

These suggestions for questions for IRB discussion are taken from the NIH site for its INTERNAL IRB boards (<http://ohsr.od.nih.gov/irb/protocol.html>).

IRB PROTOCOL REVIEW STANDARDS		
(modified slightly from NIH web site by Rob Scarrow)		
Regulatory review requirement	Check	Suggested questions for IRB discussion
1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.		(1a) Is the hypothesis clear? Is it clearly stated? (1b) Is the study design appropriate to prove the hypothesis? (1c) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result.		(2a) What does the IRB consider the level of risk to be? (See risk assessment guide on next page) (2b) What does the PI consider the level of risk / discomfort / inconvenience to be? (2c) Is there prospect of direct benefit to subjects? (See benefit assessment on next page.)
3. Subject selection is equitable.		(3a) Who is to be enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously-ill persons? Healthy volunteers? (3b) Are these subjects appropriate for the protocol?
4. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.		(4a) Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired?
5. Informed consent is obtained from research subjects or their legally authorized representative(s).		(5a) Does the informed consent document include the eight required elements? (<i>see page 3</i>) (5b) Is the consent document understandable to subjects? (5c) Who will obtain informed consent (PI, nurse, other?) & in what setting? (5d) If appropriate, is there a children's assent? (5e) Is the IRB requested to waive or alter any informed consent requirement?
6. Risks to subjects are minimized.		(6a) Does the research design minimize risks to subjects? (6b) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?
7. Subject privacy & confidentiality are maximized.		(7a) Will personally-identifiable research data be protected to the extent possible from access or use? (7b) Are any special privacy & confidentiality issues properly addressed, e.g., use of genetic information?
Additional considerations (probably rare for Haverford cases):		
A1. Ionizing radiation.		A1. If ionizing radiation is used in this protocol is it medically indicated or for research use only?
A2. Collaborative research.		A2. Is this domestic/international collaborative research? Are assurances in place? Is there a CRADA?
A3. FDA-regulated research		A3. Is an IND or IDE involved in this protocol?

Risk/Benefit Assessment

RISK

Regulatory definition of minimal risk: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests ([45 CFR 46.102\(h\)\(i\)](#)).

Check appropriate risk category:

R1. _____ The research involves no more than minimal risk to subjects.

R2. _____ The research involves more than minimal risk to subjects.

R2a _____ The risk(s) represents a minor increase over minimal risk, or

R2b _____ The risk(s) represents more than a minor increase over minimal risk.

BENEFIT

Definition: A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences.

Check appropriate benefit category:

B1. _____ no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition (mainly for patient subjects);

B2. _____ no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge to further society's understanding of the disorder or condition under study (mainly for healthy volunteers); or

B3. _____ the research involves the prospect of direct benefit to individual subjects.