

# **IAC Policy and Procedures Regarding Allegations of Non-Compliance with Human Subjects Regulations**

*Amended and Ratified January 2008*

## **I. INTRODUCTION AND POLICY**

These policies and procedures (hereafter referred to as “policy”) cover all human research conducted by any student, employee, or faculty member of Case Western Reserve University (Case), University Hospitals Case Medical Center (UHCMC) and The MetroHealth System (MHS) as part of his or her job responsibilities with that organization, or any human research conducted by an independent contractor of these organizations as part of the organization’s contract. In addition, for any human research in which Case acts as the grantee, employees of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) and the Cleveland Clinic Foundation (CCF) are also responsible for complying with this policy. The purpose of this policy is to explain to the IRBs, faculty, staff, and students of the institutions how allegations of human subject non-compliance will be reviewed what administrative bodies will perform such reviews, and justification for such authority.

Per the regulations (45 CFR§46.113 and 50 CFR§56.113), IRBs have the authority to review allegations of human subject non-compliance for their particular institution. An IRB may receive allegations in several different ways including, quality assurance auditing reports, subject complaints, internal allegations, or investigator self-reporting.

The process by which an IRB reviews allegations should be determined by the seriousness of the allegations and the probability or occurrence of subject harm. It is important to note that harm to subjects is not limited to physical harm, but also includes social/psychological harms such as breach of confidentiality. Each IRB must develop and utilize appropriate non-compliance policies that at minimum include the following:

- Definitions of non-compliance, serious non-compliance and continuing non-compliance;
- Requirement that determinations of serious non-compliance and/or continuing non-compliance must be made by the full IRB;
- Requirement that the results of any non-compliance review that did not warrant full IRB review must be reported to the full IRB and documented in the minutes; and
- Requirement that in addition to reporting serious non-compliance and/or continuing non-compliance to institutional and grantee officials of the IRB institution, the Case Compliance Officer must be notified when serious non-compliance and/or continuing non-compliance allegations are related to a project whose grantee institution is different from the IRB institution, as the grantee institution is responsible for fulfilling reporting requirements. In situations where the grantee institution is not Case, the Research Compliance Officer will be responsible for forwarding the matter appropriately.

## II. APPLICATION OF IAC PROCEDURES

Allegations of serious non-compliance and/or continuing non-compliance involving research where permanent disability or death have occurred, and in which Case is the grantee, must be administered by the following procedures. However, allegations of serious non-compliance and/or continuing non-compliance involving research, where permanent disability or death have occurred, that are performed by a Case faculty member in which Case is not the grantee, will be administered by the appropriate grantee institution's IRB(s), with consultation from Case officials.

An IRB or grantee may empower the IAC to act on its behalf and may request that allegations involving possible non-compliance be reviewed under this policy. The Case Compliance Officer will review such requests and determine whether such review would be appropriate and in compliance with other applicable policies. In instances where more than one IRB under the IAC is involved with an allegation, every attempt will be made by the involved institutions to integrate the investigations through this policy.

## III. DEFINITIONS

**Compliance Officer** shall mean the official within the Case Office of Research Compliance who has the responsibility of directing the process through disposition of the case.

**IRB Advisory Committee (IAC)** shall mean the committee consisting of members from Case, University Hospitals Case Medical Center, The MetroHealth System, Louis Stokes Cleveland Department of Veterans Affairs Medical Center and the Cleveland Clinic.

**IAC Chair** shall mean the Case HRPP Organizational Official who is the Associate Vice President for Research (AVP) at Case or an appointed alternate. He/she is responsible for weighing the recommendations received from the investigation committee, but retains final decision making authority.

**Non-Compliance** shall mean a failure to comply with federal regulations, local applicable policies and procedures, and standards of conduct that govern human subjects research, and/or failure to follow the determinations of the IRB.

**Institution** shall mean the five institutions as defined above.

**Investigation Committee** shall mean an ad hoc committee of at least three IAC members appointed by the Compliance Officer to investigate the allegation of non-compliance. The Investigation Committee will issue a report to the IAC Chair.

**Serious Non-compliance** shall mean non-compliance that in the judgment of the Investigation Committee or IAC Chair, potentially or actually increases risks to subjects, decreases potential benefits, compromises the integrity of the human research protection program or substantially deviates from accepted practices within the human research community.

**Continuing Non-Compliance** shall mean a pattern of non-compliance that in the judgment of the Investigation committee or IAC Chair, suggests a likelihood that without intervention instances of non-compliance would continue. Continuing non-compliance also includes failure to respond to a request to resolve an IRB/IAC finding of noncompliance.

**IRB** shall mean one or more of the institutional review boards listed under the Case Western Reserve University Federalwide Assurance.

**IAO** shall mean one or more of the IRB Administrative Offices.

**Suspension** shall mean that all research (except in cases where delays may pose possible harm to subjects) is temporarily stopped due to (1) continued investigator non-compliance and/or serious problems from investigator failure to follow appropriate procedures and/or regulations, or (2) unanticipated problems involving risks to subjects or others.

**Termination** shall mean that all research (except in cases where delays may pose possible harm to subjects) is permanently stopped due to (1) continued investigator non-compliance and/or serious problems from investigator failure to follow appropriate procedures and/or regulations, or (2) unanticipated problems involving risks to subjects or others.

#### **IV. RIGHTS AND RESPONSIBILITIES**

##### **A. Compliance Officer**

A Case Official in the Office of Research Compliance will serve as the Compliance Officer and will have primary responsibility for implementation of the procedures set forth in this document. The Compliance Officer will be well qualified to handle the procedural requirements involved and be sensitive to the varied demands made on those who conduct research, those who are accused of serious non-compliance and/or continuing non-compliance, and those who make allegations of non-compliance.

The Compliance Officer will appoint the investigation committee and ensure that necessary and appropriate expertise is secured to assess the allegation and to carry out a thorough and authoritative evaluation of the relevant evidence. The Compliance Officer will attempt to ensure that confidentiality of the process is maintained.

The Compliance Officer will assist investigation committees and all personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Compliance Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Compliance Officer will be responsible for reporting to appropriate Institutional and federal government officials as required by federal regulations.

**B. Complainant**

Per this policy, the complainant is defined as the individual or group of individuals that submitted the allegation. The complainant will ordinarily have an opportunity to be interviewed by the investigation committee, to review portions of the investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation.

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an investigation. An IRB may act in the role of a complainant in forwarding an allegation of non-compliance to the Compliance Officer through the IAO Head or IRB Chair.

The complainant is responsible for maintaining confidentiality and cooperating with the conduct of an investigation.

**C. Respondent**

Per this policy, the respondent is defined as the individual (or group of individuals) against whom the allegation has been made. The respondent will be informed of the allegations when an investigation is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the investigation committee, to review the draft investigation report, and to bring an advisor of choice to the investigation meetings in which the respondent is interviewed. Advisors, however, may only consult with the respondent. They may not address the committee, ask questions of the committee, or participate in the interviews.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an investigation.

**D. IAC Chair**

The Associate Vice President for Research (or his/her designee), as the IAC Chair, will receive the investigation report and any written comments made by the respondent or the complainant concerning the draft report. The IAC Chair will consult with the Compliance Officer or other appropriate officials and will make the final determination of whether non-compliance occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

#### **E. Cooperation with Investigations**

Institutional employees and those working on human subject research protocols will cooperate with the Compliance Officer, the IAC and other Institutional officials in the review of allegations and the conduct of investigations. Employees have an obligation to provide relevant evidence to the Compliance Officer or other officials on non-compliance allegations.

### **V. SUBMISSION OF AN ALLEGATION**

There are two ways allegations of non-compliance may be submitted:

1. Any individual or organization may submit a written complaint or allegation of non-compliance to the IRB or Compliance Officer.
2. The IRB itself may initiate a complaint to the Compliance Officer based on information available to the IRB (e.g., deficiencies noted in IRB files, or in media or scholarly reports of research activity subject to IRB jurisdiction). Individual IRBs may refer an investigation of the matter to the IAC.

### **VI. SUSPENSION AND REPORTING**

At any time during the investigation process, the IAC Chair may determine that it is necessary to suspend accrual of research subjects or suspend approval of research project(s) to assure the protection of human subjects if an IRB has not already done so. The investigation committee may recommend suspension to the IAC Chair. The IAC Chair cannot lift a suspension imposed by the IRB.

When the IAC Chair makes a decision to suspend approval of research, he/she will notify appropriate Institutional officials. These may include the respondent's department head, the senior administrative officers, and officials of the affiliated hospitals if patients are involved. The Compliance Officer, who serves as the authorized institutional official, will send a written notice to the following entities, as required under federal regulations: 1) the Federal Office of Human Research Protections (OHRP); 2) the Federal Food and Drug Administration (FDA) if the suspension of research approval involves an investigation drug or device; and 3) external and/or internal sponsors funding a study under suspension. Reports will be filed within ten working days of suspension. In some cases reporting to professional licensing boards or state agencies also may be required.

## **VII. CONDUCTING THE INVESTIGATION**

### **A. Preliminary Assessment and Purpose of the Investigation**

Upon receipt of an allegation, the Compliance Officer will assess whether the allegation is governed by this policy and provides sufficient evidence of possible non-compliance. If so, he or she will initiate the investigation process. In initiating the investigation, the Compliance Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether serious non-compliance and/or continuing non-compliance has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible non-compliance that would justify broadening the scope of the investigation beyond the initial allegations.

### **B. Sequestration of the Research Records**

The Compliance Officer and IRB (where applicable) must ensure that all original research records and materials relevant to the allegation are secured.

### **C. Appointment of the Investigation Committee**

The Compliance Officer, in consultation with other Institutional Officials and the IRBs as appropriate, will appoint an investigation committee and committee chair. The investigation committee should consist of at least three (3) IAC members who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise in human subject regulations to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the investigation. In cases where the IAC investigation is an extension of an IRB review of the same matter, the investigation committee, as appropriate, shall have representation from that referring IRB. The Compliance Officer or the investigation committee may ask that one or more qualified persons from inside or outside the Institution sit on the committee to serve as expert consultants if the scientific subject matter of the research is in question. Expert consultants will not have voting rights.

The Compliance Officer will notify the respondent of the proposed committee membership. If the respondent submits a written objection to any appointed member of the investigation committee or expert based on bias or conflict of interest within five (5) business days of receiving notice of the proposed membership, the Compliance Officer will determine whether to replace the challenged member or expert with a qualified substitute.

### **D. Charge to the Committee and the First Meeting**

Charge to the Committee

The Compliance Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the preliminary assessment, define serious non-compliance and continuing non-compliance, and will identify the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether non-compliance has occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Compliance Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Compliance Officer, in conjunction with the University Attorney's office when appropriate, will convene the first meeting of the investigation committee to review the charge, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this policy.

**E. Investigation Process**

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations.

**VIII. THE INVESTIGATION REPORT**

**A. Elements of the Investigation Report**

A written investigation report will be prepared by the committee. The report ordinarily will include the name and title of the committee members and any experts; the allegations; the source of support; a summary of the investigation process used; a list of the research records and evidence reviewed; summaries of any interviews; and recommendations. Possible recommendations include: 1) dismissal of the allegation or complaint; 2) referral of the matter to another more

appropriate system within the Institution for resolution (e.g., Grievance, Research Misconduct, Animal Care); 3) a finding of non-compliance that is not serious or continuing; or 4) a finding of serious non-compliance and/or continuing non-compliance, including an accurate summary of the views of any individual(s) found to have engaged in non-compliance and a description of recommended sanctions and administrative actions.

The University Attorney's office may review the report for legal sufficiency.

## **B. Comments on the Report by the Respondent and the Complainant**

The Compliance Officer will provide the respondent with a copy of the investigation report for comment and rebuttal. The Compliance Officer may provide the complainant, if he or she is identifiable; with a summary of the investigation findings that addresses the complainant's role and opinions in the investigation.

### **1. Confidentiality**

In distributing the draft report, or portions thereof, to the respondent and complainant, the Compliance Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Compliance Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

### **2. Receipt of Comments**

Within 14 calendar days of receipt of the report or summary, the respondent (and complainant, if applicable) will submit his/her written comments, if any, to the Compliance Officer. Any comments that the complainant or respondent submits on the report will become part of the record. Based on the comments, the investigation committee may revise the report as appropriate. Regardless of whether the committee revises the final report, the respondent's complete comments will be attached to the final report submitted to the IAC Chair.

## **C. Transmittal of the Final Investigation Report**

After comments have been received and the necessary changes, if any, have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and complainant's comments, to the IAC Chair, through the Compliance Officer.

**D. IAC Chair Review and Decision**

The IAC Chair will review the investigation report and the recommended actions and make a final decision as to whether serious non-compliance and/or continuing non-compliance occurred and what actions should be taken, if any. The IAC Chair may also return the report to the investigation committee with a request for further fact-finding or analysis. Actions the IAC Chair may take with respect to the investigation include, but are not limited to: 1) dismissal of the complaint; 2) remediation or educational measures; 3) increased reporting by the researcher of his/her human subjects research activities; 4) restrictions on research practice, such as limiting the privilege to minimal risk or supervised projects; 5) suspension of approval for one or more of the researcher's studies; 6) termination of approval for one or more of the researcher's studies; and 7) referral to other Institutional officials or committees for possible further review and action by those bodies.

The IAC Chair will issue the final decision and send it to the respondent and the appropriate IRB.

**D. Time Limit for Completing the Investigation**

The investigation committee will normally complete the investigation and submit its report in writing to the Compliance Officer no more than 90 calendar days following its first meeting, unless the Compliance Officer approves an extension because circumstances warrant a longer period. If the Compliance Officer approves an extension, the reason for the extension will be entered into the records. The respondent also may be notified of the extension.

**IX. DISSEMINATION OF FINDINGS**

At the stage when a final determination is made, the Compliance Officer will release the findings to the respondent and to appropriate Institutional and governmental officials as required under federal regulations. The same guidelines as set forth above for reporting suspensions will apply. Further, it may be necessary to inform these same officials of the status of the proceedings while they are pending.

Consistent with an IRB's regulatory authority, no other entity within the Institution may override the IAC's decision where it limits, imposes conditions or in any way restricts a respondent's privileges.

**X. ADDITIONAL CONSIDERATIONS**

**A. Resources**

The IAC Chair, Compliance Officer, IAC, and investigation committee shall have access to the necessary resources and staff to conduct a thorough and fair review of allegations. Internal and external consultants may be called to assist in the review.

**B. Coordination with other Investigative Processes**

Some cases require review by other institutional or external entities. The IAC will cooperate in the review of allegations of research misconduct or financial mismanagement or FDA inspections, etc. In cases that appear to involve research misconduct, the Investigation committee may report allegations of such misconduct to appropriate University officials. Where research misconduct and IAC investigations are pending against the same researcher, the IAC may coordinate processes to avoid inconsistent decisions, and duplication of effort to minimize competing use of resources.

**C. Conflict of Interest/Commitment**

As with all IRB processes, any IRB member or IAC member who has a conflict of interest or commitment relating to the matter under review will excuse himself/herself from the proceedings and an alternate will be designated by the committee chair.

**D. Confidentiality for Complainants and Witnesses**

The inquiry and investigation processes are confidential and the panels will take necessary steps to ensure confidentiality. Generally, the respondent should have access to the identity of complainant(s) and others who provide information if the matter proceeds to an investigation. However, for complainants who wish to maintain their anonymity, the IAC will attempt to protect their identities while at the same time affording the respondent access to the substance of the allegations and information presented against him/her. The IAC cannot guarantee anonymity for complainants.

**E. Retaliation**

Retaliation against good faith "complainants" will not be tolerated at this Institution. The IAC will, to the extent possible, take appropriate steps to ensure that a complainant is not subject to retaliation. Complainants who report IRB-related concerns might utilize other mechanisms at the Institution for protection from retaliation.

**F. Allegations Not Made in Good Faith**

If relevant, the Investigation committee will determine whether the complainant's allegations were made in good faith. A "good-faith allegation" is defined as an

allegation made with the honest belief that human subject research non-compliance may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation. If an allegation was not made in good faith, the IAC Chair will determine whether an administrative action should be taken against the complainant.