PROCESS FOR ADDRESSING ALLEGATIONS AND FINDINGS OF NON-COMPLIANCE

Individual (Anonymous or Named)
- Communication from any source regarding an allegation of non-compliance
  - Involves VP of Clinical Research or OCRA directors?
    - No: Conducts preliminary assessment
    - Yes: Send preliminary report of findings to IRB Chair/Institutional Official
      - Immediate Action Needed?
        - Yes: IRB Chair/Institutional Official implements immediate action
          - No further action or no Reportable Decision
        - No: No further action or no Reportable Decision

IRB Director/Designee
- Conducts preliminary assessment
- Send preliminary report of findings to IRB Chair/Institutional Official
- Immediate Action Needed?
  - Yes: IRB Chair/Institutional Official implements immediate action
  - No: No further action or no Reportable Decision

IRB Convened Board
- Convened IRB Board Reviews
- IRB determines an ancillary review is needed, such as Legal or Institutional Compliance
  - Serious or continuing?
    - Yes: Reportable Decision?
      - Yes: Determination of serious or continuing noncompliance sent to VP of Clinical Research
      - No: No further action or no Reportable Decision
    - No: No further action or no Reportable Decision

Institutional Compliance
- Conducts preliminary assessment
- Send report of findings to IRB
  - IRB Chair/Institutional Official implements immediate action
  - No further action or no Reportable Decision

Study Chair
- PI submits corrective action plan
- PI Informed of IRB decision
- IRB Chair/Institutional Official implements immediate action
  - No further action or no Reportable Decision

Results documented and filed

Reportable Decision?
- Yes: IRB Chair/Institutional Official implements immediate action
  - No further action or no Reportable Decision

Determination of serious or continuing noncompliance sent to VP of Clinical Research

No further action or no Reportable Decision

No further action or no Reportable Decision