

**UNIVERSITY OF KANSAS
WATKINS HEALTH SERVICES
ADMINISTRATION**

NUMBER: AD-402	ISSUE DATE: 02/03
TITLE: Clinical Research	REVISED: 08/08
TITLE OF OWNER/AUTHOR: Assistant Director	APPROVED: Director

PURPOSE: To define the criteria for selecting, conducting, and documenting research utilizing the resources of WHS.

POLICY: WHS will support the academic mission of the University by participating research that is consistent with our clinical capabilities and mission.

PROCEDURES:

1. Proposal

Research proposals must:

- 1.1. Provide a research/educational opportunity for KU students and/or faculty and staff and contribute to a field of knowledge that is relevant to student health.
- 1.2. Require no more than 5% of the time of the WHS Employee(s) involved in the project.
- 1.3. Be sufficiently funded from external sources to support any and all expenditures associated with the research.

2. Selection

Research proposals meeting the above criteria must:

- 2.1. Be endorsed by the Supervisor of the WHS Employee requesting to be involved in the research project.
- 2.2. Be presented to WHS Administration where the following will take place:
 - 2.2.1. Review impact on primary mission (patient care/education)
 - 2.2.2. Review funding
 - 2.2.3. Establish charges
 - 2.2.4. Coordinate with other WHS research projects
- 2.3. Be reviewed by the WHS Privacy Officer to identify and clarify the appropriate means for the use and disclosure of PHI associated with the research project.
- 2.4. All projects approved by WHS Administration must conform to University requirements and be performed in accordance with ethical and professional practices and legal requirements.

3. Participation

Provisions are made to ensure that the rights and welfare of all research subjects are adequately protected, that participation is totally voluntary and that informed consent is obtained by adequate and appropriate methods.

4. Documentation
 - 4.1. Research records must be clearly identified in the patient record or maintained in a separate chart. Records must include a copy of subject's consent.
 - 4.2. Research records will be secured, stored and destroyed in accordance with University policy and state and federal laws.
 - 4.3. Research records are excluded from the DRS for the duration of the study.
5. Use and Disclosure of PHI for Research
Contact WHS Privacy Officer prior to disclosing PHI for purposes of research.
6. Auditing
The financial status of research studies listing a WHS Employee as a principal investigator will be regularly reviewed and audited by WHS Administration.
7. Reporting
 - 7.1. WHS Employee will provide a report every six months to WHS Administration on the status of the project.
 - 7.2. WHS Employee will provide a summary report to WHS Administration within six months of completion of the research project.
8. All research projects will be maintained by the HERO Program Manager/Grant Coordinator through, but not limited to the following:
 - 8.1. Researching, planning, preparing, submitting, and management of grants and/or stipends.
 - 8.2. Communication with Human Subjects Committee of Lawrence (HSCL), KU Center of Research, Inc. (KUCR), Office of Institutional Research and Planning (OIRP), and any other necessary offices.
 - 8.3. All files and documents pertaining to research projects will be located in the office of the HERO Program Manager/Grant Coordinator.

REFERENCE:

AD-402-1 Request to Review Data Pertaining to Decedents

AD-402-2 Request to Review Data for Pre-Research

This document is on file with the KU Policy Library.