

CRG CONFLICT OF INTEREST POLICY

Centre for Genomic Regulation

GOV_COI_2016

Table of Contents

Table of Contents	2
1 Introduction	4
1.1 Background	4
1.2 Purpose.....	4
1.3 Scope and applicability	4
1.4 Definitions	4
2 Guiding principles	6
2.1 CRG members should understand when a Conflict of Interest may arise and avoid them, whenever possible.....	6
2.2 CRG members must disclose and properly address Conflicts of Interest	7
3. Implementation	7
3.1. Compliance	7
3.2. Responsibilities.....	7
3.3. Review of this Policy	8
Appendix A: Approvals and required actions for most frequent Conflicts of Interest	9
Annex 1: Conflict of Interest Disclosure Statement Form	12
Annex 2: Conflict Avoidance Statement	13
Appendix B: Procedures on Financial Conflicts of Interest (FCOI) in U.S. Public Health Service (PHS)	14
1 Guiding principles	14
2 Implementation	15

1 Introduction

1.1 Background

The Centre for Genomic Regulation (referred to as “CRG”) encourages members of its staff to engage in a wide variety of external activities related to the goals and interests of the institute, serving on scientific community boards, providing expert advice, professional practice, conducting outreach activities, international projects and collaborations with for profit companies, including via consultancy, research and development, intellectual property (IP) licensing and involvement in spin-off companies. Such activities are in the public interest and are also of benefit to the CRG and the individuals. On occasion, however, they may give rise to conflicts of interest, whether potential, or actual or perceived. All researchers and other staff are required to recognize and disclose activities that might give rise to conflicts of interest or to ensure that such conflicts are seen to be properly managed or avoided. If properly managed, activities can usually proceed as normal whilst at the same time upholding the person’s obligations to the CRG, meeting regulatory and other external requirements and protecting the integrity and reputation of the CRG and its members. By contrast, conflicts which are not managed effectively may jeopardize CRG’s public trust and may cause serious damage to the reputation of the CRG and of the individuals concerned.

1.2 Purpose

In line with the Conflict of Interest mandates of several major external funders of the institute, the purpose of this Conflict of Interest Policy is to ensure that all activities of the CRG, including but not limited to external activities, shall be conducted in a manner that ensures that the professional and decision making of CRG members is not influenced by undue personal interests, and that the interests of the CRG are not compromised.

This Policy explains the relevant principles and rules for preventing or managing conflicts of interest and how such principles and rules are to be implemented.

Additionally, the Appendix to this Policy covers the procedures on Financial Conflicts of Interest in U.S. Public Health Service (PHS) when applying for, or receiving, research funding from PHS agencies such as the National Institutes of Health (NIH), as well as from other funders that specifically request review consistent with the PHS regulations on objectivity in research, in order to safeguard the integrity of research process and prudent management of public funds.

1.3 Scope and applicability

This Policy applies to all CRG members, including employees, students and collaborators with a collaboration agreement with the CRG (referred to as “CRG members”).

This Policy enters into force as of the date of approval by the CRG Executive Committee and the CRG Board of Trustees.

1.4 Definitions

- **A Conflict of Interest:** A Conflict of Interest may arise when a situation in which there is or may be perceived to be a divergence between the private interest or benefit of a person, family member¹,

¹ Such family members include the spouse or civil partner and the parents, children, siblings, grandparents, grandchildren, aunts and uncles, nieces and nephews, cousins, great grandparents, and great grandchildren of the CRG member and his or her spouse, and the spouses of these relatives, as well adult interdependent partner or another individual to whom a CRG member is related by blood, marriage or adoption.

person with whom the person has a close personal relationship, or an outside party, and that person's obligations to the CRG, such that an impartial observer might reasonably question whether related actions to be taken or decisions made by the person would be influenced by consideration of the person's own interests. A Conflict of Interest is defined broadly: **actual** Conflicts of Interest (the CRG member faces a real, existing conflict); **potential** Conflicts of Interest (the CRG member is in or could be in a situation that may result in a conflict); and **perceived** Conflict of Interest (the CRG member is in or could be in a situation that may appear to be a conflict, even if this is not the case).

1. **Financial Conflict of Interest:** A financial Conflict of Interest is one where there is or appears to be an opportunity for personal financial gain, financial gain to family members or close relationships that might affect that person's actions, including the design, conduct, or reporting of research. Financial interests means anything of monetary value, for example payment for services, equity interests (e.g. stocks, stock options or other ownership interests) and/or intellectual property rights (e.g. patents, copyrights and royalties from such rights). The level of financial interest is not the determining factor as to whether a conflict should be disclosed.

The term financial interest does not include the following types of income:

- a) Salary, royalties, or other remuneration from the CRG,
- b) Income from seminars, conferences, lectures, or teaching engagements sponsored by public or non-profit entities or organizations and
- c) Income from service on advisory committees or review panels for public or non-profit entities or organizations²

Significant Financial Interest (SFI): Concerning the Financial Conflicts of Interest in U.S. Public Health Service (PHS), SFI means anything of monetary value (see Appendix B for further details) received from an entity in the 12 months preceding the Disclosure belonging to the investigator, his or her spouse or domestic partner and dependent children that reasonably appears to be related to the investigator's institutional responsibilities on behalf of the CRG. Institutional responsibilities may include activities such as research, research consultation, teaching and outreach activities, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or data and safety monitoring boards.

2. **Non-financial Conflict of Interest:** Non-financial Conflict of Interest may include a benefit or advantage including, but not limited to direct or indirect enhancement of an individual or gain to family members or a person with whom the person has a close personal relationship.

Examples of financial and non-financial Conflict of Interests, are provided in Section 2.1. Furthermore, Appendix A provides a summary of the most frequent Conflicts of Interest that require special approval and actions required on how to manage them properly.

The **Conflict of Interest Committee** is in charge of investigating, monitoring and providing guidance for the disclosed Conflict of Interests of CRG members. Set-up by the Director or Managing Director whenever required by the procedure established in Section 2.2, the Committee is composed of Director and/or Managing Director, Head of TBDO, Head of HR, as well as two appropriate members with relevant

² Nevertheless, CRG members will not enter into transactions, agreements or collaboration with countries, organizations, companies or individuals that openly do not respect the human rights chart of the United Nations.

expertise in the matter concerned (being one of them external, whenever appropriate) to be appointed adhoc.

2 Guiding principles

2.1 CRG members should understand when a Conflict of Interest may arise and avoid them, whenever possible

A Conflict of Interest situation may arise when personal considerations of a CRG member either influence or have the potential to compromise their professional judgement, decision making and actions at CRG. Members of the CRG, including faculty, researchers and staff acting on its behalf, should avoid or mitigate real or perceived conflicts of interest and ensure that their activities and interests do not conflict with their professional obligations to CRG. Avoiding a Conflict of Interest means that CRG members make decisions or act to ensure a Conflict of Interest does not occur, or does not have the potential to occur in the first place. CRG members should consult their direct supervisors or other superior if in doubt about what circumstances might create a Conflict of Interest.

Common examples of Conflict of Interest situations include:

- a) **Personal workplace relationships** (e.g. hiring or supervising a family member or closely related person)
- b) **Peer review evaluations** (e.g. having a significant collaborative, conflicting or ongoing mentor-mentee relationship with the principal investigator of the proposal)
- c) **External mandates** (e.g. serving as a member of an Advisory Board of a potential licensee, a spin-off, or a company with financial ties to the CRG)
- d) **Outside engagements, including employment** (accepting other employment that will impair his or her independence of judgment in the exercise of his or her duties or responsibilities at the CRG; or accepting other employment or engage in any business or professional activity that will require him or her to disclose confidential information gained by reason of his or her position or authority at the CRG; e.g. having a consulting arrangement with a potential licensee, spin-off or any type of appointment to a for-profit company)
- e) **Promoting personal financial interests** (using confidential information acquired in the course of his or her duties or responsibilities at the CRG to further his or her personal interests; e.g. holding equity interest or enjoying any other compensation arrangement or any type of contractual arrangement in a potential licensee, spin-off or receiving remuneration from such a potential licensee, spin-off or a company with financial ties to the CRG)
- f) **Relationships with external organizations in sales, supply or provision of goods/services** (e.g. staff involved in institute's supply or purchase decisions in relation to any external organizations in which they have a financial interest or in a way that have the capacity for personal gain)
- g) **Receiving fees and acting on behalf of companies** (e.g. accepting company gifts of various kinds, including meals, or acting as promotional speakers or writers on behalf of companies)

For clarification purposes, subject to a case-by-case analysis holding a participation above 10% of a company's share capital would be considered to hold a significant participation in the share capital of any entity (being a licensee or partner company, or any other) with which the CRG has a transaction or arrangement or with which the CRG is negotiating a transaction or arrangement.

2.2 CRG members must disclose and properly address Conflicts of Interest

It is the responsibility of each individual to recognize situations in which he or she has a Conflict of Interest, or might reasonably be seen by others to have a conflict, to disclose that conflict to the appropriate person and to take such further steps as may be appropriate, as set out in more detail under the procedure below. Transparency, in form of disclosure, helps to protect the integrity and reputation of the CRG and the CRG member.

There can be situations in which the appearance of Conflict of Interest is present even when no conflict actually exists. Thus, it is important for all CRG members when evaluating a potential Conflict of Interest to consider how it might be perceived by others. The duty to declare a possible conflict applies to the perception of the situation rather than the actual existence of a conflict. However, the duty is not infringed if the situation cannot reasonably be regarded as likely to give rise to a Conflict of Interest.

Conflicts of Interest are expected to be disclosed following the steps below:

1. Disclosure should be made at the time the conflict first arises, or it is recognized that a conflict might be perceived.
2. The potential Conflict of Interest should be initially discussed with the direct supervisor or the next higher level of hierarchy, if the direct superior has an interest in the matter to be discussed and disclosed in writing using the “Conflict of Interest Disclosure Statement Forms” included in Annex 1.
3. Many situations will require nothing more than a declaration and a brief written record of that declaration. The supervisor is responsible for sending the record to HR, which must be kept in HR’s records.
4. Some instances will however require further approval and need to be dealt with by agreeing how the conflict can be properly addressed. The actions adopted should be documented and copies provided to the relevant parties. A copy of the final plan must be held in the HR’s records. One or more of the following strategies, among others but not limited to, may be appropriate to manage the Conflict of Interest:
 - a) not taking part in discussions of certain matters;
 - b) not taking part in decisions in relation to certain matters;
 - c) referring to others for certain matters for decision;
 - d) resolving not to act as a particular person’s supervisor;
 - e) standing aside from any involvement in a particular project
5. Any unresolved matter shall be referred to the Conflict of Interest Committee following a due process and fair treatment of all parties involved.
6. Guidance on situations that are frequently encountered is set out at Appendix A.
7. For the sake of transparency the CRG legal representatives (Director and Managing Director) shall be required to submit an annual Conflict of Interest Disclosure Statement Form to HR using the template provided in Annex 1.

3. Implementation

3.1. Compliance

All CRG members are responsible for adhering to the principles and rules set out in this Policy. The CRG reserves the right to take appropriate action against any CRG member who does not comply with this Policy, its Appendices and Annexes.

3.2. Responsibilities

All CRG members, and particularly supervisors and members of Human Resources Department (HR) and Technology and Business Development Office (TBDO), are responsible for ensuring that Conflicts of

Interest are identified, disclosed and managed in strict confidence and in a rigorous and transparent way. HR and Selection Panel Chairs are specifically responsible for ensuring that conflicts of interest are disclosed by new hires during the hiring process.

3.3. Review of this Policy

This Policy will be reviewed every two years or whenever there is a change in relevant regulations or good practice.

Violations to the Policy may result in disciplinary sanctions as established by the CRG Internal Staff Regulations, as well as other kind of measures, like the loss and/or withdrawal of grant funding or support, ineligibility to submit grant applications to research sponsors or to participate or to continue participating in research on behalf of the CRG, and/or ineligibility to supervise the work of researchers in research projects, according to the nature and seriousness of Conflict of Interest.

Owner	Managing Director
Code	GOV_COI_2016
Version	V2
Version date	2/1/2017
Related documents	Code of Conduct and Good Governance Conflict of Interest Procedure for NIH grants

Appendix A: Approvals and required actions for most frequent Conflicts of Interest

The general rule is to discuss the case with the direct supervisor or the next higher level of hierarchy, if the direct superior has an interest in the matter to be discussed and disclose the Conflict of Interest in writing using the “Conflict of Interest Disclosure Statement Forms” included in Annex 1.

The most frequent Conflicts of Interest with necessary approvals are outlined below:

Topic	Required approval	Required actions
<p>1. Recruiting and supervision of family members and/or with a close personal relationship CRG members involved in hiring or promoting a family member or a close personal relationship</p> <p>CRG members involved as panel member in a selection, or promotion process of a family member or a close personal relationship.</p>	<p>Head of HR</p> <p>Chair of Selection Panel</p>	<p>For recruiting or promotion procedures without a selection panel, the PI/Head of Unit/Head of Department shall declare the existence of the Conflict of Interest to the HR and Programme Coordinator, Head of Core Facilities or Managing Director, so that a plan can be agreed to manage or avoid the Conflict of Interest.</p> <p>For recruiting or promotion procedures with a selection panel, the PI/Head of Unit/Head of Department shall declare the existence of the Conflict of Interest to the Chair of Selection Panel, so that a plan can be agreed to manage or avoid the Conflict of Interest, which may include withdrawing from the panel.</p> <p>In both cases, one hierarchy level higher will be required if the Programme Coordinator, Head of Core Facilities or Managing Director are involved in the Conflict of Interest.</p>
<p>2. Conflict of Interests in peer review evaluations CRG members involved in peer review evaluations at CRG level have a conflict of interest in the following cases:</p> <ul style="list-style-type: none"> a) Have close family ties or personal relationship with the principal investigator of the proposal b) Were involved in the preparation of the proposal; c) Stand to benefit directly should the proposal be accepted or rejected; d) Have a significant collaborative, conflicting or ongoing mentor-mentee relationship with the principal investigator of the proposal; e) Are in any other situation that would compromise your ability to evaluate the proposal impartially. <p>The same applies to external members involved in peer review processes at CRG.</p>	<p>Chair of Evaluation Panel</p>	<p>When this type of conflict exists, CRG members or external members must inform the Chair of the Evaluation Panel and not influence the peer review evaluation of the proposal concerned. They should then neither assist in the individual assessment (usually remote), nor speak and vote in any Panel discussion related to this proposal. In such a case they have to leave the room when the Panel discusses the individual case of this proposal.</p> <p>External members involved in peer review processes at CRG are asked to complete a conflict of interest and confidentiality agreement.</p>

<p>3. Financial interest in a Company involved in a biomedical or clinical research CRG members who have a financial interest in a company that may reasonably appear to be affected by the results of their biomedical or clinical research.</p>	Head of TBDO Director and Managing Director	CRG members who have a financial interest in a company that may reasonably appear to be affected by the results of a proposed biomedical or clinical research must disclose that interest and put to the direct supervisor and Head of TBDO, Managing Director and Director for review/approval a Conflict of Interest plan/approach designed to protect the integrity of the research and the reputation of the researcher(s), their research group(s) and the CRG.
<p>4. Spin-outs and licensees of Research Institute IP CRG members who has a financial interest or other personal interest in a spin-out or in an organization to which the Research Institute has licensed or is seeking to license Research Institute IP, wishing to:</p> <ul style="list-style-type: none"> a) be involved in the negotiation of any contract between the Research Institute and such spin-outs or IP licensees; or b) undertake a consultancy for that spin-off or organization. 	Head of TBDO and Director	<p>They should normally play no executive role in any decisions made between the CRG and such spin-outs or IP licensees. If it is believed that there are exceptional circumstances to argue for such involvement, prior permission must be sought from the Head of TBDO, Programme Coordinator and then from the Director. The proposed Conflict of Interest plan/approach to be put to the Coordinator and then Head of TBDO and Director must aim to protect the reputation of the academic(s), their research group(s) and the CRG and ensure compliance with company law; and</p> <p>If they wish to undertake a consultancy for that spin-out, they must seek prior permission from the Programme Coordinator, Head of TBDO and Director. The proposed Conflict of Interest plan/approach to be put to the Coordinator and then the Head of TBDO and Director must aim to protect the reputation of the researchers(s), their research group(s) and the CRG and ensure compliance with company law.</p> <p><u>Specific Duties for a Spin-Off:</u> In addition, a CRG member involved in a Spin-Off company will:</p> <ul style="list-style-type: none"> (a) Be able to continue working in the field of Research directly related to the subject matter of the license to that Spin-off company, provided that it is regulated in a specific collaboration or service agreement between the CRG and the Spin-off company The CRG will take into consideration the research and publishing interests of the researcher when drafting such agreements with a Spin-off company. (b) Be required to submit a completed “Conflict Avoidance Statement” to the Head of the TBDO in a form similar to the one presented in annex 2. <p>Through this Conflict Avoidance Statement, the Researcher commits himself or herself to certain actions to minimize and manage any potential Conflict of Interest. In the case of a group leader, the Conflict Avoidance Statement will be signed by the individual and countersigned by his/her Programme Coordinator and the CRG Director.</p>

		When the group leader is also a Program Coordinator, only he/she and the Director will sign. If the Researcher is any other Researcher, he/she, his/her group leader, the Program Coordinator and the Director will sign.
<p>5. Student/postdoc receiving support from a company in which his or her supervisor has a financial interest</p> <p>If a student/postdoc were to receive support from a company in which the proposed academic supervisor has a financial interest, or where the results arising from, or IP generated in the course of, the research project are related to the activities of a company in which the proposed supervisor has a financial interest</p>	Head of TBDO Program Coordinator (or the Director in case the Program Coordinator is involved)	To preserve the integrity of the research the student/postdoc and researcher must disclose the conflict to both the Coordinator and the Head of TBDO for review/approval of a Conflict of Interest plan/approach.
<p>6. Sale, supply or purchase of goods or services</p> <p>CRG members involved in CRG's supply or purchase decisions in relation to any external organization in which they have a financial interest or in any way have the capacity for personal gain</p>	Managing Director	The person shall disclose, in writing to his/her direct supervisor or next level or hierarchy, the nature of the transaction, the potential conflict and the method proposed to manage the conflict. The person and his/her supervisor must formulate a proposed plan/approach that protects the CRG and ensures compliance with the law and the integrity of the transaction(s) and public procurement regulations and the individuals involved; and the supervisor must then seek approval of that plan from the Managing Director.
<p>7. Acceptance of gifts</p> <p>Acceptance of gifts from organizations that provide supplies, goods or services to CRG</p>	Head of Finance	The acceptance of significant material gifts by an employee of the CRG from anyone doing business with, or soliciting business from, the CRG is not permitted. The only exceptions to this are minor gifts and token courtesies that do not place, or do not have the appearance of placing, the recipient under any obligation when making decisions on the CRG's behalf. In no event should an employee accept a gift or hospitality on the understanding that his/her position will be used to influence a decision. Employees shall disclose to their supervisor and Head of Finance the offer or receipt of such gifts.
<p>8. Requirements of funding bodies</p>	Head of Grants Office	Researchers need to be aware of and comply with specific Conflict of Interest requirements from funding agencies. For NIH projects, please refer to the Appendix to the COI Policy - Procedures on Financial Conflicts of Interest (FCOI) in U.S. Public Health Service (PHS). For further guidance please refer to the Head of the Grants Office.

Annex 1: Conflict of Interest Disclosure Statement Form

To whom it may concern:

I, the undersigned [name], ID: [number], [title] at the Center for Genomic Regulation Foundation (CRG), hereby declare the following interests in these companies/organizations to the CRG.

Company/Organization	Organization Information (Address, NIF, etc.)	Kind of participation (Shares, stock options, SAB member, etc.)

I also hereby agree to report any amendments to the information given in the above list (e.g. contribution changes in type or amount) at such time.

In witness thereof, I sign this declaration in Barcelona, [day] the [month], 20xx.

Yours Faithfully,

[Name/Signature]

Annex 2: Conflict Avoidance Statement

“...Because of the license (“the License”) granted by the CRG to [name of Spin-off company] (hereinafter “the Company”) and my involvement in such Company as [Researcher’s link to the Company], I acknowledge the potential for a possible Conflict of Interest between the performance of my research at the CRG and my personal interests and/or contractual or other obligations towards that Company. Therefore, I will not:

1. involve students or post-doctoral fellows at the CRG in research and development projects for the Company without the prior approval of my Program coordinator, the Head of TBDO, the CRG Director and Managing Director, and if required the Graduate Committee;
2. take decisions or carry out actions or omissions that may restrict or delay the access of CRG to information which contains an improvement to the current state of the art, or that may provide a benefit to the Company, apart from those stipulated in the collaboration or similar agreement between CRG and the Company;
3. change, adversely affect, or modify the scope or direction of my research at CRG, or that of other Researchers to the benefit of the Company, apart from those stipulated in the collaboration or similar agreement between CRG and the Company.

In addition, and in order to avoid the appearance of a conflict, I will attempt to, and adopt measures to differentiate clearly between the intellectual directions of my research at CRG, and my contributions to the Company. To that end, I will report annually (i) to my Program coordinator, ii) the Director, (iii) HR, and (iv) the TBDO the general nature of my activities on behalf of the Company and how those differ from my research at CRG.

Finally, I understand that the CRG Policies may require me to disclose my involvement in the Spin-off company, in any publications, or public statement that I make concerning research results related directly or indirectly to the license granted to the Spin-off company.”

Appendix B: Procedures on Financial Conflicts of Interest (FCOI) in U.S. Public Health Service (PHS)

1 Guiding principles

This appendix applies to any CRG Principal Investigator(s), and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the Public Health Service (PHS), or proposed for such funding, which may include but is not limited to any personnel involved in a project proposal, graduate students, collaborators, consultants, visiting researchers (hereinafter referred to as Investigators) or subrecipients.

1.1. What constitutes a Significant Financial Interest (SFI) that has to be disclosed

A Significant Financial Interest (SFI) exists:

(i) With regard to any publicly traded entity

If the aggregate value of one or more of the following exceeds \$5,000:

- Any remuneration received from the publicly traded entity in the twelve (12) months preceding the date of disclosure;
- Any remuneration reasonably anticipated to be received in the twelve (12) months following the date of disclosure;
- Any equity interest in this entity as of the date of disclosure.

For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

Exclusion: *Investigators are not required to disclose income from mutual funds, retirement accounts and other similar investment vehicles, as long as the Investigator does not directly control the investment decisions made for these investment vehicles.*

(ii) With regard to any non-publicly traded entity

- If the value of any remuneration received from the non-publicly traded entity in the twelve (12) months preceding - or reasonably anticipated to be received in the twelve (12) months following - the date of disclosure, when aggregated, exceeds \$5,000;
- When the Investigator (or the Investigator's spouse or dependent children) holds any equity interest (e.g., stock, stock option, or other ownership interest).

Exclusion: *Investigators are not required to disclose (a) payments made by the CRG, including salary, stipends, royalty payments, honoraria, reimbursement of expenses, or any other remuneration from the CRG or (b) income for seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by U.S. federal, state or local government agencies, a U.S. Institution of higher*

education, academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education.

(iii) With regard to any entity

a) Intellectual Property Rights and interests:

If the value of any income related to Intellectual property rights and interests (e.g., patents, copyrights, royalties) received from the entity in the twelve (12) months preceding the date of the Disclosure, when aggregated, exceeds \$5,000.

Exclusion: *Investigators are not required to disclose royalties, including intellectual property rights assigned to the CRG and unlicensed intellectual property rights that does not generate income, as well as agreements with the CRG to share in royalties related to such rights, if the Investigator is currently employed or otherwise appointed by the CRG.*

b) Travel:

Additionally, **Investigators must disclose the occurrence of any reimbursed or sponsored travel**, whether payment is made directly to the Investigator or expenses are paid on behalf of the Investigator, related to their institutional responsibilities, **that is not paid by CRG**. The Disclosure must include, as a minimum, the following details:

(i) purpose of the trip	(iii) destination
(ii) identity of the sponsor/organizer	(iv) duration of the trip

Investigators may be asked to provide further information (e.g., the monetary value, or the inclusion of any immediate Family member), in order to determine whether the travel constitutes a Financial conflict of interest (FCOI) with the Investigator’s PHS-funded research.

Exclusion: *Investigators are not required to disclose travel expenses that are reimbursed or sponsored by U.S. federal, state or local government agencies, a U.S. institution of higher education, academic teaching hospital, medical center, or research institute that is affiliated with a U.S. institution of higher education.*

2 Implementation

2.1 When and how to submit a Disclosure Form (FCOI Form)

CRG Investigators interested in engaging in PHS-funded research are mandated to:

A. Submit a FCOI Form (enclosed as Annex I to this Policy) to the CRG Head of Grants Office, **no later than the time of application for PHS-funding**, which is used to determine if:

- The Investigator (or the Investigator’s spouse or domestic partner and dependent children) has a Significant Financial Interest (SFI) that needs to be disclosed;
- A SFI disclosed by the Investigator appears to relate to the PHS-funded research.

B. Submit an updated FCOI Form to the CRG Head of Grants Office, at least annually during the period of the PHS award, **on or before the due date** of a Progress Report/Non-Competing Continuation Proposal, a

no-cost extension or a supplement request, **and within thirty (30) days of discovering or acquiring any new or increased Significant Financial Interest**. Updated Disclosures should also include any Significant Financial Interests identified on a project that was transferred from another institution.

Principal Investigators (PIs) are responsible to identify any anticipated personnel involved in the design, conduct or reporting of the research and to ensure they complete a Disclosure Form.

2.2 The Review Process of a Disclosure

A. Investigators provide a copy of the FCOI Form to the CRG Head of Grants Office (no later than at the time of application for PHS-funding);

B. The CRG Head of Grants Office reviews the FCOI Form and any disclosed Significant Financial Interests (SFIs) and may request the Investigator to provide additional information, if needed;

C. If appropriate, the Head of Grants Office refers the matter to the CRG Conflict of Interest Committee (COI Committee), who will analyze any disclosed SFI to determine if it is a Financial Conflict of Interest, taking into account factors such as the nature of the Investigator's relationship to an entity, its monetary value, and the overlap between that relationship and the Investigator's research.

D. If the COI Committee determines that a SFI is a Financial Conflict of Interest, a written Management Plan must be developed, consistent with all current legal and regulatory requirements, to reduce, eliminate or manage the effects of the FCOI, until completion of the research. Example of actions imposing conditions or restrictions include but are not limited to:

- (i) Disclosure of the FCOI in publications, journals, poster etc.;
- (ii) Disclosure of the FCOI to audiences at conferences and seminars, to participants in human subjects' research and to ethical committees, to collaborators;
- (iii) Modification of the research plan;
- (iv) change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
- (v) Monitoring of the research by independent researchers able of taking measures to protect its design, conduct, and reporting against bias resulting from the FCOI;
- (vi) Reduction of the value or elimination of the Significant Financial Interest;
- (vii) Modification or severance of relationships creating or likely to create the FCOI.

E. Whenever the CRG identifies a Significant Financial Interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed during an ongoing PHS-funded research project, The COI Committee shall, within sixty (60) days:

- (i) Review the Significant Financial Interest;
- (ii) Determine whether it is related to PHS-funded research;
- (iii) Determine whether a Financial Conflict of Interest exists; and, if so, implement, on at least an interim basis, a written Management Plan that shall specify the actions that have been and will be taken to manage such conflict going forward.

All FCOI reviews, including any required Management Plan, must be completed before any research begins or research expenses are incurred under a PHS-award, and a progress report, a proposal for supplemental funding or a request for no-cost extension is submitted.

In developing the Management Plan, the COI Committee may ask the Investigator to provide additional information, if not previously disclosed, and to meet with them to design appropriate measures to address a specific situation.

No Investigator for which an FCOI has been determined may participate in research activities without written approval from the CRG COI Committee.

2.3. Reporting

A. An initial FCOI report must be submitted to the PHS, prior to the CRG's expenditure of any funds, regarding both the Investigator's SFI Disclosure that has been determined to constitute an FCOI and the implementation of the Management Plan. CRG is not required to submit a report if identifies an FCOI and eliminates it prior to the expenditure of PHS-awarded funds;

B. Additional FCOI reports must be submitted to the PHS:

B.1 Throughout the lifetime of an award when progress reports are submitted, or when an award is extended (e.g. through extension notification or an NIH prior approval request). When during the course of an ongoing PHS-funded research an FCOI ceases to exist, updated information about the status of that FCOI shall be provided with the subsequent progress report;

B.2 Within sixty (60) days of determining that an FCOI exists based on Disclosure of a newly acquired SFI by an Investigator, or because of a not previously disclosed, reviewed or managed SFI, during the course of an ongoing PHS-funded research;

B.3 Within sixty (60) days of determining that an FCOI exists for an Investigator who joins an ongoing NIH research activity;

Within sixty (60) days of determining that an FCOI exists, a Management Plan must be implemented, at least on an interim basis, specifying the actions that have been or will be taken to reduce or eliminate the FCOI.

C. Corrective FCOI reports must be submitted to the PHS:

Within one hundred twenty (120) days of its determination of non-compliance, in addition to the FCOI report, CRG will complete a retrospective review of the Investigator's research to determine whether all or part of the research conducted during the period of non-compliance was biased in the design, conduct or reporting of such research. CRG may, based on the results of the retrospective review, update the previously submitted FCOI report(s), specifying the actions that will be taken to reduce or eliminate the FCOI, and submit a mitigation report.

All FCOI reports shall include sufficient information to enable the awarding PHS agency to understand the nature and extent of the FCOI and to assess the appropriateness of the Management Plan. Elements of the FCOI report shall include, but are not necessarily limited to:

(i) Grant/Project Number; (ii) Name of the Principal Investigator (or Contact PD/PI in case of a multiple PI award); (iii) Name of the Investigator with the conflict; (iv) Which method - management, reduction or elimination - was used to protect PHS-funded research from bias; (v) Name of the Entity with which the Investigator has an FCOI; (vi) Nature of the Financial Interest (e.g. equity, intellectual property, consulting fee, sponsored or reimbursed travels, honoraria); (vii) Value of the Financial Interest, or a statement that a value cannot be readily determined through reference to public prices or reasonable measures of fair market value. (viii) A description of how the FCOI relates to the PHS-funded research and the basis for the CRG's determination that that a SFI conflicts with such research; (ix) A description of the key elements of the Management Plan.

The CRG shall promptly notify the PHS if a FCOI-based bias is determined that affects the PHS-funded research and take corrective actions if an individual fails to comply with this Policy.

2.4. Training

Any Investigator, within two (2) months of joining the CRG, shall complete a Financial Conflict of Interest (FCOI) training to be provided by the CRG and covering:

- The CRG's FCOI Policy;
- The PHS 2011 revised FCOI regulations;
- Their responsibilities regarding disclosure of Significant Financial Interests.

Investigators are also due to complete the FCOI training if:

- (i) Upon implementation of this Policy, an Investigator is already involved in PHS-funded research;
- (ii) Prior to applying for - or engaging in - research related to any PHS-funded research;
- (iii) At least every four years thereafter while receiving PHS funding.

Additionally, each Investigator is due to complete the FCOI training immediately, whenever:

- (iv) The CRG revises its FCOI Policy or procedures in any manner that materially affects the obligations and responsibilities of Investigators;
- (v) The CRG finds that an Investigator is not in compliance with the terms of this Policy.

2.5. Subrecipient's obligation to comply with the CRG FCOI

Subrecipients are non-CRG Investigators who are receiving funding awarded to CRG including but not limited to collaborators, consortium members, consultants, contractors, subcontractors and subawardees. Subrecipients proposed under a PHS-funded research project of the CRG are subject to the CRG's terms and conditions of this Appendix. If the CRG carries out the PHS-funded research through a Subrecipient, the CRG will take reasonable steps to ensure that any Subrecipient complies with the applicable PHS regulations by:

- (i) Incorporating as part of a written agreement with the Subrecipient terms that establish whether the CRG's terms and conditions on FCOI of this Appendix or the ones of the Subrecipient will apply to the Subrecipient;

(ii) Providing Financial Conflict of Interest reports to the PHS regarding all financial conflicts of interest of all Subrecipients, i.e. prior to the expenditure of funds and within sixty (60) days of any subsequently identified Financial Conflict of Interest.

A. If the Subrecipient must comply with the Subrecipient's FCOI policy, the following requirements apply:

A.1 The Subrecipient shall certify as part of the agreement referenced above that its policy complies with the applicable PHS regulations. If the Subrecipient cannot provide such certification, the agreement shall state that Subrecipient is subject to this Appendix for disclosing Significant Financial Interests that are directly related to the Subrecipient's work for the CRG;

A.2 The agreement referenced above shall specify time period(s) for the Subrecipient to report all identified Financial Conflict(s) of Interest to the CRG. Such time period(s) shall be sufficient to enable the CRG to provide timely FCOI reports, as necessary, to the PHS;

B. If Subrecipients must comply with this Appendix, the agreement referenced above shall specify time period(s) for the Subrecipient to submit all Investigator disclosures of significant financial interests to the CRG. Such time period(s) shall be sufficient to enable the CRG to comply timely with its review, management and reporting obligations.

Subrecipients are responsible to identify any anticipated personnel involved in the design, conduct or reporting of the research and to ensure that they disclose their Significant Financial Interest(s).

Agreements with consultants or with a Subrecipient organization who fail to comply with its obligations under the PHS regulations may be terminated for cause.

2.6. Accessibility and record retention

This Policy will be made publicly available on the CRG website.

Information concerning Financial Conflict(s) of Interest currently held by an Investigator will be made available within 5 business days of a written request. The response will note that the information provided is current as of the date of the response and is subject to updates, on at least an annual basis within sixty (60) days of CRG's identification of a new FCOI, and that such updates should be requested subsequently by the requestor.

Additionally, Information concerning Financial Conflict(s) of Interest of an individual shall remain available, for responses to written requests for at least three (3) years from the date that the information was most recently updated. Requests for public accessibility and any enquiry concerning this Policy shall be addressed by email to FCOI@crg.eu.

Unless other applicable laws, requirements or policies require a longer period of retention, records created and maintained under this Appendix, shall be retained by the CRG for a period of no less than three (3) years after the date of submission of the award's final expenditure report, or until the resolution of any related actions initiated by the PHS, whichever is longer. Records relating to unfunded projects need not be retained.