Issuing Department: Human Subjects Protection Program (HSPP)
Policy Number: 2011-018.0
Policy Title: Complaints, Concerns, Suggestions

Purpose

The purpose of this policy is to set forth the position of the HSPP for receiving and processing complaints, concerns or suggestions. This policy does not encompass filing allegations of research misconduct for which a separate institutional policy exists.

Definitions

See policy 2011-007.0 for definitions of the following terms:

Human Subject | Research

Policy

Research participants, research personnel or others, may file complaints, concerns or suggestions with the HSPP that relate to their involvement in or the conduct of a human subject research study.

Research personnel may also file complaints, concerns or suggestions about the HSPP (inclusive of the IRB) operating practices and policies.

To encourage study participants to provide feedback about their participation as a research subject, including complaints, concerns or suggestions, participants should be provided with the Participant Feedback Form at the time of giving written consent. This form will also be made available to subjects by other means such as web postings.

Procedure

Complaints, Concerns, Suggestions: The individual filing the complaint, concern or suggestion may choose the initial means of communication. Communications should be directed to the following individuals in the order noted below, moving forward if not satisfied with the resolution provided:

- staff within the HSPP (e.g. the IRB Regulatory Specialist for a specific panel, the IRB Chair of a specific meeting etc.)
- the Director of the HSPP (DHSPP)
- the individual to whom the DHSPP reports.
    - The DHSPP, or individual to whom the DHSPP reports, may recommend or require that the HSPP implement corrective action to address the reported issue. However, no requirements can be made that would change or influence a decision of the IRB.

The person receiving the complaint/concern/suggestion will gather relevant information from the filer.

- Individuals will be asked to submit their comments in writing (e-mail is acceptable) but this is not required.
- the template titled Complaint/Concern/Suggestions Intake Form may be used to facilitate this process
- The person receiving the complaint will attempt to resolve the issue through communication with the filer and, if necessary, other relevant parties such as investigators or study coordinators.

- If unable to resolve the issue, the individual receiving the complaint will forward a summary of the issue to the next appropriate individual as noted above for further action.
    - The Chair or DHSPP (providing s/he does not influence the decision of the IRB) may require the investigator or IRB staff to take corrective action to resolve the issue, may contact the filer and/or the PI of the relevant project for additional information, or may request that the RCM perform an audit.
    - If any corrective action requires a change to previously approved documents the IRB Chair will instruct, or direct the IRB staff to instruct, the investigator in writing to submit a request for modification form that addresses the corrective action.
    - The Chair or DHSPP may issue a letter (e-mail) to the filer outlining the actions taken, or that no action was taken.
    - The Chair or DHSPP will also evaluate the nature of the complaint/concern to determine if it should be reviewed by the full board for possible determination as a reportable event (i.e., an unanticipated problem involving risk to subjects or others or serious or continuing non-compliance). Referral to the IRB may be held until such time as the results of audit findings and/or responses from the PI are available for review.

As noted above, the recipient may refer the complaint/concern to a higher authority if unable to resolve the situation on their own.

For suggestions, the individual who received the suggestion will bring it to the attention of the DHSPP or designee. The person who received the suggestion will inform the individual who made the suggestion of the outcome regarding implementation of the suggestion through email, by phone or by an announced change in policy / procedure.

Participant Feedback: Within the informed consent process and document, the person obtaining consent must inform subjects that they may contact the IRB if they have complaints, concerns or suggestions about their participation in a research study. The phone number of the IRB must be provided. The participant should also be provided with the Participant Feedback Form which s/he can elect to complete and which solicits suggestions from participants.

On approximately a bi-weekly basis a designated staff member within the HSPP will process the Participant feedback forms that have been received.

- Depending on the nature of the information provided the staff person may share comments with principal investigator and/or research staff,
- Staff person will acknowledge receipt of the form to the participant using the standard template acknowledgement letter unless the subject filed anonymously,
- For any form that expresses a concern or complaint the staff person may request that an IRB Chair review the form to determine if any additional action is needed.
    - The IRB Chair will review the form and, depending on the nature of its content, may refer it to the convened board for review as a potential unanticipated problem, serious non-compliance or continuing non-compliance
    - The IRB may request that an audit of the study occur, and/or
    - The IRB may require changes to the protocol or consent to address the concern.

The Director of the HSPP will also review all forms and, if necessary, take appropriate action.

Tracking: The HSPP/IRB will maintain a central log of complaints, concerns, suggestions and participant feedback forms that have been received by subjects and research personnel. The staff member receiving the information is responsible for logging the information and follow-up activity, or delegating this activity to the IRB Regulatory Specialist whose panel has oversight of the study. The log will contain the date of receipt and as applicable, the principal investigator involved, the subject's name, the nature of the complaint, concern or suggestion and the outcome. The information on the log will be evaluated by the Director of the HSPP as part of the annual evaluation of the HSPP to determine if any additional actions, e.g. change in policies, are required to adequately address the identified issues.

Subject complaints received by research personnel are also reported as part of the annual continuing review process. In this manner the IRB is informed of complaints that were resolved without the involvement of the IRB or HSPP.

The same process will be followed regardless of whether the study was reviewed through the expedited review process, by the full board or determined to be exempt.

Related Policies

2009-001 – Reporting Unanticipated Problems to the Institutional Review Board
2009-002 – Reporting Non-compliance to the Institutional Review Board
2011-009.3 – Institutional Review Board – Expedited Reviews
2011-009.5 – Institutional Review Board – Review by the Convened Board

Basis

Guidance on IRB Continuing Review of Research at
http://www.hhs.gov/ohrp/policy/continuingreview2010.html

Document Attributes

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Reviewed and Approved By:

Richard H. Simon *17 August 2017*

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