

REPUBLIC OF COLOMBIA - Certified Translation

Universidad de Antioquia – Translation Agency Tjebbe Donner – Resolution No. 0001046 dated Dec. 02, 2002



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

RECTORAL RESOLUTION **** November **, 2022.

By which the Financial Conflict of Interest Management for Research Policy is adopted.

THE PRESIDENT OF UNIVERSIDAD DE ANTIOQUIA, exercising his statutory powers, specifically those granted under items a, e, and h of Superior Agreement 01/1994, Article 42 of the General Bylaws and,

WHEREAS

- 1. Universities, under national law, hold autonomy for issuing their own guidelines and being governed by their own bylaws, enabling them to formulate any and all policies that will make viable the fulfillment of their missions.
- 2. The National Council for Economic and Social Policy, by adopting the National Science, Technology and Innovation Policy contained in CONPES-DNP 3582 from April 27, 2009, indicated that these have been identified by Colombian society as a source of development and economic growth.
- **3.** Article 3 of Law 1286/2009 defines the foundations for consolidating a State Policy on Science, Technology and Innovation.
- 4. Law 1952/2019, article 44, defines 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."
- 5. The code of integrity for the Colombian Public Service, adopted under Law 2016/2020, promotes an active commitment to integrity in the daily actions of public citizens, servants and organizations based on honesty, respect, commitment, diligence, and justice.

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- 6. 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.
- 7. Resolution 8430/1993, article 51 "Establishing scientific, technical and administrative standards for research in health", issued by the former Ministry of Health, states that "Whenever there is sponsorship or any other form of remuneration, the necessary measures must be implemented 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."
- 8. Resolution 2378/2008, article 7 "Adopting Good Clinical Practices for Institutions Conducting Research with Medicinal Products on Human Beings", issued by the Ministry of Social Protection, establishes that research institutions must have an Institutional Ethics Committee whose responsibility is "to guarantee the protection of rights, safety and well-being of humans involved in research studies through, among other things, constant review, approval and review of the research project and amendments to the documentation and informed consent of the subjects of the study."
- 9. The Technical Annex to Resolution 2378/2008, defines that the Research Ethics Committee must include in the requirements for making decisions after evaluating proposals during committee sessions, "restriction policies for participation in proposal reviews wherein one or more committee members could have conflicts of interest."
- **10.** The Technical Annex to Resolution 2378/2008 provides that the Research Ethics Committee, when reviewing proposals, must consider the sponsor's characteristics and its relationship with the researcher to determine any potential conflicts of interest.
- 11. Resolution 314/2018 "By which the Administrative Department of Science, Technology and Innovation adopts the Research Ethics, Bioethics and Scientific Integrity Policy" aims to make sure science, technology and innovation processes in Colombia are implemented subject to principles and guidelines of ethical, bioethical and scientific integrity in all areas of knowledge and their fields of application. It thus highlights the role of institutions and, as part of this, the adoption of guidelines to define roles, functions and responsibilities.
- 12. Superior Agreement 204 from November 6, 2001, modified by Superior Agreements 317 from January 31, 2006 and 386 from February 22, 2011, regulated the research activity at Universidad de Antioquia, and define, among other matters, research policies and principles at Universidad de Antioquia.

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- 13. The internationalization of research is one of the principles provided for under Superior Agreement 204 from November 6, 2001, article 4, and, based on this, the University constantly encourages its researchers to participate in research with international entities.
- 14. Superior Agreement 395/2011, Article 2, "By which conflicts of interests of public servants at Universidad de Antioquia are regulated", defines the following as a cause for impediment: "when a private interest exists for the university's public servants, their spouses or permanent partners or relatives within the fourth degree of consanguinity, second of affinity or first civil, or their common law or legal partner or partners, 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."
- **15.** The National Institute of Health (NIH) and other entities in the United States of America that fund scientific research require grant recipients to meet "promotion of objectivity in research" requirements set forth in the NIH Code of Federal Regulations and the NIH Grant Policy Statement (Section 4.1.10, Financial conflicts of interest).
- **16.** The functions of the Universidad de Antioquia Central Research Ethics Committee (CCEI, in Spanish), governed by Rectoral Resolutions 40455/2015 and 47765/2021 include: "Guide the University's research policies as regard the ethical aspects of research"; "Strive for compliance with the processes and operating procedures of the University's Research Ethics Committees (CEI, in Spanish)"; and "Advise other internal or external Research Ethics Committees (CEI)."
- 17. Research groups, researchers and in general any person who carries 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 or 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.
- 18. Subject to analyses performed by the Office of the Vice-President for Research, it is necessary to adopt a Financial Conflicts of Interest in Research Management Policy,

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insofar as this aims to develop the central principles and values of the public service in research matters and the internationalization of research activities.

RESOLVES

FIRST ARTICLE. Object. To adopt a Financial Conflict of Interest Management Policy, to protect research integrity and ensure compliance with legal and institutional standards and regulations.

PARAGRAPH. The policy applies to research projects funded with own resources and those that receive funding from different national and international sources, including research funded by the National Institute of Health (NIH), the Public Health Service (PHS), the Department of Health and Human Services (HHS) of the United States of America and other institutions.

SECOND ARTICLE. The 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.

THIRD ARTICLE. Policy guidelines. The University of Antioquia, based on its autonomy, defines the following guidelines for the financial conflicts of interest policy in scientific research:

- a. Compliance with the constitutional and legal principles of due administrative process, equality, morality, efficacy, economy, speed, impartiality, publicity, social control, citizen participation.
- b. Compliance and concretion of the values in the code of integrity for the Colombian public service: honesty, respect, commitment, diligence, and justice.
- c. Adoption of processes, procedures, or mechanisms aimed at providing training on issues of financial conflicts of interest in research, their prevention, self-regulation and regulation.

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d. Adoption of U.S. Federal Regulations related to Financial Conflicts of Interest (FCOI; <u>42 CFR Part 50 Subpart F</u>), on the management, reporting and resolution of financial conflicts of interest.

FOURTH ARTICLE. Regulations. The President delegates to the Office of the Vice-President for Research, the regulation of the responsibilities, requirements, procedures and instruments necessary for implementation of a policy of financial conflict of interest in scientific research, issuing the corresponding administrative acts and technical documents within the scope of its competence, for which it is granted a maximum period of sixty days from the entry into force of this administrative act.

FIFTH ARTICLE. Term. This Resolution shall apply as of the date of issue.

JOHN JAIRO ARBOLEDA CÉSPEDES President WILLIAM FREDY PÉREZ TORO General Secretary

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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

