I. Introduction

With the number and diversity of treatment regimens, the local Principal Investigator is clearly in the best position to prepare the initial version of the Informed Consent Document (ICD). This will help to ensure that potential risks and benefits are presented in the appropriate medical context, and will facilitate constructive dialogue with our local Institutional Review Board (IRB) during the review process. Multiple resources, including detailed templates, are available to facilitate this process.

This document describes procedures for preparing the initial draft and obtaining IRB review. Once the initial ICD has been approved by the IRB, including any recommended changes, the ICD will then be managed by the Protocol Office for electronic distribution, remote printing, and amendments. However, responsibility for preparing the draft ICD and obtaining the initial IRB approval resides with the local Principal Investigator.

Regulatory staff in the Protocol Office and IRB are happy to assist you in this effort. For questions and support, please contact the appropriate key staff indicated below:

Templates and general procedures: Peggy Gibbons (mailto: P_Gibbons@fccc.edu)
IRB (including readability): Nancy McNamara (mailto:Patricia.Kraus@fccc.edu)
HIPAA: Nora McCann (mailto: N_Mccann@fccc.edu)

II. Preparation of Initial ICD

A. Obtain an electronic copy of the ICD template from the sponsor.

For national cooperative group studies (ACOSOG, ECOG, GOG, RTOG), this can generally be obtained through the appropriate web resource or administrative office.

B. Merge the ICD sponsor template with the current FCCC IRB template.

The current FCCC IRB template can be obtained through the IRB website:
http://www.fccc.edu/docs/IRB/consent_form.doc

Additional guidance and templates are available through the IRB to address consent for specimen collection and utilization of data and specimens for future research, which has become a more frequent component of our cancer treatment trials.

Investigators are cautioned not to omit or change any of the NCI-approved risk language incorporated in studies from the national cooperative groups. This language is carefully reviewed by each Group during routine audits, and deletion of information can result in major violations. However, it is permissible to add supplemental language to the risks section.

In general, the IRB prefers to list the risks of study drugs in categories of "likely risks" and "unlikely risks."

The IRB highly recommends the use of their exact template language regarding reproductive risks, but will allow changes if absolutely necessary for a study.

Please note that phase III protocols from the national cooperative groups are generally using a centralized IRB, and special procedures may be applicable to these studies.
C. Readability

The IRB currently requires that new and revised ICDs be prepared with a reading level of grade 8.0 or lower, prior to the addition of drug/device names and defined medical terms. The IRB will determine the readability level using the Flesch-Kincaid method. Wherever feasible, you will need to lower the reading level within the ICD. A list of replacement words and the NCI dictionary can be found at the following websites:

Readable Replacement Words from Department of Health and Human Sciences CDC:
http://www.cdc.gov/od/ads/smog.htm

NCI Dictionary:
http://www.nci.nih.gov/dictionary/

D. HIPAA Process

The FCCC local IRB also functions as our Privacy Board. All protocols must now include specific authorization for release of Personal Health Information (PHI) or a statement that no PHI will be released. Although this can technically be accomplished within the ICD, most sponsors and protocols have included a separate HIPAA Authorization form that requires a second patient signature. Language regarding PHI within the HIPAA form should be reviewed and compared with actual data to be collected and reported on Case Report Forms (CRFs), which can vary from sponsor to sponsor. The HIPAA form should also accurately reflect which agencies and sponsors may have access to review PHI.

For assistance with HIPAA, please consult http://internal.fccc.edu/committees/hipaa/ or contact our FCCC privacy officer mailto:hipaacentral@fccc.edu.

A generic HIPAA template is available:
http://www.fccc.edu/docs/IRB/HIPAA_auth_application.pdf

More detailed templates for each national cooperative group are also available through the Protocol Office.

E. Sponsor Review (Pharmaceutical Industry-Sponsored)

If the study has pharmaceutical sponsorship, the draft ICD must be reviewed by Fox Chase contracts management staff and the pharmaceutical sponsor, before it can be submitted to the IRB.

1. Send an electronic version of the draft ICD to the FCCC Contract Administrator, Lisa Nelson (mailto: l_nelson@fccc.edu), for review of cost and compensation language.

2. After receipt of the Contract Administrator review, send the draft ICD to the pharmaceutical sponsor for review and approval.

3. After the sponsor has approved the draft ICD, sign and date a paper copy of the ICD and send to the Protocol Management Office for IRB submission.

III. Review, Approval, and Distribution

A. Research Review Committee (RRC)

1. It is preferable to have a draft ICD to reconcile with the protocol document. This can be accomplished with the sponsor-provided template. The fully-developed Fox Chase ICD is not required for RRC submission.

B. Institutional Review Board (IRB)

1. Following RRC protocol approval, development of the Fox Chase ICD (including HIPAA), and sponsor approval of the draft ICD (if necessary), the initial ICD can be
forwarded to the Protocol Management Office to accompany the protocol to the full-board IRB.

2. In general, even though the IRB may approve the protocol, this initial approval is usually contingent upon revisions to the ICD, which may include readability. The Principal Investigator is responsible for incorporating the IRB-mandated changes and obtaining the initial IRB approval.

C. Protocol Management Office

1. Once the draft ICD has been revised and approved by the IRB, an electronic copy should be forwarded to the Protocol Office. This will serve as the basis for electronic distribution and remote printing of the IRB-approved ICD for patient signature.

2. Future amendments to the ICD will be managed by the Protocol Office in collaboration with the Principal Investigator and sponsor.