This flowchart outlines the steps used by the IRB/Office of Research Compliance and Integrity to assess reports of potential IRB noncompliance. Please see IRB Policy 1030: Research Noncompliance for a detailed description of the noncompliance policy and procedures.

In the flowchart, the group/individual responsible for each action item is identified in brackets.

**Abbreviations/Acronyms**

AO  Authorizing Official  
Chair  IRB Chairperson  
GVSU  Grand Valley State University  
IRB  Institutional Review Board  
ORCI  Office of Research Compliance and Integrity  
PI  Principal Investigator  
RIO  Research Integrity Officer
Administrative Inquiry

RIO issues written statement summarizing initial assessment and inquiry plan to PI, AO, Chair, and others.

ORCI completes inquiry and sends written report to RIO.

RIO reviews report and may choose to forward report to Chair for preliminary review.

Are there questions about the report or are changes needed? [RIO]

No

ORCI amends report as needed and returns to RIO.

Yes

RIO sends report to PI and notifies AO that PI has received draft report.

PI has 10 days to review and respond to RIO with corrections.

Does PI have changes or corrections? [RIO]

No

RIO forwards final report (and PI response if applicable) to PI, Chair, AO and others.

Yes

RIO coordinates with ORCI to amend report.

Continue to IRB Review
IRB Review

- IRB Chair reviews report.
  - Does this possibly represent serious or continuing noncompliance? [Chair]
    - Yes
      - IRB Chair documents determination and notifies RIO.
    - No
      - Place on next IRB meeting agenda.

- Is an emergency IRB meeting needed? [Chair]
  - Yes
    - Schedule emergency IRB meeting.
  - No
    - Convened IRB begins review of reported information.
      - Is there sufficient information to make a serious or continuing noncompliance determination? [IRB]
        - Yes
          - Table the report and request additional facts or further investigation.
        - No
          - Follow IRB Policy 1020 (reportable events).

- Is this serious and/or continuing noncompliance? [IRB]
  - Yes
    - Determine what corrective actions are needed.
  - No
    - Continue to RIO review of noncompliance.

- Does this noncompliance also represent an unanticipated problem? [IRB]
  - Yes
    - Document determination(s) in meeting minutes and issue letter to PI and RIO.
  - No
    - Follow IRB Policy 1020 (reportable events).
RIO Review

RIO determines what, if any, administrative actions are needed.

RIO issues final letter to PI, AO, IRB Chair, and others.

RIO monitors the PI's completion of any corrective or administrative actions.

When applicable, the RIO, IRB Chair and ORCI submit written summary of noncompliance to relevant internal and external authorities.