Grand Valley State University Institutional Review Board (IRB)	
Title: Declaration of Concordance Between Grants and Protocols Submitted to the IRB	
Section: 951.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 05/13/2014 Revised by HRRPPC: 01/23/2018 Revised by IRBPPC: 03/26/2019	Approved by RIO/HRPA: 05/18/2014 Revisions approved by AIO/RIO: 4/16/2018 Revisions approved by AIO/RIO: 3/28/2019
Effective Date: 01/21/2019	
Related documents: *310: Researcher responsibilities, qualifications and training* *950: Protocol Review Agreements with External Entities Lacking an IRB*	

Policy

For non-exempt human subjects research that is Federally funded or funded by the American Heart Association, and received IRB approval prior to January 21, 2019, the IRB must be confident that the IRB protocol submission and the grant application are concordant prior to approving the research.

Exception: Concordance does not have to be declared for NIH Cooperative Group studies.

Procedures

1. Principal Investigator (PI) responsibilities:

    a. The GVSU PI must submit a copy of the entire grant, without appendices, with the IRB protocol submission.

    b. If the grant relates to more than one protocol, the GVSU PI must submit a statement declaring which protocols relate to the grant, and which portion(s) of the grant correspond with which protocols.

    c. The PI must identify any variation or discrepancy. If discrepancies between the grant and the protocol are identified, 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 IRB protocols that describe the proposed research; and (iii) either certify that the grant application or proposal is consistent with any corresponding IRB protocol(s) or submit protocol amendments to reconcile any discrepancies.

2. IRB Concordance Review Process
    a. IRB reviewers will review the following items to ensure concordance:
        i. Title
        ii. Grant number
        iii. Awardee
        iv. Sponsor
        v. Investigator and co-investigators
        vi. Study design
        vii. Appropriate staffing levels
        viii. Study objectives

ix. Research site

b. Final IRB approval for participant enrollment in the protocol will not be issued until concordance has been declared or non-concordance has been explained to the satisfaction of the IRB reviewers.

c. Protocols associated with potentially greater than minimal risk.

If a grant supports a protocol that is associated with potentially greater than minimal risk, the declaration of concordance must occur at a convened IRB meeting. All committee members will have the opportunity to review the entire grant, should they wish, prior to the convened meeting. Declarations of concordance made at a convened board meeting shall be recorded in the meeting minutes.

d. Protocols that pose no greater than minimal risk.

Declarations of concordance made using the expedited review procedure are limited to protocols that are federally funded but pose no greater than minimal risk to study participants, fit one of the DHHS categories of research for expedited review, and do not otherwise require full board review. Any such declarations will be recorded as part of the expedited review with the protocol in the Office of Research Compliance and Integrity's electronic database management system.

References

45 CFR 46.103(f);
45 CFR 46.102(j);
IRB Review of Applications for HHS Support (HHS memo dated May 31, 2000): (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/irb-review-applications-for-hhs-support/index.html)