IRB Informed Consent Checklist

Indicate whether the informed consent process provides the required basic elements of information to subjects:

	Yes	No	Comments
1. Statement that the protocol involves research and includes: • Purpose of research • Expected duration of subject's participation • Description of procedures to be followed and identifies those that are experimental			
2. A description of any reasonably foreseeable risks or discomforts to the subject.			
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.			
4. Appropriate alternative procedures, if any, that might be advantageous to subjects.			
5. How confidentiality of records identifying the subject will be maintained. • Disclose all infringements upon privacy or confidentiality which may result from participation in the research.			
6. If research is more than minimal risk, whether any compensation is available.			
7. Contact information for the research team to: • Obtain answers to questions about the research. • Voice concern or complaints about the research.			
8. Contact information for a person independent of the research team: • To obtain answers to questions about the research. • To voice concerns or complaints about the research. • In the event the research staff could not be reached. • In the event they wished to talk to someone other than the research staff.			
9. Statement that participation is voluntary, that there are no penalties if subject refuses to participate and that subject can withdraw at any time without penalty.			

If appropriate to the research, indicate whether the informed consent process provides the following 6 additional elements of information (indicate why inclusion of this element is appropriate):

	Yes	No	Comments
1. That some risks to subject may be unforeseeable.			
2. Outlines the circumstances where a subject's participation may be terminated by PI without regard to subject's consent.			
3. Whether there are any costs for which subjects will be responsible.			
4. The consequences of a subject's decision to withdraw (safety issues).			
5. That new and significant findings, which may affect subject's willingness to continue, will be disclosed.			
6. The approximate number of subjects involved in the research at the institution and nationally.			