Human Subjects
Office of Research
UNIVERSITY OF GEORGIA

Non-compliance Determinations

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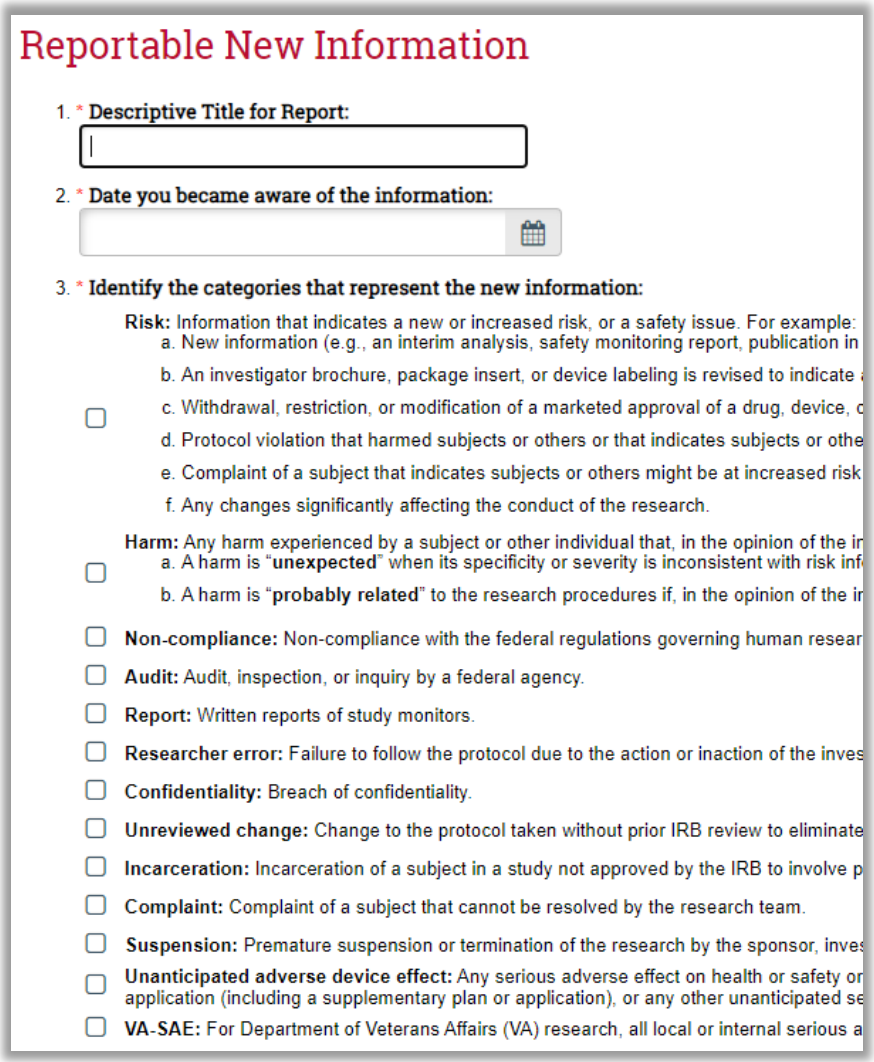
Information or Allegation?



Reportable New Information

1. * **Descriptive Title for Report:**

2. * **Date you became aware of the information:**

3. * **Identify the categories that represent the new information:**

Risk: Information that indicates a new or increased risk, or a safety issue. For example:
a. New information (e.g., an interim analysis, safety monitoring report, publication in
b. An investigator brochure, package insert, or device labeling is revised to indicate
c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, c
d. Protocol violation that harmed subjects or others or that indicates subjects or othe
e. Complaint of a subject that indicates subjects or others might be at increased risk
f. Any changes significantly affecting the conduct of the research.

Harm: Any harm experienced by a subject or other individual that, in the opinion of the ir
a. A harm is "**unexpected**" when its specificity or severity is inconsistent with risk inf
b. A harm is "**probably related**" to the research procedures if, in the opinion of the ir

Non-compliance: Non-compliance with the federal regulations governing human resear

Audit: Audit, inspection, or inquiry by a federal agency.

Report: Written reports of study monitors.

Researcher error: Failure to follow the protocol due to the action or inaction of the inves

Confidentiality: Breach of confidentiality.

Unreviewed change: Change to the protocol taken without prior IRB review to eliminate

Incarceration: Incarceration of a subject in a study not approved by the IRB to involve p

Complaint: Complaint of a subject that cannot be resolved by the research team.

Suspension: Premature suspension or termination of the research by the sponsor, inves

Unanticipated adverse device effect: Any serious adverse effect on health or safety or application (including a supplementary plan or application), or any other unanticipated se

VA-SAE: For Department of Veterans Affairs (VA) research, all local or internal serious a

- The IRB reviews Reportable New Information (RNIs)
- RNIs include, but are not limited to, noncompliance allegations

Non-compliance Review Process

Investigation

Review

Determination

Corrective Actions

Non-compliance

- Failure to adhere to:
  - Terms of IRB approval
  - Requirements or determinations of the IRB
- Failure to abide by:
  - Applicable laws or regulations
  - UGA policies

Example

- Investigator initiates human research sponsored by a Common Rule agency without submitting for review.

- Applicable laws and policies?
  - HRPP Policy
  - Federal regulation
  - Sponsor guidelines

Example Continued: Who is noncompliant?

Principal Investigator

- HRPP Policy
- Sponsor requirements

UGA

- Federal regulation: Terms of FWA
- Sponsor requirements

Continuing Noncompliance

- Persistent failure to adhere to the laws, regulations, or polices governing research.

- Pattern of repeated non-compliance actions or omissions that…
  - If unaddressed, may compromise the integrity of the UGA HRPP
  - May reflect a lack of knowledge or lack of commitment to human subject protection

Serious Non-compliance

- Failure to adhere to the laws, regulations, or policies governing research that:
  - Involves substantive harm or risk of substantive harm to safety, rights or welfare, or
  - Results from deliberate disregard for the laws, regulations or policies governing research that
  - Substantively compromises the effectiveness of the institution's research oversight program.

Corrective Actions

- Request changes to research procedures
- Educate investigators and/or study team
- Submit a letter of concern
- Require additional monitoring
- Suspend investigator's privilege to use human subjects
- Modify the continuing review schedule
- Suspend or terminate the study