Winship Cancer Institute Informed Consent Tip Sheet

Roles

- The informed consent document will be provided to the prospective subject/patient in advance of the appointment where the document is to be signed whenever possible.

- A Clinical Research Coordinator may initiate and participate in the informed consent process; however, a treating physician investigator is responsible for obtaining informed consent.

Instructions for Consent Signatures:

A treating physician investigator will discuss the study and review the informed consent document with the prospective subject, allowing for adequate time for discussion and questions.

If the prospective subject/patient presents at Winship to sign the informed consent document and the treating physician investigator is not immediately available in person, research staff should make reasonable efforts to reach the treating physician investigator (such as paging) to ask him/her to meet with the subject to sign the informed consent document. Such efforts must be noted in the research record by study staff.

If the treating physician investigator is still not available when the subject is available and the subject does not want to wait, the study staff member will make a note in the research record that the subject signed the informed consent document with the understanding that the treating physician investigator will co-sign as the person obtaining informed consent within 24 hours. The treating physician investigator must document in the medical record that informed consent has been obtained and the subject was given a copy of the informed consent.

Once the subject/patient and treating physician investigator have signed the consent document, a copy will be provided to the subject/patient. The original consent will be kept in the Clinical Trials Office. Study personnel shall document in the subject/patient’s research record the facts of (a) provision of the fully signed informed consent to the subject/patient, and (b) that the subject/patient signed the informed consent before any research procedures were performed.

Follow-up Instructions for Winship Study Staff:

- Give a copy of this signed form to the subject.

- File the original signed form in the Clinical Trials Office.

- Document in the subject’s research record the facts of (a) provision of the fully signed informed consent to the subject, and (b) that the subject signed the informed consent before any research procedures were performed.

- If you have questions, contact the CTO Director at kkrodge@emory.edu (404) 778-3524 or Medical Director or the Emory IRB Education and Quality Assurance team at irb@emory.edu (404) 712-9750.

Winship CTO 3/24/10