1.9 Resources Necessary to Protect Subjects

1.0 Purpose

The purpose of this policy is to describe the Organization’s requirements for resources that are necessary for human subject protection, care of research participants, and safety during the conduct of research.

2.0 Policy

It is the policy of the Organization that

- 2.1. There must be adequate resources to protect human subjects during the conduct of research.
- 2.2. The Principal Investigator is responsible for ensuring the necessary resources are available to protect the rights and welfare of human subjects.

3.0 PI Responsibilities

- 3.1. The PI must describe in the IRB application resources that are available to safely conduct research at each study site specified in the IRB application. Such resources include (but are not limited to):
  - 3.1.1. The PI and all investigators have the necessary qualifications, experience and credentials to conduct the research.
  - 3.1.2. There are an adequate number of qualified, licensed and credentialed research personnel available and assigned to conduct the research.
  - 3.1.3. The PI has adequate time (in consideration of other academic or employment obligations, and other research protocols in which they are participating) to conduct and complete the research.
  - 3.1.4. The PI has, or will have, necessary the financial resources to conduct the research.
  - 3.1.5. There is adequate physical space, clinical resources (as appropriate), laboratory equipment (as appropriate), clerical and administrative support, data analysis and storage capability, and other resources necessary to complete the research.

    - 3.1.6. There is appropriate emergency equipment, personnel, or services necessary to respond promptly to adverse events or unanticipated problems involving risk to the subject or others.
    - 3.1.7. For research protocols conducted solely by the Organization, investigators have ethical access to a sufficient number of potential subjects to meet the scientific aims of the research.
    - 3.1.8. As appropriate based on the nature of and potential risks associated with the research, there are adequate available medical or psychosocial resources (for example, medical services, counseling, social support services).
    - 3.1.9. As appropriate, there are adequate resources necessary to facilitate communication with individuals who do not speak English or who have additional needs or vulnerabilities.
- 3.2. Submission of the application by the PI constitutes an assurance that resources described in the application are, or will be, available for the expected duration of the protocol.
- 3.3. The PI must notify the IRB if, during the course of the research, there are significant changes in the availability of researchers or if the necessary resources become unavailable.

4.0 IRB Responsibilities

- 4.1. In accordance with HRPP policy 2.5 (Criteria for IRB Approval) the IRB or expedited reviewer will review resources available as described in the IRB application at initial submission and at continuing review.
- 4.2. Significant changes in availability of resources reported by the PI or research team will be reviewed by the IRB to determine if ethical and regulatory criteria for approval continue to be met, and if the research can continue to be safely conducted. If the necessary resources cannot be obtained and adequate protection of human subjects cannot be assured, the IRB may suspend or terminate the research, in accordance with HRPP policy 8.6 (Study Hold, Suspension, and Termination).

DOCUMENT HISTORY:

? Written: 5/6/2016 (Approved: 5/6/2016) - original author not documented

? Revised: 9/27/2017 - revision not documented

? Revised: 3/3/2018 - revision not documented

? Revised 1/16/2025 – deleted requirement for certification by Departmental Chairperson/authorized delegate or appointed review committee that resources are available; added that PI or research team must report significant changes in the availability of resources (section 3.3); added that significant changes in availability of resources reported by the PI or research team will be reviewed by the IRB; stylistic changes. {Approved Rusty McCulloh (Institutional Official), Bruce Gordon (Assistant Vice Chancellor for Regulatory Affairs, Executive Chair)}

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