THE REVIEW OF PROBLEMS, COMPLAINTS, COMMENTS, CONCERNS, OR ALLEGATIONS OF NONCOMPLIANCE FROM INVESTIGATORS OR RESEARCH PARTICIPANTS

11/22/2023

The purpose of this document is to define the process by which problems, complaints, concerns, suggestions, or comments from participants or research personnel are received, reviewed, and processed in the Duke University Health System (DUHS) Institutional Review Board (IRB) Office.

The processes described in this document apply to personnel in the DUHS IRB Office and DUHS IRB members who receive complaints, or concerns, questions about a participant's research rights, or suggestions or input from participants or research personnel concerning DUHS clinical research studies.

All complaints, concerns, suggestions, or comments are evaluated according to the DUHS prompt reporting policy titled "Problems or Events That Require Prompt Reporting to the IRB". They are also evaluated according to the policy titled "Allegations and Findings of Non-Compliance".

All correspondence from research participants or research personnel related to this policy may be received in the IRB Office by conventional mail, e-mail, telephone, or through the IRB web site. Such correspondence will be promptly forwarded to the Executive Director, the Director of Research Review, the Director of IRB Compliance, or an IRB Chair, in that order as available.

Complaints or questions that are received via the IRB's website general mailbox are initially reviewed by the Director of IRB Compliance. If that individual determines the complaint to be minor and one that can be resolved easily, they may handle the complaint themself, or forward it to an IRB Compliance Specialist to resolve, or forward it to the Executive Director. The Executive Director will be apprised of the complaint and its resolution.

Correspondence from Participants

For the purposes of this document, a "participant" is defined as an individual who has signed a consent form to participate in a research study that is both conducted by DUHS personnel and also overseen by the DUHS IRB. In the case of participants who are minors or who are otherwise not legally competent to sign a consent form, the "participant" will be considered the parent/guardian or legal representative, as appropriate, who has signed the consent form for the study participant.

The Executive Director (or designee) reviews the complaint/concern against the IRB's record of the applicable study and either responds directly to the complainant, contacts the research team for an explanation, or seeks counsel from appropriate personnel in the IRB, or the Office of Audit, Risk and Compliance (OARC), or the Office of University Counsel before responding.

Issues that are considered in the review include:

(1) Existence of valid consent form in iRIS
(2) Proper study documentation in iRIS
(3) Past history of study team
(4) Validity of participant's complaint
(5) Effect on risk/benefit to participant
(6) Liability for DUHS
(7) Whether the complaint or concern involves an allegation or finding of non-compliance according to the policy titled "Allegations and Findings of Non-Compliance"
(8) Whether the complaint or concern represents a problem or event requiring prompt reporting according to the policy titled "Problems or Events Requiring Prompt Reporting to the IRB".

If the review indicates a need, the Executive Director may request that OARC perform a directed audit of the research protocol and study team. The review process may include any of the following: (i) meeting with the complainant; (ii) meeting with the PI and relevant study team members; (iii) meeting with University Counsel or other DUHS personnel.

If the review indicates that the complaint or concern involves an allegation of non-compliance, the policy titled "Allegations and Findings of Noncompliance" will be followed.

If the review indicates that the complaint or concern involves a problem or event requiring prompt reporting to the IRB, the policy titled "Problems or Events Requiring Prompt Reporting to the IRB" will be followed.

An electronic file on complaints/concerns, the results of the review and/or any internal audits will be maintained in the office of the Executive Director.

In regards to questions from participants regarding their rights, the Executive Director or Director of Research Review reviews the question against the IRB's record of the applicable study and either responds directly to the participant or seeks counsel from OARC or the Office of University Counsel before responding. An electronic record is maintained in the Executive Director's office regarding this correspondence. The IRB Lead Chair is copied on the response to the participant.

In regards to suggestions or offers of input from a participant concerning a research study, the correspondence is forwarded to the Executive Director, IRB Lead Chair, or Director of

Research Review, in that order, as available. Where the suggestion or input affects the conduct of the study by the Principal Investigator or study staff, the suggestion/input is forwarded to the investigator.

Complaints or Concerns from Study Personnel or Duke Investigators
Complaints or concerns from study personnel or other investigators (collectively, Duke personnel) concerning any research study over which the IRB has oversight will be forwarded to the Executive Director and/or IRB Lead Chair.

Complaints/concerns from research personnel are either reviewed directly in the IRB office or forwarded promptly to OARC for review and possible audit. The Vice Dean for Clinical Research and the Vice Dean for Scientific Integrity, are promptly apprised of any such complaints or concerns by the IRB. Complaints/concerns from Duke personnel are evaluated to determine whether the complaint or concern involves an allegation or finding of non-compliance according to the policy titled “Allegations and Findings of Non-Compliance”, and whether the complaint/concern represents a problem or event requiring prompt reporting according to the policy titled “Problems or Events Requiring Prompt Reporting to the IRB”. If the review indicates that the complaint or concern involves an allegation of non-compliance, the policy titled “Allegations and Findings of Noncompliance” will be followed. If the review indicates that the complaint or concern involves a problem or event requiring prompt reporting to the IRB, the policy titled “Problems or Events Requiring Prompt Reporting to the IRB” will be followed.

Likewise, complaints or concerns are maintained electronically in the office of Executive Director. Such complaints/concerns do not become part of the permanent study record, but are supplied in confidence to Primary Reviewers at the time of annual review of the relevant study if, in the judgment of the Executive Director and IRB Lead Chair, such complaints/concerns are necessary for adequate review of the study.

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