IRB Protocol Review Standards

Minimal regulatory requirements for IRB review, discussion and documentation in the meeting minutes

Regulatory review requirement	*Suggested questions for IRB discussion*
__YES __NO *1. The proposed research design is scientifically sound & will not unnecessarily expose subjects to risk.*	*(a) Is the hypothesis clear? Is it clearly stated?* _____ _____ _____ *(b) Is the study design appropriate to prove the hypothesis?* _____ _____ _____ *(c) Will the research contribute to generalizable knowledge and is it worth exposing subjects to risk?* _____ _____ _____
__YES __NO *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.*	*(a) What does the IRB consider the level of risk to be? (See risk assessment guide on the next page.)* _____ _____ _____ _____ *(b) What does the PI consider the level of risk/discomfort/ inconvenience to be?* _____ _____ _____ _____ *(c) Is there prospect of direct benefit to subjects? (See benefit assessment guide on the next page.)* _____ _____ _____ _____
__YES __NO *3. Risks to subjects are minimized.*	*(a) Does the research design minimize risks to subjects?* _____ _____ _____ *(b) Would use of a data & safety monitoring board or other research oversight process enhance subject safety?* _____ _____ _____

__**YES** __**NO**

4. Subject selection is equitable.

(a) Who is to be enrolled? Men? Women? Ethnic minorities? Children (rationale for inclusion/exclusion addressed)? Seriously-ill persons? Healthy volunteers?

_____
_____
_____

(b) Are these subjects appropriate for the protocol?

_____
_____
_____

__**YES** __**NO**

5. Informed consent is obtained from research subjects or their legally authorized representative(s).

(a) Does the informed consent document include the eight required elements?

_____
_____
_____

(b) Is the consent document understandable to subjects?

_____
_____
_____

(c) Who will obtain informed consent (PI, nurse, other?) & in what setting?

_____
_____
_____

(d) If appropriate, is there a children's assent?

_____
_____
_____

(e) Is the IRB requested to waive or alter any informed consent requirement?

_____
_____
_____

__**YES** __**NO**

6. Additional safeguards required for subjects likely to be vulnerable to coercion or undue influence.

(a) Are appropriate protections in place for vulnerable subjects, e.g., pregnant women, fetuses, socially- or economically-disadvantaged, decisionally-impaired?

_____
_____
_____
_____
_____

__**YES** __**NO**

7. Subject privacy & confidentiality are maximized.

(a) Will personally-identifiable research data be protected to the extent possible from access or use?

_____
_____
_____

(b) Are any special privacy & confidentiality issues properly addressed, e.g., use of genetic information?

_____
_____
_____
_____

Additional considerations

__YES __NO *1. Ionizing radiation.*	*If ionizing radiation is used in this protocol is it medically indicated or for research use only?* _____ _____ _____
__YES __NO *2. Collaborative research.*	*Is this domestic/international collaborative research? If so, are SPAs or other assurances required for the sites involved?* _____ _____ _____
__YES __NO *3. FDA-regulated research*	*Is an IND or IDE involved in this protocol?* _____ _____ _____
__YES __NO *4. Other*	*Other comments/questions/concerns?* _____ _____ _____ _____ _____