

## **15 Unanticipated Problems Involving Risks to Subjects or Others**

University of Virginia complies with DHHS and FDA regulations which require organizations to have written policies on reporting unanticipated problems involving risks to subjects or others (UP/UAP/UPRIRTSO) to the IRB, organizational officials and relevant federal agencies and departments.

The following procedures describe how UAPs are handled in research under the auspices of University of Virginia. Unless specifically required by the IRB, the University of Virginia IRB does not accept reports of adverse events that do not meet the definition of an UAP.

### **15.1 IRB Review**

After a determination of a possible unanticipated problem involving risk to subjects or others (UAP), the report will be placed on the agenda for the next convened IRB meeting and a primary reviewer will be assigned.

The primary reviewer will be given the study file, the currently approved consent document, previous reports of UAPs, the investigator's brochure (if one exists), the event report, and recommendations from the IRB Chair or designee, when appropriate. All IRB members will receive the event report and have full access to all materials upon request.

After review of the study and event report, the full IRB will make findings and recommendations based on the following considerations:

- Whether the reported event is a UAP according to the definition in this policy.
  - What action in response to the report is appropriate.
  - Whether suspension or termination of approval is warranted.
1. If the IRB finds that the event is not a UAP, according to the definition in the policy, the IRB may recommend any of the following actions:
    - a. No action
    - b. Requiring modifications to the protocol/research plan
    - c. Revising the continuing review timetable
    - d. Modifying the consent process
    - e. Modifying the consent document
    - f. Providing additional information to current participants (e.g., whenever the information may relate to the subject's willingness to continue participation)
    - g. Providing additional information to past subjects
    - h. Requiring additional training of the investigator and/or study staff
    - i. Other actions as appropriate given the specific circumstances

2. If the IRB finds that the event is a UAP, according to the definition in the policy, the IRB may recommend any of the following actions:
  - a. Requiring modifications to the protocol/research plan
  - b. Revising the continuing review timetable
  - c. Modifying the consent process
  - d. Modifying the consent document
  - e. Providing additional information to current participants (e.g., whenever the information may relate to the subject's willingness to continue participation)
  - f. Providing additional information to past participants
  - g. Requiring additional training of the investigator and/or study staff
  - h. Reconsidering approval
  - i. Requiring that current subjects re-consent to participation
  - j. Monitoring the research
  - k. Monitoring consent
  - l. Referral to other organizational entities (e.g., legal counsel, risk management, Institutional Official)
  - m. Suspending the research approval
  - n. Terminating the research approval
  - o. Other actions as appropriate given the specific circumstances
3. If a report suggests that participant safety is at risk, the IRB may immediately suspend or terminate the research. Any suspension or termination of research by the IRB must be promptly reported to the IO and relevant federal regulatory agencies through the IO. This should be done in writing.
4. If, after reviewing a report, the IRB finds that the event is a UAP or that suspension or termination of approval is warranted, the IRB will:
  - a. Notify the investigator in writing of its findings, with copies to the Chair of the investigator's department and/or research unit, other affected units and the investigator's supervisor, and
  - b. Report its findings and recommendations to the Vice President for Research for further reporting to the appropriate federal officials (see Section 18).