

1.9 Resources Necessary to Protect Subjects

1.0 Purpose

The purpose of this policy and procedure 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

- **2.1.** It is the policy of the Organization that during the conduct of research there must be adequate resources to protect human subjects
 - **2.2.** It is the policy of the Organization that the Principal Investigator is responsible for ensuring the necessary resources are available to protect the rights and welfare of human subjects.
 - **2.3.** It is the policy of the Organization that Departmental Chairperson/authorized delegate or appointed review committee of the Principal Investigator's school, department or division must certify that the necessary resources are available to conduct and complete the study in a manner which fully protects the rights and welfare of research subjects
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3.0 PI and Certifier Obligation

- **3.1.** The PI is required to sign an assurance (that is part of the IRB application) stating that there are adequate resources to protect the rights and welfare of subjects. These resources include (but are not limited to):
 - **3.1.1.** The PI has the necessary qualifications, experience and credentials to conduct the research.
 - **3.1.2.** There is an adequate number of qualified, licensed and credentialed research personnel and facilities/equipment to complete the research.
 - **3.1.3.** The PI has adequate time (in consideration of other academic or employment obligations, and other open research protocols in which he/she is participating) to conduct and complete the research.
 - **3.1.4.** The investigator has, or will have, necessary the financial resources to conduct the research.
 - **3.1.5.** There is adequate physical space, laboratory equipment, clerical support, data 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 other
 - **3.1.7.** Investigators have ethical access to a sufficient number of potential subjects for the purposes of the research.
 - **3.1.8.** There are adequate available medical or psychosocial resources in consideration of the nature of the research (for example, medical services, counseling, social support services), and resources necessary to facilitate communication with individuals who do not speak English or who have other impairments.
 - **3.2.** The Departmental Chairperson/authorized delegate or appointed review committee of the PI's school, department or division must also certify (as part of the IRB application) that the resources described above, and any others necessary to fully protects the rights and welfare of research subjects, are available to the PI and research staff.
 - **3.3.** The PI is required to notify the IRB if, during the course of the research, the necessary resources become unavailable. 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).
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4.0 IRB Review of Resources

- **4.1.** The IRB will review resources available as part of its review of the research at initial submission and at continuing review.
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