

I.1.B: Department or Entity Scientific and Feasibility Review of Initial Submissions for IRB Review and Determination

Policy: This policy establishes the provisions under which all new protocols must be reviewed prior to submission to the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) for review and determination. All New submissions must be reviewed by the Principal Investigator's (PI) Primary Campus Entity prior to IRB determination.

- I. All new protocols submitted to the UMB IRB for review must first be reviewed for scientific merit, available resources, and feasibility by the primary campus entity.
- II. Each entity may develop its own mechanism for conducting the scientific review and must designate an appropriate individual ("Designated individual") to be responsible for overseeing the review process. This individual must be a Dean or Chair of his/her respective School or Department, or alternatively, a Vice-Dean or Vice-Chair for Research as indicated by the Dean or Chair.
- III. The electronic signature of the designated individual on the BRAAN protocol signifies that the protocol has passed entity-level review. Only protocols that have been signed off on by the designated individual can be submitted to the IRB via BRAAN. Only those protocols that pass entity-level review will be considered by the IRB.
- IV. It is the policy of the University of Maryland Baltimore (UMB) Institutional Review Board (IRB) to work in coordination with other Committees and external review resources to provide protections to research participants. (See [SOP I.2.D](#))
- V. All research submissions which involve the diagnosis, treatment, imaging, or prevention of cancer must be reviewed by the University of Maryland Marlene and Stewart Greenebaum Cancer Center (UMGCC) Clinical Research Committee (CRC).

Process and Rationale:

- VI. All New protocols submitted to the UMB IRB for review must first be reviewed for scientific merit, available resources (i.e., adequate number of qualified staff, adequate facilities, and availability of medical or psychological resources that participants may need as a consequence of the research), and feasibility by the primary campus entity and the Marlene and Stewart Greenebaum Cancer Center (UMSGCC) Clinical Research Committee (CRC) where applicable.
- VII. The following are considered campus entities for the purpose of this policy:
 - A. School of Medicine Individual Departments
 - B. Dental School
 - C. School of Law
 - D. School of Nursing

- E. School of Pharmacy
 - F. School of Social Work
 - G. Greenebaum Cancer Center
- VIII. Each entity may develop its own mechanism for conducting the scientific review and must designate an appropriate individual (“Designated individual”) to be responsible for overseeing the review process.
- A. The designated individual must be:
 - 1. A Dean or Chair of his/her respective School or Department, or
 - 2. A Vice-Dean or Vice-Chair for Research as indicated by the Dean or Chair, or
 - 3. Associate Deans for Research, or
 - 4. Appointed/approved by the Institutional Official.
 - B. The designated individual, also known as the signatory, acts on behalf of the Entity Head (Department Chair or Dean).
- IX. Designation of Responsible Individual & Documentation of Review Mechanism
- A. The head of each Campus Entity (Dean, School of Medicine Department Chair, or Center Director) must submit a brief letter, addressed to the Institutional Official, outlining the mechanism for review and indicating the designated individual who will oversee the review process.
 - B. Each entity is responsible for developing a mechanism for documenting the substance and content of entity-level review.
 - C. The Institutional Official and the Human Protections Administrator (HPA), who is also the Executive Director of the Human Research Protections Program (HRPP), must be provided with written updates whenever information concerning the review mechanism or the designated individual changes.
- X. Purpose of Scientific and Feasibility Review
- A. At a minimum, the review should address the following questions/issues:
 - 1. Is the research question meritorious?
 - 2. Is the study design sound/valid?
 - 3. Is the study design able to answer the proposed questions and is it likely to result in significant new information for the field?
 - 4. Is the sample size adequate to answer the major scientific questions in the project?
 - 5. Have all potential risks been identified?
 - 6. Does the protocol incorporate all possible mechanisms for reducing risks?
 - 7. Are there adequate resources (i.e., adequate number of qualified staff, adequate facilities, availability of medical or psychological resources that participants may need as a consequence of the research, and adequate access to patients/participants) to carry out the study and ensure the safety and welfare of all participants?
 - 8. Are all investigators aware of their individual responsibilities with respect to this study?
 - 9. Does the principal investigator have adequate time and expertise to

- supervise the study appropriately?
10. Have the financial implications of the research been considered and deemed acceptable to the department?
 11. Have ethical principles AND CONFLICT OF INTEREST ISSUES been appropriately addressed?
 12. Confirmation that the protocol has been reviewed and approved at the unit level for scientific value, validity of study design, and feasibility.

XI. Documentation of Scientific and Feasibility Review

- A. The electronic signature of the designated individual on the BRAAN protocol will indicate that:
 1. The responsible entity has endorsed the study and agrees to take full oversight responsibility for the study if it is implemented
 2. The protocol has passed entity-level review.

The protocol can be submitted to the IRB via BRAAN for review and determination by the IRB.