Clinical Trials Enterprise (CRE)

Standard Operating Procedure for
Site Specific Informed Consent Form

SOP #: 2.04

Version: 1.0

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Approval: **Approved By** **Date**

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2.13.19

Revision History:	**Version**	**Effective Date**	**Description**

Purpose

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

References

- 21 CFR 50
- Guidelines for Investigators (UAB IRB)
- Appendix

Scope

This SOP applies to the following – Study Personnel, Regulatory Affairs, Industry Sponsors and the FDA (if applicable).

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.

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 template which includes the specific format for Industry Sponsored research may be accessed at www.uab.edu/irb/forms

c. Verbatim elements that are required by UAB will not be revised by the Sponsor. These elements 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)

d. The study participant will not be required to initial each page of the consent.

For more information on the site's Informed Consent Process and Documentation, please see the applicable Standard Operating Procedure and forms.

III. Editing the Sponsor Template

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

IIII. Sponsor Approval

a. 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 the initial submission of the study to the IRB for review.

Training