GUIDELINES FOR MAINTAINING RESEARCH AND PEER REVIEW INTEGRITY

The Crohn’s & Colitis Foundation seeks excellence in the discovery and dissemination of knowledge regarding the cause, prevention, detection and diagnosis, treatment, survivorship and health policy of Crohn’s disease and ulcerative colitis, collectively known as inflammatory bowel diseases (IBD). This requires that all individuals affiliated with, or funded by, the Crohn’s & Colitis Foundation adhere to the highest standards of professional integrity. Volunteer grant reviewers for the Crohn’s & Colitis Foundation will also be held to the highest codes of conduct and integrity in performing their essential function of peer review.

The Crohn’s & Colitis Foundation provides grant funds for individuals at academic and other not-for-profit institutions to promote IBD-related training, research and treatment. This represents a contractual relationship with such institutions, and it is an accepted responsibility and obligation of those institutions to provide policies and procedures for their faculty, staff and students that address possible misconduct in training, research and treatment of patients. Moreover, it is the responsibility and obligation of faculty, students and staff engaged in scientific research and training to be aware of policies and procedures for addressing possible misconduct at their institutions, and to follow those procedures in reporting possible misconduct.

While questions of the integrity of applicants, grantees, and reviewers are very infrequent, they do occur. It is the responsibility of the Program Directors managing the review process and portfolios of funded grants and the responsibility of the Chief Scientific Officer to ensure that all questions regarding research integrity are handled in a discrete, but thorough manner. Management of allegations of research misconduct is not the responsibility of the chairs and co-chairs of the review committees. The actions of the Program Directors and the Chief Scientific Officer must ensure the confidentiality and anonymity of the individual raising the question of misconduct; ensure the integrity of the Crohn’s & Colitis Foundation and its review processes; ensure the rights of the individual accused of misconduct; and ensure their own credibility and integrity.

Article I

Standards and Definitions:

1.1 Research Misconduct by Applicants or Grantees

The Crohn’s & Colitis Foundation uses the following definitions related to scientific misconduct outlined in the Federal Guidelines [Federal Register, Vol. 65, No. 235, ppg. 76260-76264].

- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.¹
- Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, biology,
chemistry, psychology, natural sciences, social sciences, statistics, and research involving human subjects or animals.¹

- Fabrication is defined as making up data or results and recording or reporting them.¹
- Falsification is defined as manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.¹
- The research record is defined as the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.¹
- Plagiarism is defined as the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- Research misconduct does not include honest error or differences of opinion.¹
- Reported Qualifications must be accurate (e.g. years since degree earned).

1.2 Research Misconduct by Peer Review Committee Members

The Crohn's & Colitis Foundation has adopted the following definitions of misconduct in review by members of a Peer Review Committee. Misconduct in review is defined as:

- Review for an application for which there is a clear conflict of interest between the reviewer and applicant as defined in §1.4.
- Failure to notify Crohn’s & Colitis Foundation personnel of actual, potential, perceived or potentially perceived conflicts of interest.
- Any communication pertaining to review related materials between a member[s] of a peer review committee and an applicant, mentor of an applicant, or a colleague of the applicant without approval by the Program Director for such communication.
- Any communication of the unpublished content of a grant application by a member or members of a peer review committee with any individual who is not a permanent or ad hoc member of the peer review committee to which an application is assigned, or who has not been approved by the Research Director for such communication.
- Any use of the unpublished content or concepts of a grant application in pursuit of scientific or career goals by a member of a peer review committee.
- Any review of, or use of, the contents of a grant application by a member or members of a peer review committee who might have, or be perceived to have, a conflict of interest with the applicant or his/her mentor, in the case of applications with an element of training as part of the application.

1.3 Confidentiality Standard for Reviewers

¹ The above definitions are outlined in the Federal Guidelines [Federal Register, Vol.65, No.235, ppg: 76260-76264]
To preserve the integrity of the peer review process, all parties involved in the review process must adhere to the following practices regarding confidentiality and non-disclosure:

- Reviewers must not discuss applications reviewed with any individual not designated as a part of the review process; and especially not with applicants, or their mentors in the case of training grants, either before or after the peer review meetings.
- Any inquiries regarding an application from an applicant, PI, Co-PIs, collaborators, or an applicant’s mentor(s), to a member of a Peer Review Committee must be reported immediately to the Program Director.
- Reviewers must manage and maintain all review material, audio and video portions of review meetings in a confidential environment when participating from any location.
- All materials related to the review process must be appropriately destroyed – paper copies shredded, electronic copies deleted and storage devices cleared at the end of the review process. For purposes of meeting this standard, materials related to the review process include, but are not limited to: paper, bound volumes, compact disks (CDs), flashdrives, electronic files accessed via the internet, or oral presentations, audio or video discussions, and audio or video recordings of the meeting.

1.4 Conflict of Interest Standard for Reviewers

To preserve the integrity of the peer review process, all participants in the process must adhere to these principles and practices:

- Reviewers must not be an employer or employee of an applicant, and may not be employed by the same institution as an applicant within three years of the date of submission of an application.
- Reviewers must not be a party to any agreement for future employment or other agreements or arrangements with an applicant or any person listed as key personnel on an application.
- Reviewers must not have served as mentors or collaborators of an applicant within 3 years of the date of an application. (Note: Crohn’s & Colitis Foundation follows the NIH guidelines on defining collaborator relationships: http://grants.nih.gov/grants/peer/COI_Information.pdf)
- Reviewers must not participate in the review of an application submitted by a standing member of a Peer Review Committee serving on the same review committee. Reviewers must not be under the health care of, or providing health care to, an applicant or any person listed as key personnel on an application.
- Reviewers must not have received or have the potential to receive direct financial benefit from the application.
- Reviewers must not be pursuing research projects which might be viewed as being in direct competition with applicants or their collaborators and colleagues; nor have potential to receive direct benefit from failure of the application to be funded.
• Reviewers must not have any cause of action against, any dispute with, any long-standing scientific or personal differences with, or any claim whatsoever against the applicant or any person listed as Principal Investigator or key personnel on an application.

Articles II

Policies:

2.1 Policy Governing Misconduct by Applicants and Grantees

2.1.1 Applicants:

Any allegations of scientific misconduct must be brought to the immediate attention of the Program Director in charge of the Peer Review Committee which is responsible for reviewing the work in question. If possible, allegations of misconduct on the part of an applicant in the submission of a grant proposal should be raised in advance of the review meeting. The Program Director will then bring the allegation to the attention of the Chief Scientific Officer at Crohn’s & Colitis Foundation. The Chief Scientific Officer will evaluate the allegation and make a determination on the misconduct issue and the appropriate next steps to be taken to engage in further investigation or action in accordance with Article III “Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct in Research and Peer Review”.

2.1.2 Grantees:

In instances where alleged scientific misconduct occurs after the awarding of a grant, such as in the publication of falsified data, the Program Director will bring the allegation to the attention of the Chief Scientific Officer at Crohn’s & Colitis Foundation. The Chief Scientific Officer will evaluate the allegation and make a determination of the appropriate steps to be taken to engage in further investigation or action as defined in Article III, “Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct in Research and Peer Review”.

2.2 Policy Governing Misconduct by Peer Review Committee Members

2.2.1 Confidentiality:

Confidentiality is at the heart of the peer review process and is imperative for objective evaluation and free expression in the review process. The applicant-reviewer relationship is a privileged alliance founded on the ethical rule of confidentiality. To maintain the essence and integrity of the peer review process, the Crohn’s & Colitis Foundation and its appointed peer reviewers must ensure and be assured that the confidentiality of the applicant’s information, the contents of the grant application, and of the proceedings of the review panel will be maintained. Such confidentiality is maintained when an applicant discloses information to a reviewer or member of the Review Committee with the understanding that the information will not be divulged to others without the discloser’s consent, or as otherwise required by law. In the context of peer review, this rule upholds the applicants’ rights to have the information they submit,
whether in proposal form or in communications, kept confidential. The rule also ensures that those involved in the review process maintain their obligation to keep confidential any information concerning an application. In fact, the very existence of a submission should not be revealed (or confirmed) to anyone other than those within the review process unless and until the application is funded.

To this end, all contents, evaluation and discussion of applications shall be confined to Peer Review Committee (PRC) members and Crohn’s & Colitis Foundation staff personnel (Program Directors, Chief Scientific Officer, Grants Managers, support staff) responsible for managing the review process of that PRC. For these purposes, reviewers include all standing and ad hoc reviewers of PRCs and members of the Grants Council of Crohn’s & Colitis Foundation’s National Scientific Advisory Committee. In rare and specific instances, discussion of applications with, or in the presence of, non-committee members can occur after obtaining the written consent of the Program Director. Reviewers must not discuss reviews with applicants, their mentors in the case of training grants, or collaborators either before or after the review meetings. Reviewers also must not communicate the contents of any grant applications with individuals not associated with the review process. Any materials related to the review process must be disposed of immediately after the meeting, and all final critiques given to the Program Director for inclusion in summary statements.

The Volunteer Confidentiality form shall be signed electronically on proposal Central prior to release of any application information in the review cycle. A Volunteer Confidentiality form and a Disclosure statement containing an original signature must be submitted annually for review as requested by Crohn’s & Colitis Foundation staff.

If an allegation of a breach of reviewer confidentiality is brought forward, that allegation will be communicated to Crohn’s & Colitis Foundation’s Chief Scientific Officer who will determine if an investigation of that allegation is warranted. The Chief Scientific Officer will then follow the appropriate steps as defined in Article III, “Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct in Research and Peer Review”.

2.2.2 Conflict of Interest:

An objective evaluation of grant proposals is essential to the peer review process. In achieving this goal, there must be no conflict of interest, apparent conflict of interest or pending future conflict of interest between any participant in the review process and the applicants or their collaborators and colleagues. In this setting, reviewers include standing and ad hoc Peer Review Committee (PRC) members and members of the Crohn’s & Colitis Foundation Grants Council responsible for, and participating in, the review process. There are numerous bases for conflicts of interest, and these can include: employment, professional relationships, personal relationships, financial benefit, industry affiliation or other interests. The conflicts can be real or apparent. For Definitions of Conflict of Interest, refer to Section 1.4.

Reviewers may not make use of any of the contents of a grant for their own research purposes or those of their collaborators and colleagues. Reviewers must exercise proper due diligence in investigating and disclosing any potential conflict of interest that might exist.
between themselves and an applicant or the applicant’s collaborators or mentors. If an allegation of a reviewer conflict of interest is brought forward, that allegation will be communicated to the Chief Medical Officer who will determine if an investigation of that allegation is warranted. The Chief Scientific Officer will then follow the appropriate steps as defined in Article III “Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct”.

**Article III**

**Procedures for Handling Conflicts of Interest and Allegations or Findings of Misconduct:**

To ensure the integrity of the peer review process and the integrity of Crohn’s & Colitis Foundation-sponsored research, it is necessary that the procedures for dealing with allegations of misconduct be clearly understood by all reviewers and Crohn’s & Colitis Foundation personnel. Procedures for handling allegations of misconduct by applicants, grantees and reviewers are detailed in the following sections.

3.1 Procedures for Handling an Allegation of Scientific Misconduct by Applicants or Grantees

3.1.1 Misconduct by Applicants:

In the event that an allegation of scientific misconduct by an applicant is brought forward to a Program Director or other Crohn’s & Colitis Foundation staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the individual making the allegation, the anonymity of the person against whom the allegation is made, and the integrity of the review process. The Program Director must immediately inform the Chief Scientific Officer of the allegation, and provide all relevant information regarding the allegation. It is the Chief Scientific Officer’s responsibility to evaluate the likelihood of scientific misconduct; and, if warranted, it is the Chief Scientific Officer’s responsibility to contact the appropriate institutional office at the applicant’s institution regarding the allegation. The Chief Scientific Officer will then serve as the point of contact between the Crohn’s & Colitis Foundation and the institutional official[s] handling issues of scientific misconduct.

If determined to be appropriate, the Chief Scientific Officer will forward an allegation of misconduct and all pertinent information to the Research Integrity Officer at the institution sponsoring the grant application in question or at which the alleged misconduct was carried out. If there is not a Research Integrity Officer, the Dean of the School in question or its chief academic officer will be contacted. In the instance that the person[s] making the allegation does not contact the Crohn’s & Colitis Foundation but raises the allegation of misconduct with the appropriate institutional official according to their established institutional procedures, it is the responsibility of the institution to contact the Crohn’s & Colitis Foundation regarding the allegation, any investigation of the allegation, and the outcome of that investigation. All such correspondence will be held in strict confidence, and will not be made public by the Crohn’s & Colitis Foundation irrespective of the outcome of the investigation. The Crohn’s & Colitis Foundation assumes no responsibility in carrying out the investigation of scientific misconduct, or in determining an individual’s innocence or guilt of the allegation of misconduct. However,
acceptance or non-acceptance of the findings of the institutional investigation is at the discretion of the Chief Scientific Officer, and additional clarification may be requested.

Allegations of scientific misconduct in a grant application may be made by individuals who are colleagues, trainees, or reviewers. In the instance that an allegation of misconduct is made in reference to a grant application, the Chief Scientific Officer will contact the institutional official at the sponsoring research institution and seek to follow their established protocol for investigating such allegations. If an investigation is deemed necessary, it will be the responsibility of the sponsoring institution to carry out the investigation, to keep the Crohn’s & Colitis Foundation aware of the progress, and to report the outcome of the investigation to the Chief Scientific Officer.

In fairness to the applicant, the review process must continue while the allegation of misconduct undergoes assessment. Review may continue in the standing review committee mechanism. Under no circumstance should a reviewer, Program Director or Crohn’s & Colitis Foundation staff raise the issue of the allegation in a peer review meeting or meeting of Crohn’s & Colitis Foundation Grants Council. If that were to occur, review of that application could not be completed without bias; and review of the application must therefore be deferred to ad hoc reviewers or the Crohn’s & Colitis Foundation Grants Council. If a reviewer suspects misconduct, which is discovered at the time of the meeting, it is appropriate to request the Chair of the PRC or Council to take a "break" and discuss the issue privately with the Program Director. The Program Director will then take the proscribed administrative steps following the adjournment of the review meeting.

The Crohn’s & Colitis Foundation will complete the process of peer review of the application, but will suspend any administrative action which would result in funding of the award in question until the resolution of the investigation. At the conclusion of the investigation, the Crohn’s & Colitis Foundation will require the Office of Research Integrity or comparable entity at the applicant’s sponsoring institution to provide a written statement detailing the results of the investigation. Failure of the institution to carry out such an investigation in a timely manner or to provide written results of the investigation will result in the administrative disapproval of the application. If the applicant is absolved of any scientific misconduct, the Crohn’s & Colitis Foundation will reinstitute administrative action that can result in funding for the award if it was approved and is within the pay-line established by Crohn’s & Colitis Foundation. In the instance that misconduct has occurred, the Crohn’s & Colitis Foundation will administratively inactivate the application. Also, in the case of a finding of scientific misconduct, the investigator may no longer be eligible to participate in Crohn’s & Colitis Foundation funded awards, either as principal investigator, co-investigator, collaborator, mentor or consultant. The investigator also may not be eligible to serve in any capacity in reviewing Crohn’s & Colitis Foundation grant proposals.

3.1.2 Misconduct by Grantees:

In the event that an allegation of scientific misconduct by a grantee is brought forward to a Program Director or other Crohn’s & Colitis Foundation staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the individual
making the allegation and the anonymity of the person against whom the allegation is made. The Program Director or Crohn’s & Colitis Foundation staff contacted about the alleged misconduct must immediately inform the Chief Scientific Officer of the allegation, and provide all relevant information regarding the allegation. It is the Chief Scientific Officer’s responsibility to evaluate the likelihood of scientific misconduct; and, if warranted, it is the Chief Scientific Officer’s responsibility to contact the appropriate institutional office at the applicant’s institution regarding the allegation. The Chief Scientific Officer will then serve as the point of contact between the Crohn’s & Colitis Foundation and the institutional official[s] handling issues of scientific misconduct.

If determined to be appropriate, the Chief Scientific Officer will forward an allegation of misconduct and all pertinent information to the Research Integrity Officer at the institution sponsoring the grant in question or at which the alleged misconduct was carried out. If there is not a Research Integrity Officer, the Dean of the School in question or its chief academic officer will be contacted. In the instance that the person[s] making the allegation does not contact the Crohn’s & Colitis Foundation but raises the allegation does not contact the Crohn’s & Colitis Foundation but raises the allegation of misconduct with the appropriate institutional official according to their established institutional procedures, it is the responsibility of the institution to contact the Crohn’s & Colitis Foundation regarding the allegation, any investigation of the allegation, and the outcome of that investigation. All such correspondence will be held in strict confidence, and will not be made public by the Crohn’s & Colitis Foundation irrespective of the outcome of the investigation. The Crohn’s & Colitis Foundation assumes no responsibility in carrying out the investigation of scientific misconduct, or in determining an individual’s innocence or guilt of the allegation of misconduct. However, failure of the institution to immediately notify the Crohn’s & Colitis Foundation of an allegation and/or investigation of misconduct, or to carry out a misconduct investigation in a timely manner, or to provide written results of the investigation, is in non-conformance with the terms and obligations of the grant and may result in the suspension of Crohn’s & Colitis Foundation funds for all grants awarded at the institution, to be decided by Crohn’s & Colitis Foundation in its sole discretion. However, acceptance or non-acceptance of the findings of the institutional investigation is at the discretion of Crohn’s & Colitis Foundation’s Chief Scientific Officer, and additional clarification may be requested.

If the investigator has an active Crohn’s & Colitis Foundation award, funding of that award will be suspended until the allegation has either been confirmed or been proven to be erroneous. If the allegation is proven not to have merit, the award may be reinstated by Crohn’s & Colitis Foundation at the date of notification of those findings by the sponsoring institution. If the allegation of misconduct is confirmed, the award will be terminated and any residual funds, as of the date of notification of the sponsoring institution of the allegation, must be returned to the Crohn’s & Colitis Foundation. In the case of a finding of scientific misconduct, the investigator may no longer be eligible to participate in Crohn’s & Colitis Foundation funded awards, either as principal investigator, co-investigator, collaborator, mentor, or consultant. The investigator may also not be eligible to serve in any capacity in reviewing Crohn’s & Colitis Foundation grant proposals.

The publication of data supported by Crohn’s & Colitis Foundation funds serves to further the interests of the scientific pursuit, and specifically in the case of the Crohn’s & Colitis
Foundation, the pursuit of eliminating the burden of inflammatory bowel diseases. Therefore, it is incumbent on both the Crohn’s & Colitis Foundation and the scientific community to insure that any instances of misrepresentation of findings in a scientific study are apparent to the scientific community. To that end, a finding of falsification or misrepresentation of data in a published forum must be reported to the editor-in-chief of the journal in which such data is reported. It is the responsibility of the Chief Scientific Officer to coordinate such notification with the appropriate sponsoring institutional official according to their established policies and in conjunction with the policies of the journal. If the sponsoring institution does not have a policy regarding notification of the journal, then the Chief Scientific Officer will notify the editor-in-chief of the journal according to the journal’s established policies.

In the case of findings of falsification or misrepresentation of published data supported by Crohn’s & Colitis Foundation funds, any active grant[s] held by the responsible individual will be terminated and that individual may no longer be eligible for Crohn’s & Colitis Foundation funding via any mechanism as a principal investigator, co-investigator, collaborator, mentor, or consultant. That individual may also not be eligible to participate in Crohn’s & Colitis Foundation review in any capacity.

3.1.3 Reviewer Misconduct and Conflict of Interest

In the event that an allegation of reviewer misconduct, such as failure to acknowledge a conflict of interest, is brought forward to a Program Director or other Crohn’s & Colitis Foundation staff, all effort must be made to investigate the validity of the allegation while maintaining the confidentiality of the individual making the allegation, the anonymity of the person against whom the allegation is made, and the integrity of the review process. The Program Director or other Crohn’s & Colitis Foundation staff contacted regarding the alleged misconduct must immediately inform the Chief Scientific Officer of the allegation, and provide all relevant information regarding the allegation. It is the Chief Scientific Officer’s responsibility to evaluate the likelihood of reviewer conflict of interest or misconduct; and, if warranted, it is the Chief Scientific Officer’s responsibility to handle the investigation internally or to inform the appropriate institutional office at the reviewer’s institution about the allegation if aspects of the reviewer misconduct violate any of the tenets of professional behavior established by that institution. The Chief Scientific Officer will then serve as the point of contact between the Crohn’s & Colitis Foundation and the institutional official handling issues of reviewer misconduct.

Some elements of reviewer misconduct represent conduct that will only have relevance for the appropriateness of the reviewer’s role as a member of a peer review committee. Possible examples include inappropriate communication between reviewer and applicant or an applicant’s mentor or colleagues. In a case of this type, all elements of the investigation of the reviewer misconduct will be handled by Crohn’s & Colitis Foundation personnel at the discretion of the Chief Scientific Officer. In cases where a reviewer does not retain the confidentiality of the applicant’s information or the content of his or her application, and makes that information available to a third party, it will be at the discretion of the Chief Scientific Officer to handle the issue internally at Crohn’s & Colitis Foundation or contact the Office of Research Integrity at the reviewer’s institution, based upon an initial assessment of whether such conduct violates the
rules of conduct established by that institution. Possible examples include communication of the contents of a grant proposal by a reviewer to a competitor in the same field as the applicant, or if the reviewer makes use of findings or ideas in an application to further his or her own research interests. In the instance of such an allegation, the Crohn’s & Colitis Foundation assumes no responsibility for carrying out the investigation of scientific misconduct, or in determining an individual’s innocence or guilt of the allegation of misconduct. It is the institution’s responsibility to handle the misconduct according to their established procedures. However, acceptance or non-acceptance of the findings of the institutional investigation is at the discretion of the Chief Scientific Officer, and additional clarification may be requested. In any instance of a finding of reviewer misconduct, that individual may no longer be eligible to serve in any capacity in reviewing Crohn’s & Colitis Foundation grant proposals, and may be barred from receiving any Crohn’s & Colitis Foundation grant funds.

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