HUMAN STUDIES[1]

What regulatory approvals are necessary to conduct research at Penn State Hershey Medical Center?*

rev. April 2010

[2]If your research involves …	**Human Subjects** Studies that involve human participants, human tissues, human fluids, or the collection/use of human information.	**Potential Conflict of Interest**	**Biohazards[3,4] and/or Recombinant DNA**	**Radioisotopes/Ionizing Radiation/Lasers**	**Investigational Drug/Device (IND/IDE)**
… you must submit a protocol for approval to the …*	Institutional Review Board	Conflict of Interest Review Committee	Biosafety and Recombinant DNA Committee (BRDC)	Subcommittee on Human Use of Radioisotopes[5]	Food and Drug Administration
The form is called the …	PRAMS e-submission	Financial Interest Disclosure	Assurances Form	IRB Application-Supplement Radiation Review Form	FDA 1571 (IND) 21CFR812.50 (IDE)
This form may be obtained from the …	IRB Web site PennStateHershey.org/irb	Faculty Affairs Web site PennStateHershey.org/web/administration/home/conflict	Department of Safety Web site infonet.hmc.psu.edu/safety/biological/rDNA/index.htm	IRB Web site PennStateHershey.org/irb	FDA Web site www.fda.gov
This form must be submitted and approved prior to …	initiating any study involving humans	final IRB approval	initiating the study	IRB review	initiating any study involving an investigational drug or device
Protocol re-approval will be required …	at least every year	depending on the committee's determination	every other year	in the form of quarterly reports	as an annual report
For more information, contact …	Kathy Hay, Ph.D. x5687 khay@hmc.psu.edu	Don Martin, M.D., x6140 dmartin1@psu.edu Neal Thomas, M.D., x5337 nthomas@psu.edu	Ralph L. Keil, Ph.D. x8595 rkeil@psu.edu	Steve King, M.S. x8765 sking@psu.edu	Kathy Gifford x5687 kgifford@psu.edu

1 Studies that involve human participants, human tissues, human fluids, or the collection/use of human information.

2 If your research involves materials from more than one category, you should submit your approval forms for use of biohazards, radioisotopes or hazardous chemicals prior to your submission to the IRB or IACUC.

3 Infectious agents, select agents and toxins, unfixed human or animal cells or tissues.

4 Biosafety requirements apply to all human tissues, in addition to requirements mandated by human subjects protection and processes for obtaining samples. For more details, visit PennStateHershey.org/web/irb.

5 Also need an Authorization to Procure and Use Radioactive Material form.

* All approvals are contingent on completion of the appropriate safety training. Also be sure to follow your department's and institute's policy for pre-submission approval or scientific review.

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