Human Research Protection Program: Policy

Principal Investigator Status for UW-Madison Human Subjects Protocols

Adopted By: Human Research Protection Program Advisory Committee
Adoption Date: July 10, 2008
Revised: December 4, 2008

Purpose: This policy defines who may act as Principal Investigator on a UW-Madison human subjects protocol.

Policy

I. To qualify as a principal investigator (PI) on a human subjects protocol, individuals must have a UW-Madison appointment and be working within the scope of that appointment in performing the research.

II. Additionally, individuals must fall into one of the following categories below:

A. Individuals with a UW-Madison faculty appointment (generally, a 50% or more appointment). This includes faculty with a full-time UW-Madison position but who hold a $0 UW-Madison appointment only because their position is funded by the federal government.

B. Individuals with a UW-Madison Clinical/Health Sciences (CHS) appointment.

C. UW-Madison unclassified staff (academic staff and limited appointees) who have obtained approval of their Chair/Director using the attached form “Request for Approval to Serve as Principal Investigator on a Human Subjects Protocol” (This includes Emeritus professors).

D. UW-Madison postdoctoral scholars, visiting faculty, or visiting academic staff who have obtained approval of their Chair/Director using the attached form “Request for Approval to Serve as Principal Investigator on a Human Subjects Protocol”.

E. UW Hospital and Clinics’ (UWHC) employees with the approval of their supervising UWHC Vice President.

F. Individuals who have an appointment at the William S. Middleton VA Hospital with approval of the VA Research & Development Committee.

G. Physician staff at UW Comprehensive Cancer Center (UWCCC) outreach clinics who hold a UW-Madison appointment (subject to an IRB Authorization Agreement).

II. Individuals who do not meet the above requirements may qualify as co-investigators or key personnel if an individual as described in Section I.A – G. above is listed as PI.

III. Exception: When approved by a UW-Madison IRB, a UW-Madison faculty member who leaves the university but maintains a 0% or other small percentage appointment with UW-Madison may remain as PI on a human subjects protocol for one year to complete the research or transition the research to a new PI.

IV. A reviewing IRB may determine that an individual does not qualify for PI status on a human subjects protocol, even though the individual meets the criteria in Sections I or III, above, if the IRB determines that the research is more than minimal risk and subject safety may be compromised due to existing circumstances (such as the individual’s lack of training or expertise or physical location in proximity to research subjects). In such cases, the individual may qualify as a co-investigator or key personnel.

Request for Approval to Serve as Principal Investigator on a University of Wisconsin-Madison Human Subjects Protocol

This form is to be used by individuals with a UW-Madison appointment to request approval from their chairs/directors to serve as principal investigator (PI) on a UW-Madison human subjects protocols per UW-Madison's policy entitled "Principal Investigator Status for UW-Madison Human Subjects Protocols" [http://www.grad.wisc.edu/hrpp/10235.htm]. This form is <u>not</u> to be used to request permanent or limited PI status for grant purposes.

Name: _____
Title: _____
Highest Degree Earned: _____ Year: _____
Department/Center: _____
College/School: _____

Approval requested for a period of ____ (up to three) years.

Justification: Please indicate why this individual is an appropriate candidate to serve as the PI on human subjects protocols and provide information about his/her experience and qualifications for providing oversight on a research protocol involving human subjects, addressing, at a minimum:

1. Experience serving as Co-PI or collaborator on human subjects protocols; and
2. Demonstrated ability to carry out the responsibilities of PI, including meeting administrative management of protocols.
3. Include any recommendations for limitations, such as, that the individual should be permitted to serve as PI only for minimal risk protocols as determined by the IRB

Approval Signature Chair/Center Director: _____