

INSTITUTIONAL REVIEW BOARD CHECKLIST FOR A STANDARD NEW APPLICATION

SUBMIT THE FOLLOWING TO THE GRANTS AND CONTRACTS OFFICE (GCO):

- All necessary GCO pages (including Page 1 signed by Chair)
- This completed checklist
- Clarification memorandum explaining any special issues or circumstances, particularly if the project consists of more than one sub-project, phases, etc, is related to another project, is identical to another project under another funding source, or other issues the Principal investigator (PI) would like to call to IRB attention.
- IRB form 1 – “Protocol Summary”
- IRB form 2 – Consent Document
(A prototype of a Consent Document can be found in Section IV of Guidelines Manual. Also see checklist for consent document.) If consent will not be obtained, please submit appropriate waiver forms (see below or provide an explanation in a memorandum)
- IRB form 3 - Drug information Form (if applicable). This sheet must be signed by the PI and the Director of pharmacy at the time of logging the projects in to the GCO.
- IRB form 4 - Assurance page
Top section: *Informed Consent Authorization and Assurance* (Fill in the names of those fully trained and delegated by the PI to obtain informed consent)
Bottom section: *Programmatic Assurance* (Include the signatures of the PI and Co-investigators to indicate that they take responsibility for the research)
- IRB form 7 – Request for Waiver of Informed Consent, if applicable
- IRB form 8 – Request for Waiver of Signed Consent, if applicable
- IRB form 20 – Device form, if applicable
- Working Research Protocol (*If a formal application/grant to an outside funding source has been prepared, that protocol will be reviewed by the IRB; however, PIs should also create a “working protocol” that can be modified as necessary and contain all of the elements below:*)
All documents serving as protocols should contain the following elements:
 - a)** Project Abstract (underline up to 10 key words)
 - b)** Specific Aims: (purpose of study)
 - c)** Significance/Background
 - d)** Preliminary Data (if available)
 - e)** Research Design and Methods (Protocol). Include the following information:
 - (1)** what will be done to the subjects during the study:
 - (a)** specify what will be done for research purposes as opposed to what will be done as part of standard clinical care;
 - (b)** describe all tests and procedures that will be performed for research purposes;
 - (c)** itemize the analyses that will be performed on biologic or nonbiologic samples collected;
 - (d)** describe the investigational drugs to be administered and/or investigational devices to be used;
 - (e)** indicate the financial responsibilities of subjects vs. what will be provided without cost to the subjects; and
 - (f)** provide an assessment of the risk/benefit ratio of participating in the research. Summarize literature or data that provides information

about potential risks.

(2) number of subjects to be enrolled;

(3) characteristics of the subject population (e.g., gender, age, racial and ethnic origin). Justify exclusion of specific gender, age, and racial or ethnic groups. Indicate if vulnerable subjects will be enrolled (individuals with diminished mental capacity, children, pregnant women, fetuses, economically or educationally disadvantaged persons, prisoners)

(4) inclusion and exclusion criteria;

(5) source of research material(s) (e.g., blood, urine, biopsy or pathology specimens, medical records, computerized or other data bases, etc.) and mechanism of storage and information on the security measure taken to protect the research data;

(6) whether research material will or will not be identifiable to subject's name (either directly or by code);

(7) where and when informed consent will be obtained (e.g. preadmission screening, day-of-admission waiting room, emergency room, clinic, medical office, etc.);

(8) how subjects will be identified and recruited;

(9) indicate if the study will be monitored. If monitored, indicate the frequency of monitoring, who will do the monitoring (e.g. regulatory monitors, an external data and safety monitoring board (DSMB), a DSMB composed of local individual(s) unaffiliated with the study and to whom the monitors will report (e.g. NIH, FDA, industry sponsor, IRB);

(10) indicate if biologic samples (e.g. tissue, blood, urine, DNA, etc.) will be banked. If banked, indicate whether samples will be banked indefinitely or for a specified period of time. Indicate whether the samples will be labeled with any identifiers (direct or indirect links to the subject), will be anonymous, or whether the samples will be anonymized (all identifiers will be deleted leaving no means of ever linking the sample back to the subject); and

(11) indicate if data will be stored in computerized database. If stored, indicate whether individual subjects will be identifiable or whether identifiers will be removed and the information anonymized when entered into the database.

- Grant/application to an extramural agency (e.g. NIH, a Foundation).
- Investigator's Brochure or equivalent information for studies using drug(s) that require an IND, if applicable
- HIPAA forms applicable to the project (authorizations, waivers, etc.)
- Other relevant documents or forms as applicable (e.g. retrospective specimen form, IND application to FDA for investigator-initiated project) Please list the names of the other forms submitted:
- Advertisements/publicity that will be used to recruit participants (print, audio, video, WEB based, etc.), if applicable
- Copies of Subject Surveys and/or Questionnaires, if applicable
- Approval letter from affiliate review committees (e.g. Elmhurst/Queens/Bronx VA), if applicable and available

Note: Assistance for completion of these forms may be obtained from the IRB Administrators, East Bldg., 4-78, ext. 88980