Reporting to Regulatory Agencies & Sponsors Regarding Research Involving Human Participants

Purpose

The purpose of this policy is to establish guidelines to ensure that Chapman University meets its reporting obligations when reporting to federal agencies is required.

Policy

The Chapman University Institutional Official (IO) will ensure that full, accurate, and timely reports are submitted to the appropriate regulatory agencies when required.

Procedures

1) The VP for Research Integrity is responsible for drafting a letter to the relevant federal agencies for the following:
    a) Terminations of previously approved research
    b) Suspension of previously approved research, regardless of the reason for the suspension
    c) Serious or continuing noncompliance as determined by the IRB
    d) Unanticipated problems involving risks to participants and others
2) Generally, all correspondence should consist of the following:
    a) Name of the institution conducting the research
    b) Title of the research and grant proposal, as applicable
    c) As applicable, funding source and award number
    d) Name of the principal investigator (PI)
    e) The IRB study number
    f) A detailed description of the issue
    g) The IRB's findings
    h) Actions the IRB is taking or plans to take to address the issue
    i) Any information regarding further recommendations, actions, or investigation to be taken, if applicable
3) The IO is responsible for reviewing, signing, and sending the letter to the relevant federal agencies within fifteen (15) working days following the actions taken by Chapman, if any. Letters should be sent to:

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a) The Office of Human Research Protections (OHRP) for research regulated by the Common Rule. OHRP has guidance on reporting incidents which will be used by Chapman for such reporting.

b) The Food and Drug Administration (FDA) for FDA regulated research.

4) A copy of the letter (signed by the IO) be submitted to Chapman's Office of Sponsored Projects for reporting to project sponsors (federal state, foundation or private), as applicable.

5) A copy of the letter should also be sent to:

a) The Assistant Vice President for Research Integrity and Compliance

b) Legal Affairs, when appropriate

c) Institutional Compliance, as appropriate

d) The PI

e) The PI's Dean or Department Chair

References:

Guidance on Reporting Incidents to OHRP 2022 (hhs.gov)
Unanticipated Problems Involving Risks & Adverse Events Guidance (2007) | HHS.gov

Revision history:

Oct. 2025 – added references, updated the title "Director of Research Integrity" to "Assistant Vice President for Research Integrity and Compliance"

May 2023 -

- Funding source and award number added as among recommended information to include in external reporting
- Clarification on workflow
- Updated the link to OHRP's reporting guidance

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