

## IRB CHECKLIST FOR CONTINUATION APPLICATIONS

### SUBMIT THE FOLLOWING TO THE GRANTS AND CONTRACTS OFFICE ALONG WITH THEIR CONTINUATION SUBMISSION REQUIREMENTS:

- This completed Checklist
- Clarification memorandum explaining any changes being made to the project, any special issues or circumstances the PI would like to call attention to, particularly if the project consists of more than one sub-project or phase. Please include a statement on the status of the project (e.g. study remains open for enrollment; study is closed to enrollment with subjects continuing to receive study medication and follow-up; study is closed to enrollment and open for follow-up only (the follow-up activities to be conducted are...); study is closed to enrollment and open only for data analysis).
- Progress Report (memorandum): This report **must** include **all** of the following information:
  - (1) indicate whether or not any subjects withdrew from the study. If any subjects withdrew, indicate why this happened;
  - (2) indicate whether or not any complaints were received about the research; and
  - (3) provide a summary of:
    - (a) relevant recent literature (includes any reports/findings that may impact our understanding of the risks & benefits of this research)
    - (b) findings obtained to date (if any)
    - (c) amendments and/or modifications since the last IRB review and justifications for these changes
    - (d) reports of the parent or multi-center trial (if applicable)
    - (e) any risks or information about risks identified since the last IRB review
- Data and Safety Monitoring Board reports, if applicable. If the report is not available at the time of submission, it remains the responsibility of the PI to submit the DSMB report promptly after it has been received.
- IRB form 1 - Protocol Summary for New and Continuing Protocols. The **ONLY** exception to the requirement for submission of a protocol summary is if the PI indicates in a memo to the IRB that all 3 of the following pertain:
  - a) the research is permanently closed to enrollment of new subjects; **AND**
  - b) all subjects have completed all research-related interventions; **AND**
  - c) the research remains active only for:
    - (1) long-term follow-up of subjects (simple record review only)
    - OR**
    - (2) data analysis.
- IRB form 2- If a Consent document will need to be used during the next approved period, submit:
  - IRB form 2 –Consent Document(s), with any proposed changes from the previously approved version, with those changes underlined
  - IRB form 2 –Consent Document(s), with any proposed changes from the previously approved version without any underlining (“clean version”)
  - Copy of the previously approved stamped consent form.
- IRB form 3 - Drug Information Sheets (*only if modifications need to be made to previous form for it to be currently accurate and complete-- must be re-signed by Pharmacy*), if applicable
- 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 Coinvestigators to indicate that they take responsibility for the research)
- IRB form 5 – Annual Human Subject Adverse Event Report
- IRB form 6 – Annual Human Subject Enrollment Form
- IRB form 7 – Request for Waiver of Informed Consent, if applicable, newly signed
- IRB form 8 – Request for Waiver of Signed Consent, if applicable, newly signed

- IRB form 20 – Device Form, *(only if modifications need to be made to previous form for it to be currently accurate and complete-- must be re-signed by any required departmental representative)*, if applicable
- Most recent version of the Working Research Protocol and grant application to an extramural agency (if applicable) (e.g. NIH, a Foundation) that incorporates modifications that have already been approved as well as new modifications. The **ONLY** exception to the requirement for submission of a working protocol is if the PI indicates in a memo to the IRB that all 3 of the following pertain:
  - a)** the research is permanently closed to enrollment of new subjects; **AND**
  - b)** all subjects have completed all research-related interventions; **AND**
  - c)** the research remains active only for:
    - (1)** long-term follow-up of subjects (simple record review only)
    - OR**
    - (2)** data analysis.
- Most recent version of Investigator's Brochure (for industry sponsored research) with the version designated, if applicable; If there have been any modifications, also submit Form 27 (CIB Change Form)
- Any other IRB form that is applicable
- A copy of HIPAA Authorization forms approved last year (if applicable), new authorization forms if any changes have been made (along with an explanation of changes) and any new requests for waivers or alterations
- Advertisements/publicity that will be used to recruit participants (print, audio, video, WEB-based, etc.), if applicable; Advertisements put through the Sinai Central website should be renewed there.
- Copies of Subject Surveys and/or Questionnaires, if applicable
- Approval letter from affiliate review committees (e.g. Elmhurst/Queens/Bronx VA), if applicable
- Receipt Form, optional

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