

IRB Policy #:	320
Policy Title:	<i>Appealing an IRB Decision</i>
Date Approved:	
Date Reviewed:	

Purpose: To describe the mechanisms for appealing a decision of the IRB.

Policy:

If the IRB makes a decision that an investigator believes to be unfair, unsubstantiated, or unduly restrictive to his or her proposed research, the investigator should first discuss the matter with the IRB chair and the ORC. The investigator should be prepared to present reasons that he or she believes that the proposed research is in compliance with University policy and Federal regulations for the protection of human subjects.

If the issue cannot be resolved satisfactorily by negotiation, the PI may appeal the decision, in writing, to the full IRB. The results of any negotiations that require approval by the full IRB will be taken to the next convened meeting for decision and vote.

In developing his or her appeal, the investigator is encouraged to seek the advice or opinion of an objective, qualified consultant to support the claim that the proposed research is in compliance with human subjects policy and regulations.

The investigator may appear before the IRB to present his or her appeal and any supportive material or documentation obtained through consultation, but the investigator cannot be present during the vote on the IRB's final recommendation.