CONFLICT OF INTEREST REGULATIONS



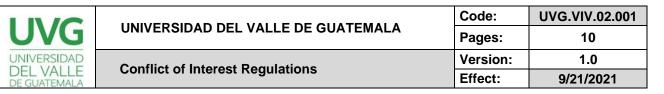
UNIVERSIDAD DEL VALLE DE GUATEMALA



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Prepared by:	Dr. Monica Stein	Authorized by:	_
Reviewed by:	María Luisa de Boehm, Eugenia Rosales, Claudia Véliz, Linda Asturias, Floridalma Correa	Meeting of Board of Directors on 9/21/2021	Page 1 of 10



1. Overview

Universidad del Valle de Guatemala (UVG) and its faculty members, investigators, administrative staff, and students are committed to the principle of a free, open, and objective investigation in supporting its mission of teaching, investigation, and outreach. There are multifaceted relationships among the UVG community and other actors, who often complement their work.

These regulations seek to communicate to collaborators of the situations that create conflicts of interest and conflicts of commitment by providing guidelines and mechanisms to manage these conflicts appropriately, and to describe unacceptable situations. These regulations set out the general framework of the expected code of conduct for the whole community in order to protect the financial well-being, the reputation, and the legal obligations of the university. They establish a method to protect the UVG community from questionable circumstances that may arise, and to solve the apparent, potential, or actual conflicts when necessary. All members of the UVG community should follow the procedures described in these regulations.

2. Application

These regulations apply to all collaborators in the Universidad del Valle de Guatemala, regardless of the type of engagement.

3. Guiding Principles

A. Conflict of Commitment

Fixed-term collaborators of the UVG have a duty of professional loyalty to the university. Their main intellectual energy and time commitment are devoted to education, investigation, and other programs that support the university mission, as well as all the administrative activities that allow the university to meet its mission. A conflict of commitment arises when the professional loyalty of a collaborator towards the UVG is affected due to the time spent on other external activities, which unfavorably impacts their ability to comply with their responsibilities at the UVG set out in the signed contract.

The effort to find balance in responsibilities at the university and external activities, such as consulting, public services, or *ad honorem* activities, may lead to conflict regarding allocation of time and resources. There is a conflict of commitment whenever the external consulting activities of a collaborator exceed the admissible limits. It is considered a significant effort when the time dedicated to an external activity exceeds 20 hours per week.

Professors and staff who intend to participate in an activity that involves a significant effort outside the UVG, which may represent a conflict of commitment, must have written authorization of the corresponding department head, center director, and dean or chief of department or unit.

B. Conflict of Interest

The considerations of personal benefit must not influence the actions or decisions of individuals in performing their duties at the university. Said personal benefits may create a perception of inappropriateness; therefore, such conflicts require to be identified and then managed, reduced, mitigated, or eliminated.

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The following are examples of situations that may raise questions about an apparent or actual conflict of interest:

- External professional activities;
- Use of students' time or work by collaborators for professional activities unrelated to the UVG or not having an agreement or endorsement from the UVG;
- Use of work or time of collaborators by other collaborators for professional activities unrelated to the UVG;
- Undue personal profit from UVG funds or resources;
- Unauthorized or excessive use of university time or resources for professional activities other than the assigned, charitable, or community activities;
- Take undue advantage of students' work or time, investigation results, or graduation projects for own advantage;
- Compromise the university's priorities due to personal financial considerations;
- An undue access by a third party to UVG programs, services, information, or technology, including the use of UVG programs and materials of courses, or UVG investigation results in other universities or entities;
- Selecting an entity as university supplier by an individual with a personal or economic interest in such entity. This includes hiring an independent advisor, contractor, or sub-contractor related or kindred persons with a fourth degree of relationship by consanguinity or second degree of relationship by affinity.

The UVG will supervise and be careful about eliminating or managing conflicts of interest arising or that may arise from a personal interest of an individual in the UVG activities. The university must not approve or go into agreements or contracts, accept gifts or make purchases that will lead to a conflict of interest, unless the conflict can be eliminated or managed correctly by the administrative supervision to protect the interests of the individual and the university.

C. Appropriate use of resources owned by the university

University resources should be used solely in the interest of the university and for the purposes for which they have been provided. Professors, investigators, and administrative staff cannot use university resources, including facilities, personnel, equipment, or information as part of their external consulting activities, or for any purpose other than those of the university. The inadequate use of university resources is considered ethical misconduct, and includes, among others, the following:

- A collaborator assigns university tasks to their students or staff (including extra hours, professional internships, fellowship hours, graduation work, field work, or other university requirements) to promote the financial interest of the collaborator, rather than supporting academic competencies or learning needs.
- Grant access to UVG programs, resources, services, information, or technology to external entities for purposes unrelated to the university mission or without previous agreement with the university.
- Offer inappropriate favors to external entities in an attempt to unduly influence their relationship with the university.
- Use for personal benefit or grant others non-authorized access to confidential information acquired by commercial or investigation activities of the university.
- Using the study programs of the university to benefit other universities or education institutions, without proper authorization.

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D. General Requirements

The UVG will ensure that the collaborator's activities related to the university are free from biases derived from significant personal income. All collaborators must inform the UVG about the income that could affect or be affected by the activities on which they are working or proposing to work in the UVG. The UVG will check the significant income form disclosed by a collaborator and will determine an adequate management plan. Upon engaging in these provisions, the UVG will work to achieve the following objectives:

- Safeguard the academic integrity of the investigation and education programs of the UVG.
- Ensure that activities are objective and free from biases regarding their design, implementation, and reporting.
- Make sure that access to UVG equipment, supplies, and intellectual property rights by investigation sponsors and faculty members is adequate and consistent with the signed agreement or contract, the applicable law, the UVG policy, and the income and reputation of the UVG.
- Address unique circumstances and conditions that may arise in individual cases.

E. Processes and Requirements Report

<u>Overview:</u> The definitions in these regulations describe the significant income requiring disclosure. Persons with questions about whether an interest falls into the different categories must contact the Conflict of Interest Review Committee for assistance. Through its Conflict of Interest Review Committee ("the Committee") or its delegates, the UVG will recommend whether the interest should be managed, reduced, or eliminated, or whether there is a conflict of income. Based on these regulations, collaborators cannot decide whether a significant income should be managed or if it is a conflict of income. This decision will be made through a review process.

Institutional Official: The institutional official is the person designated by UVG to supervise the request and review the financial statement reports of any collaborator that will engage in sponsored activities.

<u>Reporting requirements and methods for reporting:</u> All fixed-term collaborators must report the significant yearly income during the first quarter.

<u>Annual investigation certification reports</u>: Every person engaging in a working relationship with the UVG and every collaborator from any school, division, department, or center of the UVG dedicated to investigation or wishing to be eligible to participate in an investigation must complete an annual certification form. Once submitted, this form will be reviewed by the dean or head (or their designee) of the unit for which the investigator works. The Conflict of Interest Review Committee can adjust the dates to consult with the deans. Professors who are investigators must include in this form any information requested by their administrative unit, which at least must report any significant income obtained in the preceding 12 months and which requires disclosure.

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• External activity reports:

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Consulting, teaching, and other services outside the university. All collaborators are required to report all external professional activities (not assigned by the UVG). These include all external consulting, investigation, or teaching activities. Before participating in these activities, the activity should be disclosed and reviewed by the dean or head of the unit for which the fixed-term collaborator works. When these activities are related to the institutional responsibilities of a person, they could be deemed as significant income that requires disclosure.

• Transaction reports:

The significant income requiring disclosure refers to the income obtained independently (such as dividends, fees, royalties, ownerships, allowances, shares of stock, interests, or other) by the collaborator, their spouse or common law partner, and dependent children, which should be added, and the added-value must be used to determine the limits established as follows:

(a) Compensations or fees received from a single source if exceeding Q 40,000.00 per month.

(b) Rights or royalties from intellectual property licenses, regardless of the amount.

(c) Shares of ownership (i.e., shares/options, dividends, capital) valued over Q40,000.00 per month.

(d) Any share of ownership (i.e., shares/options, dividends, capital) in private entities (i.e., newly created companies, regardless of its incorporation type).

(e) Holding a management role (e.g., head, official, trustee, employee of the senior management) in an entity not belonging to the UVG.

It is not required to report travel expenses paid by a third party through a grant, agreement, or memorandum of understanding with the UVG.

Each collaborator who has a <u>significant income requiring disclosure</u> must report its existence and the nature of interest. Investigation and teaching personnel must do so before signing a project with external funding. When awarding a grant or submitting an agreement proposal for sponsored activities, the investigators and faculty are responsible for accurately completing an <u>income statement of an</u> <u>investigation proposal</u>, detailing information about the study and a list of UVG collaborators who will participate in the study. Collaborators will then be asked to complete an <u>income statement of the</u> <u>collaborator in the investigation.</u> When the income statement of the collaborator in the investigation has been submitted, the Committee will review the forms and point out to the institutional official or their designee if there is any significant income that requires disclosure to be managed, reduced, or eliminated.

• Update and change of status report:

Collaborators must update the reports reflecting changes or additions to significant income requiring disclosure. Where collaborators are not aware of the existence of a <u>significant income requiring</u> <u>disclosure</u> at the time of a funding proposal for the investigation, or if the <u>significant income requiring</u> <u>disclosure</u> is received after submitting a proposal, collaborators will report the interest to the Committee within thirty (30) working days after being aware or receiving the income.

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In every year of a grant or agreement, each participating collaborator must update the income statement in the activity. The form should be updated at the time of rendering the annual progress report, twelve (12) months after the awarding notification or the start of the activity, whichever comes first.

F. Conflict of Interest Review Committee

UVG authorities will appoint a Conflict of Interest Review Committee ("Committee") with an odd number of voting members, no less than five or more than nine.

This Committee will review and recommend management, reduction, or elimination plans for significant income requiring disclosure.

The Committee will have the following responsibilities:

- To review any report containing significant income requiring disclosure, either included in the corresponding forms or brought to the attention of the Committee;
- To request and review any additional material necessary to assess the interest relation with the investigation.
- To advise if the disclosure of the significant income requires a plan to manage, reduce, or eliminate the income and develop such plan;
- To communicate the Committee's plan to the collaborator and dean or head of the unit for their approval.

G. Management, reduction, or elimination plans for a significant income requiring disclosure

The Committee will develop management plans, as appropriate, focusing on steps to ensure the objectiveness of the activities. The components of said plan may include among others:

- Public disclosure of the significant income of a collaborator.
- Disclosure of the investigator's income directly to the participants in investigations involving human beings.
- Appointment of an independent reviewer of data, manuscripts, and presentations.
- Appointment of an independent monitor capable of taking measures to protect the design, implementation, and reporting of an investigation against the bias derived from an investigator's income.
- Modification of any activity proposal or plan.
- Personnel turnover or change in personnel responsibilities, or partially or fully restricting a collaborator from taking part in any activity.
- Reduction or elimination of an income by a collaborator, and/or
- Breaking off any relationship that produced the income.

H. Notification of the Committee's decision and recommended approval of the plan

When the Committee notices that a collaborator's significant income requiring disclosure should be managed, reduced, or eliminated, the Committee will inform the dean or head, and unit head about this recommendation and the management plan. The dean or head will notify the Conflict of Interest Review Committee within seven (7) days if there is any objection to the proposed plan. If no objection to the proposed plan is notified

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within the following (7) days of receipt, the Committee's decision and any resulting plan will be final and definitive. The Conflict of Interest Revision Committee will then notify the plan to the collaborator. If the dean or head object, the Committee representatives will discuss the issue with them and will try to develop a plan by mutual agreement. If an agreement cannot be reached regarding the plan within fourteen (14) days after receipt of objection, then the recommendations of all parties will be presented for a final decision from the UVG Ethics Committee. The final decision will be issued within ten days following the receipt of recommendations.

I. Notification and Appeals from the Collaborator

The Conflict of Interest Revision Committee will notify the collaborators when a significant income requiring disclosure should be managed and whenever a conflict of income may arise. The recommended final management, reduction, or elimination plan for the significant income requiring disclosure or the conflict of income will be sent to the collaborator. If the collaborator decides to appeal the plan, an appeal can be filed to the Conflict of Interest Revision Committee within the following 10 days of the notification receipt. If the collaborator does not file a written appeal to the Committee in said time, it will be considered that the collaborator has waived the right of appeal and the decision of the Committee will be final. If the Committee refuses the collaborator's appeal, the collaborator may further appeal to the Ethics Committee, as appropriate. The Ethics Committee will notify the collaborator if the appeal was granted admission or refused within no more than 10 days. During the proceedings of any appeal before the Committee or suitable authority, the collaborator must (a) accept to comply with the initial recommendations of the Committee, or (b) withdraw from the activity, or (c) do not implement the sponsor's funds for the activity under consideration.

J. Investigation with Human Subjects

Special precautions should be taken to prevent biases regarding investigations involving human subjects or the assessment of strategies or products that can affect or be affected by income of the UVG or UVG investigator typically does not take part in any investigation with human subjects that involves the assessment of said strategy or product if they have a significant income that could affect significantly and directly the investigation design, implementation, or reporting, unless the investigator presents a persuasive justification to be exempt from this regulation, based on their unique qualifications as investigator. The Ethics Committee for the Investigation. If compelling circumstances justify being exempt from this regulation, the investigation will be subject to rigorous management measures to ensure the safety of human participants and the integrity of the investigation. The Ethics Committee for the Investigation with and the integrity of the investigation of the investigation with human subjects, which may require further safeguards to protect human participants.

K. Notification of Fund Expenditures

No sponsor funding expenditure will be made for the investigation regarding any project for which the Committee had required a management plan, unless and until all reporting requirements have been met. For any significant income requiring disclosure, identified after the funding for the investigation has been granted, the Conflict of Interest Committee will determine if a management plan is required and whether it involves a financial conflict of interest. Based on the regulations or policies of the sponsor, the designated UVG unit will report any management plan or conflict of income to the funding agency within 60 days following the identification of the interest.

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The result of revisions by the Committee will be notified to the Ethics Committee for the Investigation with Human Subjects for all investigations involving human subjects and to the Institutional Committee for Animal Care and Use (ICACU) for all investigations involving animal subjects. The Ethics Committee for the Investigation with Human Subjects may require additional measures to ensure the safety and well-being of the investigation subjects within its competence.

4. Definitions

The following terms, as used in this regulation, shall have the following meanings:

Compensation will mean anything with monetary value, including, among others, salary, consulting fees, fees or other payments for services of any type, including lecturing, teaching, education, as well as gifts to collaborators.

Conflict of commitment is a situation where an individual is involved in external activities, paid or not, that interfere with their duties and commitment to the UVG.

Conflict of Interest Committee refers to the committee of the institution or person advising the institutional official about affairs of conflict of interest.

Participation in stocks are shares, options of shares, and other participation in ownership.

Family means any member of the immediate family of the collaborator, specifically any relative within the fourth degree of relationship by consanguinity or second degree of relationship by affinity, as contractor, sub-contractor, or independent consultant.

Conflict of Interest. There is an actual, potential, or apparent conflict of interest in all those situations in which indirect (relatives or related persons) and direct personal interests of the worker can interfere, be total or partially competing or incompatible with the interest of the university, as to prevent or hinder or that can prevent or hinder the worker from fulfilling the obligations bound by the employment relationship, by minimizing objectivity, transparency, balance of their actions and decisions.

Conflict of significant income is any income additional to Q40,000 per month generated from a single source or personal activity requiring disclosure and that the UVG considers that affects directly and significantly the design, implementation, or reporting of the investigation.

Income means any earning with monetary value received or kept by a collaborator or collaborator's family that is easy to determine or not, including, among others, a salary or other payments due to services (e.g., consulting fees, fees or payments of authorships of non-academic works); any participation in capital stock (e.g., shares, share options, or any other participation in ownership); rights and interests of intellectual property (e.g., patents, trademarks, service marks, and copyrights), collecting royalties or other income related to said rights and interests of intellectual property.

Income does NOT include:

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a) Salary, royalties, or other compensation from the institution;

b) Income from authorship of academic works;

c) Participation in capital stock or income from investment mechanisms, such as mutual funds and retirement accounts, provided that the collaborator has no direct control over investment decisions in these investment vehicles.

For the investigators, income also includes any reimbursed or sponsored travel made by the investigator and related to their institutional responsibilities. These includes trips paid on behalf of the investigator and reimbursed trips, even if the exact amount is not available.

Member of the immediate family of a faculty member or a staff includes the spouse, dependent children, common law partner or civil union and others, as defined in the UVG recruitment policy.

Institution is any domestic or foreign, public or private entity or organization. *Institutional official* is the person designated by the UVG or its designee(s) to request and review statements of significant income requiring disclosure from collaborators.

Investigator will mean at least the project director, lead investigators, members of the investigation team identified as senior/key personnel in the grant application or agreement, progress report, or any other report. Further, persons identified by the lead investigator or project director who are responsible and have substantial and independent decision making regarding the investigation design, implementation, or reporting, as well as collaborators or consultants appointed in the grant.

Institutional responsibilities of the collaborator are understood as those activities related to the contract roles of investigation, teaching, administration or other profession within the UVG.

Manage means to take measures to address a conflict of income that may include reducing or eliminating the conflict of income to ensure as much as possible a bias-free design, implementation, and reporting of the investigation. It also applies to other types of actual, apparent, or commitment conflict.

External professional activities refer to any paid or voluntary activity carried out by a faculty member or personnel out of the scope or their regular university duties. These activities may include consulting, participating in civic or charitable organizations, working as advisor or professional or technical intern, or holding a part-time job with another employer, either holding an occupation in the same university or other.

Investigation means any systematic experiment, study, or investigation designed to develop or contribute to the availability of knowledge, including the investigation in behavioral and social sciences. The term covers the basic and applied investigation, as well as trial and development of products. The term includes any research activity as a grant, professional development award, unit fellowship, individual scholarship, infrastructure award, institutional capacity building scholarship, program project, or investigation resource award.

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Senor/Key Personnel means the project director or lead investigator (PD/LI) and any other person identified as senior/key by the institution in the grant application, progress report, or any other report.

Significant income means that assets, earnings, or other income kept individually by the collaborator, their spouse and dependent children must be added and the added value must be used to determine the following established limits:

- Remunerations or fees received from entities if are valued over Q40,000.00
- Rights or royalties from intellectual property licenses
- Participation in ownership (i.e., shares/options, dividends, capital stock) valued over Q40,000.00.
- Any participation in ownership (i.e., shares / options, dividends, capital) in private entities (i.e., newly created companies, regardless of its incorporation type).
- Hold any management role (e.g., head, official, trustee, senior management employee) in an entity that does not belong to the UVG.

The following items are NOT considered a significant income:

- Salary or other payments for services of the UVG.
- Gifts to the university, provided that the collaborator does not have the clearance to sign in the UVG account or making decisions related to approvals involving the provider of the gift.

Significant income requiring disclosure refers to the significant income that (a) reasonably would seem to be affected by the activity in which the collaborator works, or (b) remains in an entity of which the income reasonably would seem affected by the collaborator's activity. Any significant income requiring disclosure must be reported to the Committee.

Significant gift means any item, service, favor, money, credit, or discount unavailable to others.

5. Amendment Control

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