investment income, such as mutual funds and retirement accounts, provided that the researcher does not directly control the investment decisions that are made; income from seminars, conferences, or teaching engagements sponsored by a federal, state, or local government agency, institution of higher education, academic teaching hospital, medical center, or research institute affiliated with an institution of higher education; or service income on advisory committees or review panels for a federal, state, or local government agency, institution of higher education, academic teaching hospital, medical center, or research institute affiliated with an institution of higher education.*

POLICY GUIDELINES:

Scope of application and recipients:

1. This policy applies to public servants, private contractors that fulfill public scientific research functions within the framework of higher education, regarding resources from any public - national, departmental, district, municipal or similar level - entity that funds science, technology and innovation projects.
2. The financial conflict of interest policy extends to financial resources from NIH, PHS and HHS research funds from the United States of America that operate under the figure of a grant or cooperative agreement. Without prejudice to any other rules that may give rise to adjustments to this document.
3. All main researchers are responsible for ensuring that all participants in a research project that are responsible for the design, execution, or submission of research reports declare any relevant financial interest related to their legal and regulatory responsibilities, including, where applicable, those of the NIH, PHS, and HHS of the United States of America.
4. This policy also applies to the researcher's direct family, understood as their spouse, partner, or permanent partner, or any relative within the fourth degree of

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consanguinity, second of affinity, or first civil, or their de jure or de facto partner(s).

5. Collaborators, subcontractors, indirect awardees, and scientific advisors must comply with this policy or submit a certificate to the research center managing the project at UdeA indicating that their institutions are in compliance with any and all relevant policies and that they, in turn, are in compliance with their own institutional policies.

Declaration of Financial Conflicts of Interest

1. All main researchers are responsible for the design, execution, or submission of research reports for funded research activities or proposed for funding, especially those funded by or requesting funding from the NIH, PHS, and HHS of the United States of America must declare their conflicts, and specifically financial conflicts of interest.
2. All researchers with relevant financial interests related to their institutional responsibilities governed by national regulations must declare themselves impeded before the head of the Research Center to which the research project is attached.
3. All researchers with relevant financial interests related to their institutional responsibilities governed by national regulations must fill out a research-related financial conflict of interest declaration form and submit all required supporting documentation to the head of the Research Center to which the research project is attached. If the head of the Research Center determines that there is indeed a financial conflict of interest, he or she will ask the researcher to submit a conflict management plan defining the steps necessary to control, reduce, or eliminate the financial conflict of interest. For UdeA to authorize any expenditure of funds under an allocation of international resources, any and all financial conflicts of interest must have been resolved or an acceptable management plan must be implemented.
4. UdeA researchers must report and keep up to date any and all information related to potential conflicts of interest in the Public Employment Information and Management System -SIGEP, in Spanish - and attach the proper certification to research projects that will be funded using domestic and international public resources. In the case of research funded by the NIH, PHS and HHS of the United States of America, they must submit an updated statement of relevant financial interests to the head of the Research Center to which the project is attached at least once a year during the award period. That declaration shall include all information not initially declared.
5. All researchers participating in research funded by the U.S. NIH, PHS, and HHS must submit an updated disclosure of relevant financial interests within thirty (30) business days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a significant new financial interest.
6. All statements and related documents are considered sensitive information and will be treated confidentially and will not be disclosed beyond the head of the Research Center without the consent of the researcher, except in response to an express request from the funder; or pursuant to a court order or lawful subpoena.
7. The heads of Research Centers will report any relevant financial conflicts of interest to the Office of the Vice-President for Research, which will, in turn,

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notify the funder in writing of the existence and nature of a financial conflict of interest and whether the conflict has been controlled, reduced, or eliminated.

8. The Office of the Vice-Rector for Research will train and advise Research Center Heads, Research Group Coordinators, and researchers on financial conflicts of interest.
9. The Central Research Ethics Committee (CCEI, in Spanish) will train the University's ethics and bioethics committees in identifying, assessing, and monitoring conflicts of interest, especially financial conflicts of interest.

Review of Financial Declarations of Interest:

1. Before making any expenditure of funds on a project and in particular research funded by the US NIH, PHS and HHS, research centers managing the resources must verify that researchers have attached certifications of updated declarations of financial conflicts of interest and that their certifications have been approved by the Research Center Head or, in the event of appeals, by the Office of the Vice-President for Research.
2. The Research Center Head shall review, with support from the Technical Committee or whoever takes its place, the statements and accompanying documentation to determine whether the researcher's relevant financial interests are related to the funded research and, if so, whether the relevant financial interests represent a financial conflict of interest. The Research Center Head may request additional information from the researcher for clarification, which will be treated as non-public information to the extent permitted by law.
3. If a financial conflict of interest exists, the Research Center Head must ask the researcher to submit a conflict management plan defining the steps necessary to control, reduce, or eliminate the financial conflict of interest. The Research Center Head shall review the proposed conflict management plan, with support from the Technical Committee or whoever takes its place, and approve it or add conditions or restrictions to make sure any conflict is controlled, reduced, or eliminated. Such conditions or restrictions may include the following, without limitation: Public disclosure of financial conflicts of interest (e.g., when research is presented or published); Oversight of research by independent reviewers; Modification of planned activities (possibly subject to sponsor approval); Disqualification of project participation in whole or in part; Waiver of relevant financial interests; Termination of relationships that give rise to conflicts; For research involving human subjects, disclosure of financial conflicts of interest directly to research subjects.
4. In all cases, conflict resolution or an acceptable conflict management plan must be implemented before any expenditure of funds under an award is made, especially in proposals funded by the U.S. NIH, PHS, and HHS.
5. When a researcher participating in a research project for the first time, particularly in a project funded by the U.S. NIH, PHS and HHS, declares a relevant financial interest, or an existing researcher declares a new relevant financial interest, the head of the research center to which the project is assigned shall: review the relevant financial interest disclosed within sixty (60) business days; determine whether it is related to the funded research; determine whether a financial conflict of interest exists; and, if so, implement, at least provisionally, a management plan that must specify any measures taken now and in the future to control such a financial conflict of interest. Depending on the nature of the relevant financial

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- interest, the Research Center Head should review, with support from the Technical Committee or whoever takes its place, whether additional interim measures are needed in relation to the researcher's participation in the funded research project, between the date of disclosure and the completion of the review.
6. Whenever the head of an UdeA research center identifies a relevant financial interest not declared by a researcher at the appropriate time, or which, for whatever reason, was not previously reviewed for an ongoing research process (e.g., an indirect awardee did not review or report it on time), the Research Center Head shall: review the relevant financial interest disclosed within sixty (30) business days; determine whether it is related to the funded research; determine whether a financial conflict of interest exists; and, if so, implement, at least provisionally, a management plan that must specify any measures taken now and in the future to control such a financial conflict of interest from then on.
 7. Whenever the Research Center identifies a relevant financial interest not declared by a researcher at the appropriate time, or which, for whatever reason, was not previously reviewed for an ongoing research process (e.g., an indirect awardee did not review or report it on time), the UdeA ethics or bioethics committee must notify the Research Center Head immediately or within a maximum of ten (10) days after the finding for an ethical evaluation of the case, so that the Head can adopt the corresponding measures.
 8. Likewise, whenever a financial conflict of interest is not identified or managed in a timely manner, even if not declared by the researcher, the Research Center Head must make a retrospective review of the researcher's activities and the project within 120 working days of the determination of non-compliance to decide whether the research design, conduct, or reporting was biased.
 9. The Research Center shall document the retrospective review. This documentation must include at least the following: (1) Project Number; (2) Project title; (3) research team name; (4) Name of the researcher with the financial conflict of interest; (5) Name of the entity with which the researcher has a financial conflict of interest; (6) Reasons for retrospective review; (7) Detailed approach used for retrospective review (e.g., review process methodology, review panel composition, review documents); (8) Review findings; and (9) Review conclusions.
 10. The researcher should update the relevant conflict of interest report based on the results of the retrospective review, if necessary, specifying the measures to be taken to manage the financial conflict of interest going forward. If bias is detected, the head of the research center will immediately inform the Office of the Vice-President for Research and the funder with a corresponding mitigation plan. The mitigation report should include, at a minimum, the key elements documented in the above retrospective review, a description of the impact of the bias found in the research project, and an action plan adopted to eliminate or mitigate the effect of bias. Thereafter, the researcher will submit annual financial conflict of interest reports. Depending on the nature of the financial conflict of interest, the Office of the Vice-President for Research, with support from the Central Ethics Committee, may decide that additional measures are needed regarding the researcher's participation in a research project, between the date the financial conflict of interest or the researcher's non-compliance is determined and completion of the UdeA retrospective review.

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Enforcement Mechanisms and Remedies and Non-compliance:

Appeal for reconsideration:

Researchers may optionally file appeals for reconsideration with the person issuing a decision related to a potential financial conflict, seeking to clarify, modify, add to, or revoke it. Appeals for reconsideration must be filed within 10 days after the personal notification or other forms of notification under the terms of the then current Administrative Procedural and Contentious Administrative code..

Appeals:

Researchers may appeal – with or without a previous appeal for reconsideration – any unfavorable decision related to financial conflicts of interest before the Office of the Vice-President for Research. The Vice-President for Research will have a maximum of one (1) month to review the appeal and make the corresponding decision, and may rely on the CCEI or other qualified instances that deemed appropriate, pertinent, and conducive to the resolution of the appeal.

Appeals must be filed in writing with and served personally on the official that rendered the decision, or within ten (10) days following the decision or using other forms of service; and in accordance with the requirements established by the then current Administrative Procedural and Contentious Administrative Code (Colombia, Law 1437/2011, articles 74-82).

Compliance:

As part of the financial conflict of interest declaration, each researcher must prove that, if the UdeA determines that a financial conflict of interest exists, the researcher will comply with any conditions or restrictions imposed on the project and fully cooperate with the individual(s) designated to oversee compliance.

Application:

Failure to properly declare relevant financial interests or failure to comply with the conditions or restrictions imposed by UdeA will be considered non-compliance with the accepted standards for carrying out research at UdeA.

The Disciplinary Affairs Unit will, ex officio or via information submitted or complaints made by any person, initiate in the first instance any investigation and ruling related to violations of this policy by action or omission and will recommend measures to be taken by the University's corresponding instances. Violations to this policy include, among others: failure to file declarations on the SIGEP or other platforms made available for this purpose, disclosure forms filled out incompletely or with deliberately erroneous or misleading information; or non-compliance with the procedures defined by the Office of the Vice-President for Research. If a determination is made that the policy has been breached, this will be notified to whomsoever has disciplinary powers within Universidad de Antioquia so they can begin the appropriate disciplinary process and apply, if necessary, any corresponding sanctions according to the University's General Statute, its internal regulations, and the General Disciplinary Code for Public Servants. The above, without prejudice to the adoption of administrative measures including notifying the funding entity so it can cease allocating resources.

Record keeping:

The research center that the project is attached to will keep secure and confidential records of all declarations and associated activities.

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All records will be kept for three years after the projects completion or termination.

Reports:

Before the Research Center to which the project is attached can make any expenditure of funds under a research project funded by external entities, particularly in the case of projects funded by the U.S. NIH, PHS and HHS, it must provide the Office of the Vice-President for Research with information related to any relevant financial interest found for any researcher so that it can, in turn, inform the Funding entity. Whenever the Research Center Head identifies a financial conflict of interest and finds it has been eliminated prior to spending the awarded funds, it will not need to be reported to the Office of the Vice-President for Research or the funding entity.

For any relevant financial interest identified as conflicting after the initial FCOI report within an ongoing research project funded by an external entity (e.g., when a new researcher enters the research project), the Office of the Vice-President for Research must submit to the awarding body a report of the financial interest related to the financial conflict of interest within sixty (60) business days and ensure implementation of a management plan, especially for projects funded by the U.S. NIH, PHS and HHS (as provided by: 42 CFR 50 subpart F).

Wherever an FCOI report includes a relevant financial interest that a researcher did not disclose in time or that the UdeA did not previously review or manage, for whatever reason (e.g., an indirect awardee failed to review or report it in time), UdeA will also conduct a retrospective review to determine whether this introduced bias into the design, execution or reporting of any PHS-funded research. Additionally, if bias is detected, the Office of the Vice-President for Research, using information supplied by the head of the Research Center that manages the project, must immediately report it and submit a mitigation report to the awarding body.

The Office of the Vice-President for Research, with information provided by the head of the Research Center managing the project, must include sufficient information in the FCOI reports required under this policy to allow the awarding body to understand the nature and magnitude of the financial conflict and evaluate the adequacy of the proposed management plan. The financial conflict report shall include the following elements, among others: Project number; researchers' data, name of the researcher with a financial conflict of interest; name of the entity with which the researcher has a financial conflict of interest; nature of the financial interest (e.g., shareholding, consulting expenses, travel reimbursements, fees); amount of financial interest (using dollar ranges) or a statement that the amount of the interest cannot be easily determined by reference to government prices or other reasonable measures of fair market value; a description of how financial interest relates to the funded research and the rationale for the determination made that such financial interests conflict with the research; and a description of the key elements of the management plan submitted, including the main role and tasks of the conflicting researcher within the research project, management plan conditions; how the management plan is designed to safeguard research project objectivity, confirmation of acceptance of the management plan by the researcher, how the management plan will be monitored to ensure researcher compliance, and any other required information.

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For any conflict of interest previously reported by the Office of the Vice-President for Research of the UdeA regarding an ongoing research project funded by an external entity, UdeA must provide the awarding body, through the Office of the Vice-President for Research, supported by information provided by the Research Center Head and/or the ethics or bioethics committee, indicating the status of the financial conflict of interest and any changes to the management plan during the term of the research project. The conflict report submitted to the funding entity shall specify whether the financial conflict is still being managed or explain why the financial conflict no longer exists. UdeA, through the Office of the Vice-President for Research, must provide annual conflict of interest reports to the funding body during the project period (including extensions, whether funded or not) throughout the term and in the manner indicated by the funding body.

If a researcher's failure to comply with this policy or with a conflict-of-interest management plan appears to have influenced the design, execution or reporting of the funded research, the Office of the Vice-President for Research shall immediately inform the funding body of the corrective action taken or planned. The funding body may consider the situation and either implement appropriate measures or refer the matter to the UdeA Office of the Vice-President for Research for further action, which may include instructions to the UdeA Office of the Vice-President for Research on how to maintain appropriate objectivity within the funded research project.

At any time, the funding body may ask for the declaration of financial interests made by any researcher and the review (including any retrospective review) performed by the Office of the Vice-President for Research through the Research Center the project is attached to, and the response to that disclosure, regardless of whether the institution's declaration identified a financial conflict of interest or not. The Office of the Vice-President of Research, with support from the Research Center, will be required to submit all pertinent records, or allow their review on site. The funder shall maintain the confidentiality of all records of financial interests. Based on its review of the records or any other available information, the awarding entity may decide whether a given financial conflict of interest could affect the objectivity of the funded research to such an extent that additional corrective action is required, or, in research funded by the U.S., NIH, PHS, and HHS, that UdeA failed to manage the financial conflict of interest pursuant to . The funding body may determine that special award conditions need to be imposed or that it will suspend funding or implement other enforcement actions until the matter is resolved. For projects funded by the U.S. NIH, PHS, and HHS, records must be submitted subject to [42 CFR Part 50, Subpart F](#)

In any case where the funding body of a clinical investigation that aims to evaluate the safety or efficacy of a drug, medical device or treatment, determines that it has been designed, executed, or reported on by a researcher with a financial conflict of interest that the UdeA did not manage or report, the Office of the Vice-President for Research, with support from the Research Center, must ask the researcher involved to declare the financial conflict of interest in all public presentations of research results and request an annex to previously published presentations.

UdeA may require that other financial conflicts of interest be reported to the funding body as it deems appropriate.

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Requirements for sub-awardees:

- a. For PHS-funded research carried out through a sub-awardee (e.g., subcontractors or consortium members) where UdeA is the awardee institution, researchers in the sub-awardee institution must comply with this policy, which will be included in the agreement to be signed between the parties. That agreement will define whether the UdeA financial conflict of interest policy or the policy of the sub-awardee will apply. If sub-awardee researchers are required to comply with the sub-awardee's financial conflicts of interest policy, the sub-awardee will certify that it meets national conflict of interest management and Code of Federal Regulations ([42 CFR Part 50, Subpart E](#)) requirements.
- b. Sub-awardee institutions shall submit ongoing FCOI reports to UdeA addressing the status of significant conflicts of interest and any changes to management plans (where applicable) at the following times: prior to project implementation; within 60 days of identifying researchers that participate in the project; within 60 days of new or newly identified FCOIs for existing researchers; once a year to provide FCOI status and any changes to management plans (where applicable) until project completion; and when updates are required to a previously submitted report, if applicable.

Public accessibility:

UdeA must ensure public accessibility by means of a written response to any applicant within five (5) business days of receiving of a request for information related to any relevant financial interest disclosed to UdeA that meets the following three (3) criteria:

- The relevant financial interest has been disclosed and continues to await main/key personnel as defined in this policy;
- UdeA determines that the financial interest is related to research funded by the external entity requiring it; and
- UdeA determines that financial interest represents a financial conflict of interest.

The Administrative Department of the Civil Service makes the [SIGEP](#) available for citizens to query declarations of conflicts of interest made by individuals or corporate persons. In turn, UdeA will respond to any request for information on financial conflicts of interest related to a researcher within ten (10) days of receiving any such request. To this end, the university authority will fully examine the request and proceed to respond as requested so long as it is not subject to legal reserve. Its response will include the following, at a minimum: (i) The researcher's name; (ii) The researcher's position and function within the research project; (iii) The name of the entity with which the relevant financial interest is maintained; (iv) The nature of the relevant financial interest; and (v) The approximate dollar amount of the relevant financial interest using dollar ranges or a statement that the amount of the interest cannot be easily determined, making reference to publicly available prices or other reasonable measures of fair market value.

Information related to the relevant financial interests under this policy must remain available to respond to written requests during at least three (3) years from the date the information was last updated.

Training:

1. UdeA will keep this policy updated and available through its website.
2. Researchers must be aware of this policy, their responsibilities regarding financial conflicts of interest, and the rules of the funding body prior to participating in a research study, and must refresh this information at least every four (4) years.

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3. Researchers must be trained within thirty (30) days whenever one or more of the following circumstances arise: *i)* UdeA modifies its financial conflict of interest policy in research for funded projects or the procedures related to this policy; *ii)* the researcher is new to UdeA; or *iii)* UdeA discovers that a researcher is out of compliance with this policy or with the management plan.

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ANNEXES:

Declaration of Financial Conflicts of Interest

Footer on all pages:

Office of the Vice-President for Research

Address: Calle 67 No. 53-108 Bl. 16 Of. 210 • **Mailing address:** Calle 70 No. 52 - 21

PBX: [57] 604 219 83 32 • **Telephone No.:** 604 219 51 90 • **TIN:** 890.980.040-8 • **A.A.:** 1226

E-mail: viceinvestigacion@udea.edu.co • <http://www.udea.edu.co> • Medellín, Colombia

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