DREXEL UNIVERSITY
Office of
Research &
Innovation

**Self-Assessment Checklist Instructions**

The Self-Assessment Checklist can be used to assist study sites with maintaining regulatory compliance. Please note, not all sections of the checklist may apply to your study. You have the option of completing each section individually or going through the entire checklist. Do not leave blank responses for sections that apply to your study. If 'No' is answered to any of the questions, report a violation/deviation according to IRB policy or file a note-to-file to document the reason for indicating 'no.'

Once you have completed the Self-Assessment Checklist, you can save the document to your local drive and/or print out a hard copy for your records. IRB staff can assist you and answer any questions you may have.

## SECTION 1: REGULATORY DOCUMENTATION

Regulatory documentation includes the essential documents that individually and collectively permit the evaluation of the conduct of the trial and the quality of the data produced. The QI Program recommends a separate study file or binder in which these documents can be kept.

Depending on the type of study you are conducting and the study sponsor, different regulatory documents are required. To ensure that your study site is compliant with Food and Drug Administration (FDA) regulations, Good Clinical Practice (GCP) guidelines and IRB policies, complete Section I which is required for *all* studies.

Investigators are required to ensure that the study is being conducted in accordance to the protocol and that data integrity and subject safety is being maintained as outlined in the protocol summary. Section 1.1 should be completed in order to ensure a data safety monitoring plan (DSMP) is in place and/or a data and safety monitoring board (DSMB) if required, has been assembled.

Section 1.2 should be completed for all studies using an investigational drug/device/biologic. The sub-sections (*'Clinical Investigator'* or *'Sponsor-Investigator'*) should be completed depending on the investigator's role on the study. Check 'NA' for the questions to the sub-section which does not apply.

## SECTION 2: IRB DOCUMENTATION

In addition to initial review and approval, all subsequent actions by an investigator/study site must be approved by the IRB prior to implementation. This includes protocol amendments, consent document revisions, and study staff changes. All correspondence with the IRB must be maintained on file. Copies of correspondences may be retained in hardcopy or electronic format (e.g. shared folder space).

## SECTION 3: SUBJECT RECRUITMENT PROCEDURES

Subjects can be recruited to a study in a variety of ways, including for example, bulletins, newspaper, T.V. and radio ads. The IRB must review and approve *all* methods used to recruit all subjects. File IRB approved recruitment documents with all IRB correspondences.

## SECTION 4: SUBJECT SELECTION CRITERIA

Study subjects are screened for involvement in a study based on IRB approved inclusion/exclusion criteria. Investigators should develop an eligibility checklist with specific objective criteria to document that each subject has met the selection criteria. In addition, the PI is responsible for ensuring that source documentation supporting eligibility is available in the subject's medical record and/or study file. Choose a sample of subjects to review and then answer the questions on the checklist.

## SECTION 5: INFORMED CONSENT PROCESS

During the course of the study, changes to the IRB approved protocol may necessitate a change to the consent document(s). These changes can include new safety information, revised study procedures or eligibility criteria, or text clarifications. All consent document revisions must be IRB-approved. IRB approval is documented by use of a stamp, containing a valid date and expiration date. A consent document that does not contain this approval stamp, or a consent document used after the expiration date, is considered invalid. It is essential that the study site use only the most recently approved version of the consent document to consent subjects. Whenever a new approved consent document is generated, and stamped with a valid date, it replaces all previously approved versions. New versions are also generated (with or without change) at the time of continuing review. Choose a sample of subjects to review and then answer the questions on the checklist.

## SECTION 6: DATA COLLECTION & SOURCE DOCUMENTS

Investigators are required to maintain adequate, complete, and accurate records of all observations and data pertinent to each study subject. A case report form (CRF) or site-developed data collection sheet is a form on which all study data are recorded for each subject. All data entries on CRFs or data collection sheets should be verified by existing source data. Choose a sample of subjects to review and then answer the questions on the checklist.

## SECTION 7: DRUG/DEVICE DISPENSING ACCOUNTABILITY

The investigator is responsible for investigational product accountability. When possible, the investigator may delegate accountability to an appropriate individual under the investigator's supervision. It is common that an investigator will assign investigational drug or biologic accountability to a Pharmacy. Devices are typically maintained at the trial site. Product accountability information can be filed with other Regulatory documentation or in a separate file/binder. The following section should be completed in order to ensure that investigational product accountability is being maintained. Although the research pharmacy may be responsible for drug accountability, this section should still be completed by the study site. Contact the pharmacy if the answers to any of the questions are unclear.

## SECTION 8: LABORATORY DOCUMENTATION

Laboratory Documentation attests to the competency of the selected laboratory facilities being utilized and supports the reliability of the test results. A current lab certification (CLIA or CAP) should be on file for all laboratories used in the protocol. Also, a list of reference ranges (normal values) should be on file for each laboratory. Reference ranges can vary from one laboratory to another, so having the selected lab's reference range on hand is essential in helping the investigator determine any change and its clinical significance. All lab reports should be signed and dated by a licensed physician investigator, thus indicating that the reports were reviewed by the investigator. Any out-of-range values should be marked by the investigator as to their clinical (or non-clinical) significance.

**Questions?** If you have any questions, please contact:

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