***TITLE: Site Specific Informed Consent Form***

***SOP*** CL XX.XX

***Author(s):***

***Approved by Date***

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***Revision Version Effective date Description***

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| **Instructions for modifying this template:**   1. This is a template and should be used as such. Please use this in the manner most appropriate for your research unit. 2. Text in blue is language you may want to modify as most applicable for your area. However, anything in this template can and may be modified as appropriate for your area while accounting for your interpretation of the most current FDA Guidance. 3. After you have modified this SOP template, do not forget to remove the “Instructions for modifying this template” table. |

1. **SCOPE/PURPOSE**

The purpose of this SOP is to explain the requirements and editing of Informed Consent Form Templates prior to Initial IRB submission.

**II. ALLOWABLE EXCEPTIONS**

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or by the sponsor. If a deviation from this SOP occurs, a description of this event will be written and filed with this list of SOPs and the protocol.

**III. RELEVANT REGULATIONS/GCPS**

• 21 CFR 50

• Guidelines for Investigators (UAB IRB)

• FDA (Food and Drug Administration) Requirements

**IV. DEFINITIONS/ACRONYMS**

CCC – Comprehensive Cancer Center

CTRC – Clinical Trials Review Committee

**V. RESPONSIBLE PERSONNEL**

This SOP applies to the following – Study Investigators, Study Coordinators, Regulatory Affairs, and Sponsors.

**VI. DETAILS**

**I. Sponsor Template**

a. The study Sponsor usually will provide a template Informed Consent Form with suggested language for the site’s use.

**II. UAB Requirements**

a. UAB requires specific elements to be reflected in all Informed Consent Forms.

b. The UAB/WIRB templates which include the specific format for sponsored research may be accessed at www.uab.edu/irb/forms.

c. Verbatim elements that are required by UAB that should not be revised by the Sponsor include:

• Incidental Findings (if applicable)

• Risks and Discomforts (if applicable)

• Information for Women of Childbearing Potential and/or Men Capable of Fathering a Child (if applicable)

• Confidentiality

• Cost of Participation

• Payment for Participation in Research

• Payment for Research-Related Injuries

• Questions

• Storage of Specimens for Future Use (if applicable)

**III. Editing the Sponsor Template**

a. The Sponsor template should be redlined edited (via tracked changes) incorporating UAB requirements, CTRC requirements, as well as interoperating federal and ethical guidelines.

b. Sponsor templates that have been reviewed and approved previously by WIRB do not require incorporating UAB required language. CTRC requirements will be incorporated as applicable.

**IIII. Sponsor Approval**

a. After the revisions have been made, the redlined/revised Informed Consent Form should be returned to the Sponsor for review and approval before it is submitted to the IRB for review.

b. Sponsor Approval must be received for the Informed Consent Form before submitting of the study to the IRB for review**.**

**VII. QA**

Prior to IRB submission of any consent, a second designated staff member will review the informed consent to assure that the site required specific language is included.

**VIII. APPENDICES / RESOURCES**

UAB IRB template: <http://www.uab.edu/research/administration/offices/IRB/Forms/Pages/Forms.aspx>

WIRB template:

<http://www.uab.edu/research/administration/offices/IRB/WIRB/Pages/WIRB-Forms.aspx>

**IX. RELATED SOPS**

**N/A**