Procedure Statement:

This procedure establishes the process to manage New Information. The procedure begins when the IRB or the Office of Research Integrity (ORI) receives:

- information that is not a request for a Human Subjects Research determination (regardless of whether the information is reportable), or
- a Reportable New Information submission in IRBNet.

The procedure ends when an ORI staff member or an IRB committee co-chair determines whether the information requires reporting to the convened IRB.

Policy:

When it is determined through this procedure that new information represents any of the following, the determination must be confirmed by the full convened IRB Committee as described in the Policy for Reporting Unanticipated Problems/Adverse Events to the IRB:

- Serious Noncompliance
- Continuing Noncompliance
- Unanticipated Problem Involving Risks to Subjects or Others
- Suspension of IRB Approval
- Termination of IRB Approval

RESPONSIBILITY

ORI staff are responsible for making decisions about New Information. ORI staff execute these procedures or ensure they are executed by other personnel. Individuals unsure of how to arrive at a decision by using this procedure are to bring the New Information to a higher-level official for a determination. The IRB co-chairs will follow this procedure before placing an item of New Information on an IRB committee meeting agenda.

PROCEDURE

- Ask the following six questions.
    1. Does the information represent an Allegation of Noncompliance? If yes:
        a. Inform the Director of Research Policy and Compliance of the Allegation of Noncompliance.
        b. The Director of Research Policy and Compliance evaluates the Allegation of Noncompliance to determine whether there is a basis in fact.
        c. If the final determination is that the Allegation of Noncompliance has basis in fact, then it represents Noncompliance.
    2. Does the information represent Noncompliance? If yes:
        a. Inform the Director of Research Policy and Compliance of the Noncompliance.

b. The Director of Research Policy and Compliance evaluates the Noncompliance to determine whether it is Serious Noncompliance or Continuing Noncompliance.

3. Does the information represent Serious Noncompliance?
4. Does the information represent Continuing Noncompliance?
5. Does the information represent an Unanticipated Problem Involving Risks to Subjects or Others?
6. Does the information represent a Suspension of IRB Approval or a Termination of IRB Approval?

- If the answers to all six questions above are "no":

1. Respond as needed to any complaint, query, or input.
2. Follow any other applicable SOPs.
3. If an acknowledgement is expected, notify the submitter.
4. No further action is required under this SOP.

- Consider whether any immediate actions might be necessary to protect the rights and welfare of current or future subjects while additional information is gathered.

1. If so, take those actions, notify the institution and sponsor, as applicable, and notify the Director of Research Policy and Compliance.

- Consider whether immediate notification of the institution or sponsor might be appropriate.

1. If so, notify the institution and sponsor, as applicable, and notify the Director of Research Policy and Compliance.

- If more information is needed, contact the submitter to gather new information.

- If the information represents Noncompliance that is neither Serious Noncompliance, nor Continuing Noncompliance:

1. Request a written Corrective Action Plan from the PI, and provide a reasonable deadline.
2. Evaluate the Corrective Action Plan.
   a. If the corrective action plan is insufficient, work with the PI to develop a sufficient correction action plan.
   b. If the PI is unable to develop a sufficient corrective action, consider the Noncompliance to be Continuing Noncompliance.
   c. Notify the PI if they have submitted a sufficient Corrective Action Plan.

- If the information represents Serious Noncompliance, Continuing Noncompliance, an Unanticipated Problem Involving Risks to Subjects or Others, a Suspension of IRB Approval, or a Termination of IRB Approval:

1. Notify the Director of Research Policy and Compliance.

2. Bring the information to the attention of an IRB Co-chairs for consideration of whether any immediate actions are necessary to protect the rights and welfare of subjects in advance of the meeting.
3. Send for IRB Committee Review.

- If the information represents Misconduct in Research, as defined in Ethical Conduct in Academic Research, Scholarship, and Creative Activities Policy, the Director of Research Policy and Compliance will liaise with appropriate entities within the Office for the Vice Provost for Research in accordance with the policy.

REFERENCES

45 CFR §46.103
21 CFR §56.108