Purpose: To define the conditions under which a protocol may be suspended or terminated.

Policy:

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected harm to subjects. (45 CFR 46.113)

Once a study has been terminated, human research subjects cannot be recruited or enrolled, there can be no intervention, interaction or follow-up with enrolled human subjects, nor any continued collection of data or analysis of data previously collected as part of the research protocol.

Any suspension or termination of approval by the IRB shall include a statement of the reasons for the action and shall be reported promptly to the investigator and advisor as well as to the Vice Chancellor for Research.

The IRB has the authority to re-open terminated projects if it deems this action is necessary and in the best interests of the subjects.