

Chapter 4

NONCOMPLIANCE

Whenever questions arise concerning possible noncompliance with IRB guidelines and other applicable regulations, the Chair and the Board have the authority to investigate and take appropriate action to ensure compliance or to terminate the research.

A. Action by the Chair

1. Authority

The Chair has discretion to temporarily suspend research under any of the following circumstances:

- a. Substantial evidence of noncompliance;
- b. Reasonable suspicion of noncompliance, which may be associated with more than minimal risk to human subjects;
- c. Information suggesting that the research involves substantially greater risk than was anticipated at the time of initial IRB approval.

2. Procedures

If the Chair does suspend research, he or she will:

- a. Promptly and in writing notify the investigator(s) and members of the Board of the suspension and the reasons for it.
- b. Provide the investigator(s) with a copy of this section of the guidelines.
- c. Offer the investigator(s) an opportunity to meet immediately with the chair.
- d. Place the matter on the agenda for the next monthly IRB meeting, at which time the Board may confirm or rescind the suspension, convert the suspension to a termination, or take any other action consistent with its authority and obligations.

B. Action by the Board

1. Authority

If the Board finds research has been conducted in violation of IRB guidelines or other applicable regulations, it may:

- Disallow the publication of data collected during periods of noncompliance,
- Require destruction of data collected during periods of noncompliance,
- Impose restrictions as a condition for continuation of the research,

- Suspend or terminate the research,
- Take other action as appropriate.

2. Procedures

- a. Questions or concerns regarding noncompliance with IRB Guidelines should be directed to the IRB Coordinator and/or the Chair, who will report preliminary findings to the Board. The Board may involve the hospital or university's general counsel.
- b. If the Board believes further action may be appropriate, it will investigate the matter in question.
- c. The Board may suspend research during the investigation.
- d. The Board will notify the investigator(s) of the nature of the concerns that have been raised and the time, date and place of the meeting to discuss them. The investigator will have an opportunity to attend and explain. It is the duty and responsibility of the principal investigator to cooperate with the IRB and to provide any documentation the Board may request.

3. Board Decisions

Within seven calendar days of its decision to uphold a suspension, the Board will provide written notice to the investigator(s) and to the department chair(s), dean(s), vice president(s), office of the provost, and the office of the general counsel. In accordance with WVU's agreement of assurance with HHS, the Board will submit an initial report of any serious or continuing noncompliance with IRB requirements to the Office for Protection from Research Risks (OPRR), the Food and Drug Administration (FDA) and other agencies (as appropriate). This report will include a statement of the reasons for the Board's decision and other appropriate information; copies of this report will be sent to all appropriate parties.