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
Additional materials appropriate to the study (i.e., recruiting materials, questionnaires, interview schedules, etc.)
Consent/Assent forms as appropriate to the study (usually not needed for exempt)
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 (Typically not required with exempt protocols)
Basic Elements
Statement explaining why the subject would want to participate in the study
Statement explaining why the subject would NOT want to participate in the study
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