1. PURPOSE
   1. This procedure establishes the process to manage new information.
   2. This procedure begins when an IRB receives information that is not a request for a determination (regardless of whether the information is reportable) or receives reportable new information as part of a submission.
   3. This procedure ends when an HRPP staff member or IRB Executive Chair has determined whether the information requires reporting to the convened IRB.
2. POLICY
   1. None
3. RESPONSIBILITY
   1. All individuals who can make decisions about new information carry out these procedures or ensure they are carried out by other personnel.
   2. Individuals unsure of a decision in this SOP are to bring new information to higher level official for a determination.
4. PROCEDURE
   1. Ask the following six questions.
      1. Does the information represent an Allegation of Noncompliance? If yes:
         1. Evaluate the Allegation of Noncompliance to determine whether there is a basis in fact.
         2. If the final determination is that the Allegation of Noncompliance has basis in fact, then this represents Noncompliance.
      2. Does the information represent Noncompliance? If yes:
         1. Evaluate 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?
   2. 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, follow “SOP: Post Review (HRP-111)” to notify the submitter.
      4. No further action is required under this SOP.
   3. If the information represents Noncompliance that is neither Serious Noncompliance, nor Continuing Noncompliance, evaluate any submitted corrective action.
      1. If the corrective action plan is insufficient, contact the research team to develop a sufficient correction action plan.
         1. If the research team is unable to develop a sufficient corrective action, consider the Noncompliance to be Continuing Noncompliance.
      2. If the research team develops a sufficient corrective action, follow “SOP: Post Review (HRP-111)” to notify the submitter.
   4. 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. Obtain confirmation by the Organizational Official.
      2. Bring the information to the attention of an IRB chair or IRB vice-chair 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 Committee Review.
5. REFERENCES
   1. 45 CFR §46.103(b)(5)
   2. 21 CFR §56.108