



Scientific Assessment of Extramural Research

The purpose of this policy is to promote research excellence and scholarly activity conducted by individuals affiliated with Northwestern Health Sciences University (NWSU). This policy describes an internal review process for assessing the scientific merit and validity of extramural (research presented outside of NWSU) research.

A project qualifies as extramural research if it meets the federal guidelines for research:

- a) Involves the systematic gathering of information designed to develop or contribute to generalizable knowledge, and
- b) May either be presented outside of the University or published

Revision History

Originally issued: November 2017

Persons Affected

All Northwestern Health Sciences University faculty, staff and students engaged in extramural research.

Policy

In an effort to produce high quality, methodologically sound research, any extramural research must have undergone peer review. This applies to research done either at the University, or in conjunction with another institution. Note, this policy is prior to and independent of IRB review required of human subjects research.

EXEMPTIONS

- Exempt research reviewed by the IRB via expedited review
- Book chapters, journal articles, and other materials that undergo an editorial review process

Scientific Assessment

For all extramural research, investigators are required to provide documentation of scientific assessment and approval obtained by one of the three mechanisms described below.

For research involving human subjects, the approval shall be included in the application materials submitted to the NWSU IRB. Nonexempt research will not be processed by the IRB or assigned to an IRB meeting if scientific assessment has not been completed.

For research that does not involve human subjects, the approval shall be submitted to the Executive Director of Research and Innovation.

For all research, scientific assessment and approval must be obtained prior to commencing the research.



Scientific Assessment Mechanisms

1. **Research has received full peer review (e.g., review by a study section or grant committee) by a nationally or internationally-based, federal funding organization (e.g., NIH, NSF) or by a non-federal funding organization (e.g., March of Dimes, American Academy of Pediatrics)**

Required documentation:

- copy of the program announcement/funding opportunity/RFP, and
- notice of award by the funding agency, and
- copy of the approved research proposal/protocol

2. **Research has received scientific assessment and approval at another institution (e.g., other college or university) or by another organization (e.g., non-profit group, corporate partner).**

Required documentation:

- copy of approved research proposal/protocol, and
- copy of external IRB approval, if applicable

3. **Research has received scientific assessment conducted at NWSHU**

Required documentation:

- copy of approved research proposal/protocol, and
- approval notice from the Executive Director of Research and Innovation

NWSHU Scientific Review Committee

Internal review will be conducted by the NWSHU Scientific Review Committee (SRC). The SRC will consist of individuals with expertise in a range of scientific and methodological backgrounds, to ensure an informed review of applications and the ability to connect applicants with guidance and supporting resources as needed. The SRC will evaluate the scientific merit of a proposed study using the following criteria:

Is the scientific question reasonable?

- Is the question precisely articulated?
- Does the research have the potential to provide new and/or useful knowledge?
- Is the potential to provide useful knowledge supported by literature review?

Will the methods described in the protocol answer the question?

- Are the research tests and procedures appropriate to answer the scientific question?
- Are the research measures valid and reliable, or are there methods proposed to establish validity and reliability (when applicable)?
- Is the proposed subject population appropriate (when applicable)?
- Is the principal investigator qualified to conduct the research?
- Have adequate resources been secured to allow for the conduct and completion of this study?
- Is there a clearly articulated dissemination plan (e.g. presentations, publications, incorporation into curricula or clinic)

Review by a statistician is advised for all applicable research prior to scientific assessment conducted at NWSHU to establish that the study is powered to yield results.



Procedure

1. Determine which one of the three scientific assessments is applicable to your research.
2. If assessment by the NWHSU SRC (#3) is required, please submit a project proposal (template available) to the Executive Director of Research and Innovation.
3. Provide required documentation of scientific assessment to the IRB or Executive Director of Research and Innovation, as applicable.

For questions or additional information, please contact:

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