



DECLARATION OF CONCORDANCE BETWEEN GRANTS AND THE PROTOCOLS SUBMITTED TO THE DUHS IRB

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This document describes the process the DUHS IRB uses to declare concordance between a grant submitted by or awarded to a DUHS investigator and an IRB protocol proposed to be conducted under that grant.

For research with humans that is Federally funded or funded by the American Heart Association, prior to approving the research the IRB must compare the IRB protocol submission to the grant application and declare them to be concordant. If a grant relates to a protocol that is associated with greater than minimal risk, the declaration of concordance must occur at a convened IRB meeting. To declare concordance, the IRB requires a copy of the entire grant, without appendices, submitted by the Duke PI. A copy of the entire grant must be uploaded into the e-IRB system when the PI prepares his/her IRB protocol submission. If the grant relates to more than one protocol, the Duke PI must submit a statement declaring which protocols relate to the grant, and which portions of the grant correspond with which protocols.

The primary reviewer reviews the entire grant application to ensure that the research described in the IRB protocol is concordant with the grant application. When a protocol needs to be declared concordant at a convened IRB meeting, all board members have the opportunity to review the entire grant (visible for that protocol submission in the e-IRB) should they wish, prior to the convened meeting.

The IRB may require the Investigator(s) to: (i) summarize, and cross-reference to the application, specific information contained in the grant application; (ii) identify any IRB-approved protocols that describe the proposed research; and (iii) either certify that the application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol amendments to reconcile any discrepancies.

In comparing the grant application and the protocol submission, the reviewer will assess whether the proposed research as described in the grant is consistent with any relevant protocol(s) submitted to, or previously approved by, the IRB. Final IRB approval for the protocol to begin will not be issued until concordance has been declared. Declarations of concordance made at a convened board meeting are recorded in the meeting minutes, and those made using the expedited procedure are reported to a convened board along with other reportable items.

The following is an exception to this policy: Concordance does not have to be declared for NIH Cooperative Group studies.

REFERENCES

45CFR46.103(f)

45CFR46.102(j)

IRB Review of Applications for HHS Support (HHS memo dated May 31, 2000):

(<http://www.hhs.gov/ohrp/humansubjects/guidance/aplrev.htm>)