GUIDELINES FOR SCIENTIFIC REVIEW OF INVESTIGATOR-INITIATED RESEARCH

A. Introduction

Investigator-initiated research is frequently the most creative and cutting-edge type of human subject research. However, this type of research does not always undergo scientific peer review before submission to the IRB, particularly if it is not sponsored (i.e., funded). Therefore, it is the policy of the IRB that investigator-initiated research proposals must be submitted and undergo review for scientific merit to the Scientific Review Committee before submission to the IRB. The goal of this policy is to assure that the conduct of research conforms to the highest standards of research methodology, while most effectively minimizing risks to volunteer participants. Finally, consistent with the Institute of Medicine's 2002 Report: *Responsible Research: A Systems Approach to Protecting Research Participants*[1], this policy is designed to allow the IRB to focus its efforts primarily on ethics issues regarding human participant protections. While the IRB will continue to review issues of scientific design and participant safety as needed, that role will be a secondary one. The scientific review policy will enable those with the most relevant scientific expertise to have principal responsibility for assessing scientific merit.

B. Scientific Review Committee

The Scientific Review Committee (SRC) is an ad hoc committee that consists of faculty/staff reviewers that have appropriate expertise to evaluate the scientific merit of the research proposal. Reviewers should be in a position to conduct an objective review; therefore, it is IRB policy to not allow scientific reviews to be completed by a research team member. The review also may not be done by the Department Chairperson or Faculty Advisor.

The Director of Research Services serves as the Chairperson of the SRC, and is the liaison between the SRC and the investigator regarding any questions raised by the committee members.

If no member of the SRC has expertise relevant to the research proposal, a subject matter expert(s) may be recruited by the SRC from inside or outside the OSU community to assist in evaluating the scientific merit of the study. This expert will serve as a consultant.

The SRC will review studies predominately through email communication, but will meet as needed. Once the reviewer(s) has completed the scientific review, this person can sign the attached 'Scientific Review Verification Form'. This will confirm that the research proposal has been scientifically reviewed. The SRC Chairperson will promptly send the signed "Scientific Review Verification Form" to the investigator and to the IRB Administrator.

The research proposals and related documents will then undergo standard review by the IRB. All research proposals that are deferred by the IRB for lack of scientific merit or lack of risk/safety

monitoring will be returned to the investigator. These deferred research proposals may be required to have a new scientific review prior to re-submission to the IRB.

C. Nature of Required Scientific Review

Reviewers should be in a position to conduct an objective review of the research proposal for the following applicable elements[1]:

- Importance and novelty of the scientific question
- Strength of the scientific design and methodology
- Feasibility of the research as designed
- Appropriateness of the statistical analysis plan (including sample size, use of controls, randomization, population stratification, stopping rules, and the feasibility of relating endpoints to objectives)
- Estimate of the probability of meeting the recruitment goals
- Need for, and structure of, a Data and Safety Monitoring Board/Data Monitoring Committee (DSMB/DMC)
- Assessment of the thoroughness of the investigator's evaluation of the relevant literature and previous studies, if available
- Strength of the qualifications of the investigator to carry out the protocol and the facilities available to him or her
- Appropriateness of the inclusion/exclusion criteria
- Dissemination plan (to enrolled participants and through formal publication)

Reviewer(s) are asked to provide an opinion as to whether risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk AND whether risks to participants are reasonable in relation to anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result.

[1] adapted from National Research Council. *Responsible Research: A Systems Approach to Protecting Research Participants*. Washington, DC: The National Academies Press, 2002. Elements of Scientific Review, p. 77

Scientific Review Verification Form

This completed and signed form is to be submitted to the Institutional Review Board (IRB) office as an attachment to investigator-initiated research proposals.

Date:	
Department:	
Investigator:	
Study Title:	

The above referenced human research proposal was reviewed thoroughly and critically for the following applicable elements:

- ☐ Importance and novelty of the scientific question
- ☐ Strength of the scientific design and methodology
- ☐ Feasibility of the research as designed
- ☐ Appropriateness of the statistical analysis plan (including sample size, use of controls, randomization, population stratification, stopping rules, and the feasibility of relating endpoints to objectives)
- ☐ Estimate of the probability of meeting the recruitment goals
- ☐ Need for, and structure of, a Data and Safety Monitoring Board/Data Monitoring Committee
- ☐ Assessment of the thoroughness of the investigator's evaluation of the relevant literature and previous studies, if available
- ☐ Strength of the qualifications of the investigator to carry out the protocol and the facilities available to him or her
- ☐ Appropriateness of the inclusion/exclusion criteria
- ☐ Dissemination plan (to enrolled participants and through formal publication)

In signing here, I attest that it is my opinion that in this research study, as designed or with changes that I have requested, risks to participants are minimized by using procedures consistent with sound research design that do not unnecessarily expose participants to risk AND risks to participants are reasonable in relation to anticipated benefits to participants and the importance of the knowledge that may result.

Printed Name	Signature	Title	Department/Division

(Note: At least one scientific reviewer is required. The reviewer(s) listed in the table above may not be a member of the research team, the Department Chair, or the Faculty Advisor.)