SOP 1.2  Exigent Circumstances

General Description:

42 CFR 93.318 requires that institutions notify ORI immediately if, in the handling of an allegation of misconduct in research, any of the “special circumstances” detailed in this arise when PHS funding is involved. Other federal funding agencies have similar expectations and this list is pertinent whatever the source of funding.

Procedures:

1. The RIO will review this list on receipt of new allegations and thereafter as new circumstances arise. It may lead to reporting to ORI or other federal agency and internal discussions with those managing other research regulations per SOP 1.1 Triage and Precedence of Procedures.

(a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.

(b) HHS, other sponsor, or institutional resources or interests are threatened.

(c) Research activities should be suspended.

(d) There is reasonable indication of possible violations of civil or criminal law.

(e) Federal action is required to protect the interests of those involved in the research misconduct proceeding.

(f) The research institution believes the research misconduct proceeding may be made public prematurely so that HHS or other federal agency may take appropriate steps to safeguard evidence and protect the rights of those involved.

(g) The research community or public should be informed.

2. The RIO will consult with legal counsel and advise the Deciding Official prior to taking any action notifying external agencies or administrators managing other research regulations. Interim action might include:

(a) additional monitoring of the research process and the handling of federal funds and equipment,

(b) reassignment of personnel or of the responsibility for the handling of federal funds and equipment, or

(c) additional review of research data and results or delaying publication.

3. The RIO shall, at any time during a research misconduct proceeding, notify funding agencies immediately if there is reason to believe that any of the following conditions exist:

(a) health or safety of the public is at risk, including an immediate need to protect human or animal subjects;

(b) federal resources or interests are threatened;

(c) research activities should be suspended;
(d) there is a reasonable indication of possible violations of civil or criminal law;
(e) federal action is required to protect the interests of those involved in the research misconduct proceeding;
(f) the research misconduct proceeding may be made public prematurely and federal action may be necessary to safeguard evidence and protect the rights of those involved; or
(g) the research community or public should be informed.

**Related Forms, Guidance, and SOPs:**

Policy 4007, Misconduct in Research and Scholarship
SOP 1.1 Triage and Precedence of Procedures

**Responsibility:**

Execution of SOP:
Deciding Official
Research Integrity Officer

**Approval and Version History:**

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