IRB Protocol Review Standards

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*	_____ _____ _____ _____ *(c) Is there prospect of direct benefit to subjects? (See benefit assessment guide on the next page.)* _____ _____ _____ _____
__YES __NO	_____ *(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 *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?* _____ _____ _____ _____ _____