UMKC
Office of Research Services

## 10. Complaints and Non-Compliance

### 10.1. Policy

As part of the commitment to protecting the rights and welfare of human subjects in research, UMKC reviews all complaints and allegations of Non-Compliance and takes any necessary action to ensure the ethical conduct of research.

All investigators and other study personnel involved in human subjects research are required to comply with all laws and regulations governing their research activities, as well as with requirements and determinations of the IRB. The University of Missouri Kansas City defines study personnel as persons who have direct contact with subjects, contribute to the research in a substantive way, have contact with subjects' identifiable data or biological samples (e.g., tissue, blood, urine, plasma, saliva), or use subjects' personal information.

The following procedures describe how complaints and allegations of Non-Compliance are handled by the IRB. In cases where Serious Non-Compliance or Continuing Non-Compliance has occurred, the IRB may exercise its authority to monitor, suspend, or terminate the research.

**Regulations & Guidance:** DHHS 45 CFR 46.103(b)(5)(i); 45 CFR 46.116(b)(5); FDA 21 CFR 50.25(b)(5); 21 CFR 56.108(b)(2); OHRP Guidance on reporting incidents to OHRP.

### 10.2. Definitions

**Non-Compliance:** is a failure to comply with any of the regulations and policies described in this document and failure to follow the determinations of the IRB. Non-Compliance may be minor or sporadic or it may be serious or continuing.

**Allegation of Non-Compliance:** is defined as an unproved assertion of Non-Compliance.

**Finding of Non-Compliance:** is an allegation of Non-Compliance that is proven true or a report of Non-Compliance that is clearly true (e.g., a finding on an audit of an unsigned consent document, or an admission of an investigator that the protocol was willfully not followed would represent reports of Non-Compliance that would require no further action to determine their truth and would therefore represent findings of Non-Compliance).

**Continuing Non-Compliance**: is defined as a pattern of Non-Compliance that, in the judgment of the convened IRB, suggests a likelihood that instances of Non-Compliance will continue without intervention. Continuing Non-Compliance also includes failure to respond to a request to resolve an episode of Non-Compliance.

**Serious Non-Compliance:** is the failure to follow any of the regulations and policies described in these SOPs or failure to follow the determinations of the IRB and which, in the judgment of the convened IRB, increases risks to participants, decreases potential benefits, or compromises

the integrity of the HRPP. Research being conducted without prior IRB approval is considered serious Non-Compliance.

### 10.3. Complaints

The IRB Chair will promptly handle (or delegate staff to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the IRB. This includes complaints, concerns, and appeals from investigators, research participants and others.

All complaints, written or verbal (including telephone complaints), and regardless of point of origin, are forwarded to the IRB Chair and RCO Director.

Upon receipt of the complaint, the IRB Chair will make a preliminary assessment whether the complaint warrants immediate suspension of the research project. If a suspension is warranted, the procedures in section 3.10.1 will be followed.

If the complaint meets the definition of Non-Compliance, it will be considered an allegation of Non-Compliance according to section 10.4.1 below.

If the complaint meets the definition of an Unanticipated Problem, it will be handled according to section 8.

Within 5 days of receipt of the complaint, the IRB Chair and/or RCO Director shall acknowledge the complaint has been received and is being investigated.

### 10.4. Non-Compliance

Investigators and their study staff are required to report instances of possible Non-Compliance to the IRB. Common reports to the IRB that are not serious or continuing are typically protocol violations. However, any Individual or employee may report observed or apparent instances of Non-Compliance to the UMKC IRB. In such cases, the reporting party is responsible for making these reports in good faith, maintaining confidentiality and cooperating with any IRB and/or institutional review of these reports.

If an Individual, whether investigator, study staff or other, is uncertain whether there is cause to report Non-Compliance, he or she may contact the IRB Chair or RCO staff directly to discuss the situation informally.

Reports of Non-Compliance must be promptly submitted to the RCO upon discovery of the Non-Compliance. The report must include a complete description of the Non-Compliance, the personnel involved and a description of the Non-Compliance.

**Regulations & Guidance:** FDA 21 CFR 56.108(b).

### 10.4.1. Review of Allegations of Non-Compliance

All allegations of Non-Compliance will initially be reviewed by the RCO, who will review:

- All documents relevant to the allegation
- All applicable study related materials
- The grant, if applicable; and
- Any other pertinent information (e.g., questionnaires, DSMB reports, etc.).

The allegation will be reviewed and a recommendation made as to the credibility of the allegation. Review of the allegation of Non-Compliance should happen within a reasonable time frame (e.g. 10 days is reasonable for a non-serious allegation of Non-Compliance). The allegation will also be reviewed to determine whether the protocol has issues pertinent to other research compliance committees (i.e. Institutional Biosafety Committee, Radiation Safety Committee, and Institutional Animal Care and Use Committee).

When a recommendation of Non-Compliance is made because the incident was within the limits of an approved protocol for the research involved, the determination is reported by the IRB in writing to the PI following the review and, if applicable, the reporting party.

If in the judgment of the IRB, any allegation or findings of Non-Compliance is considered true, the Non-Compliance will be processed according to section 10.4.2.

If in the judgment of the IRB, any allegation or findings of Non-Compliance warrants suspension of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the IRB Chair (or designee) may suspend the research as described in section 3.10 with subsequent review by the IRB committee.

The IRB Chair (or designee) may determine that additional expertise or assistance is required to make these determinations and may form an ad hoc committee to assist with the review and fact gathering process. When an ad hoc committee assists in the review process, the Chair (or designee) is responsible for assuring that minutes of the ad hoc committee meeting are generated and kept to help support any determinations or findings made by the ad hoc committee.

### 10.4.2. Review of Findings of Non-Compliance

#### 10.4.2.1. Non-Compliance is Not Serious or Continuing

When the IRB determines that Non-Compliance occurred, but the Non-Compliance does not meet the definition of serious Non-Compliance or continuing Non-Compliance, the determination is reported to the PI and if applicable the reporting party. The RCO will work with the PI to develop a corrective action plan to prevent future Non-Compliance. If necessary, the Non-Compliance and corrective action is reported to the IRB at a convened meeting, and reflected in the IRB minutes. If, however, the PI refuses to cooperate with the corrective action

plan, the matter is presented to the convened IRB with notification to the PIs department Chair/Dean and the IO.

#### 10.4.2.2. Serious Non-Compliance or Continuing Non-Compliance

When the IRB Chair (or designee) determines that Non-Compliance has occurred and that the Non-Compliance meets the definition of serious Non-Compliance or continuing Non-Compliance, the report of Non-Compliance is referred for review by the IRB at the next convened available meeting. However, the IRB Chair (or designee) may use discretion and call an emergency IRB meeting should the circumstances warrant such an urgent meeting.

Examples of serious Non-Compliance may include the following:

- Falsifying IRB documents;
- Conducting human subjects research without IRB approval;
- Deviating from the IRB-approved protocol or consent process;
- Modifying the protocol or consent process without prior IRB approval.

All findings of Serious or Continuing Non-Compliance referred to the IRB will be reviewed at a convened meeting. All IRB members will receive:

- All documents relevant to the allegation
- All applicable study related materials
- The grant, if applicable; and
- Any other pertinent information (e.g., questionnaires, DSMB reports, etc.).

At this stage, the IRB may:

- Find that there is no issue of Non-Compliance
- Find that there is Non-Compliance that is neither Serious Non-Compliance nor Continuing Non-Compliance and an adequate corrective action plan is in place
- Find that there is Serious or Continuing Non-Compliance and approve any changes and/or corrective action proposed by the IRB Chair, Chair designee and/or ad hoc committee
- Find that there may be Serious or Continuing Non-Compliance and direct that a formal inquiry (described below) be held; or
- Request additional information.

### 10.5. Inquiry Procedures

A determination may be made by the IRB that an inquiry is necessary based on several issues that may include but are not limited to:

- Subjects' complaint(s) that rights were violated;

- Report(s) that investigator is not following the protocol as approved by the IRB;
- Unusual and/or unexplained AEs in a study;
- Repeated failure of investigator to report required information to the IRB.

A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise. The subcommittee is given a charge by the IRB, which can include any or all of the following:

- Review of the protocol(s) in question;
- Review of the sponsor audit report of the investigator, if appropriate;
- Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of her/his study involving human subjects;
- Interview of appropriate personnel if necessary;
- Preparation of either a written or oral report of the findings, which is presented to the convened IRB at the next meeting;
- Recommend actions if appropriate.

### 10.6. Final Review

The results of the inquiry will be reviewed at a convened IRB meeting where the IRB will receive a report from the subcommittee. If the results of the inquiry substantiate the initial finding of Serious or Continuing Non-Compliance, the IRB's possible actions could include, but are not limited to:

- Request a corrective action plan from the investigator
- Verification that participant selection is appropriate and observation of the actual consent process
- An increase in data and safety monitoring of the research activity
- Request a directed audit of targeted areas of concern
- Request a status report after each participant receives intervention
- Modify the continuing review cycle
- Request additional investigator and staff education
- Notify current subjects, if the information about the Non-Compliance might affect their willingness to continue participation
- Require modification of the protocol
- Require modification of the information disclosed during the consent process
- Require current participants to re-consent to participation
- Suspend the study (see relevant SOP)
- Terminate the study (see relevant SOP)

The investigator is informed of the IRB determination and the basis for the determination in writing and is given a chance to respond. If the IRB determines the Non-Compliance was Serious or Continuing, the results of the final review will be reported to the relevant authorities as described in the applicable policy (section 11).

Approved by: Lawrence Dreyfus, PhD
Name of University Institutional Official

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Signature of University Institutional Official Date