Final IRB Proposal Checklist

A complete proposal will contain all of the items in the checklist below (as applicable to the study). IRB members use this checklist in their review of all submitted proposals. To expedite the review process, double check your proposal to ensure that each of the items listed below has been addressed in adequate detail.

COMPLETE IRB APPLICATION	
	Cover page
	Proposal narrative (includes parts I through V)
	Exemption claim form or Expedited review form (if required)
	Additional materials appropriate to the study (i.e., recruiting materials, questionnaires, interview schedules, etc.)
	Consent/Assent forms as appropriate to the study
	Other documentation as appropriate to the study (i.e., related grant proposal)
I.	RATIONALE
	Description of the problem
	Description of the state of present knowledge relevant to the problem
	Aims of the proposed study
	Potential benefits of the work to the subjects involved
	Importance of the knowledge to be obtained
	Adequate detail justifying the level of potential risk
II.	SUBJECTS
	Description of the specific population of human subjects involved
	Number of subjects is identified
	Salient characteristics of subjects are addressed
	Inclusion/exclusion criteria identified
	Recruitment methods are identified
	Appendices as appropriate to the study are attached
III.	PROCEDURES
	Description of step-by-step procedures involving all subjects
	Explain what the subjects do or what is done to them
	Indicate the number of observations that will be made
	Explain how confidentiality will be maintained
	Identify and assess all potential risks, if any, with an estimate of their frequency, severity, and reversibility
	Narrative includes any precautions that will be taken to avoid such risks (including breeches of confidentiality), and actions to be taken if these risks materialize
	Description of any inducement or compensation for subject participation
IV.	ADVERSE EVENTS AND LIABILITY
	Steps to be taken to deal with unexpected adverse events
	Arrangements for handling liability for unexpected injuries
	No specific liability plan is offered and it is stated in Section IV of the proposal
V.	INFORMED CONSENT
	Basic Elements
	Statement that the study involves research
	Explanation of the purposes of the research
	Expected duration of the subject's participation
	Description of the procedures to be followed
	Identification of any procedures which are experimental

	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to the subject or to others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
	A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
	Additional Elements
	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
	The approximate number of subjects involved in the study
	Assurance of Understanding
	Explanation of how the researcher will ascertain that the subjects understand what they are agreeing to do