ASENTRAL, INC.
INSTITUTIONAL REVIEW BOARD
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GUIDELINES FOR THE IRB SUBMISSION PACKET

Below is a list of information and forms to be included in your IRB submission packet from the Principal Investigator and Sponsor/CRO. A review cannot be performed until all appropriate information has been received. **All documents needed for this submission can be found at www.asentralirb.com.**

☐ ** Please note that if this is a multi-site study, the Sponsor needs to fill out the **Sponsor** Application Form. The sites will fill out the Study Application Form.

☐ When submitting a Protocol, ICF, Questionnaire, survey or other documents the following guidelines should be followed.

a.) All documents must be typed
b.) Document control is required including Version No. and Date.
c.) Protocol Name and Number
d.) Pagination of all documents is required

☐ Indemnification Agreement (form available at www.asentralirb.com) between Sponsor and IRB (note that if the study is an Investigator-initiated study, the Investigator needs to indemnify the IRB).

☐ Shipping & Invoicing Information Form.

☐ **Study Application Form along with the following documents:** ☐ Investigator's Financial Disclosure statements.

- ☐ Documentation of any FDA audits within the past three years.
- ☐ Letters of explanation (if needed) to support the study application questions

☐ Satellite Site Application(s) for each site listed in section #3 of the Form FDA 1572 (if applicable).

☐ Curriculum vitae (CV) of the Principal Investigator and all Sub-Investigators (CVs must be current within 2 years, include any medical license information and must be signed and dated).
Massachusetts sites please include the Massachusetts Research Registration Number from the Department of Public Health for the Principal Investigator Financial Disclosure Form.

☐ Protocol Signature Page signed by the site Principal Investigator. This form should be provided by the sponsor.

☐ Standard Operating Procedure for obtaining Informed Consent Process – this document should be signed and dated by Principal Investigator or authorized designee and show document control (version # and date).

☐ If a **vulnerable population(s)** is/are involved in the plans of the study, the following appropriate form needs to be submitted in the initial submission.

- ☐ Additional Information for Research Involving Children
- ☐ Asentral, Inc. IRB's Checklist for Research Involving Pregnant Women, Fetuses, and Neonates.
- ☐ Asentral, Inc. IRB's Checklist for Research Involving Cognitively Impaired.
- ☐ Asentral, Inc. IRB Checklist for Economically Disadvantaged Population.
- ☐ Asentral, Inc. IRB Checklist for Research Involving Students Employees and Relatives.

☐ Proposed Advertising/Recruitment material (if any) and participant study materials. The rule of thumb is that anything that the study subjects are asked to read, listen to, watch, or respond to needs to be submitted for IRB review.

☐ Investigational Drug Brochure or Package Insert(s), if applicable.

☐ For medical device studies:

- ☐ Copy of the operator's manual
- ☐ Letter from the FDA granting the Investigational Device Exemption (IDE) **or:**
- ☐ Letter of non-significant risk from Sponsor **or:**
- ☐ Letter of explanation as to why the investigation is exempt from the IDE requirements under 21CFR812.2(c) or otherwise exempt.

☐ Study Protocol with signed Protocol Signature Page. Please submit an electronic file that is Microsoft Word compatible.

☐ Informed Consent(s) with hard copy and electronic file that is Microsoft Word compatible. A subject compensation schedule needs to be part of this Informed Consent Form.

☐ Proposed Subject Information (*if any*).

☐ Copy of the signed Form FDA 1572 (if applicable).

Please compile all of the requested materials and information listed above and email to:

info@asentralirb.com
or forward to the following address:

Asentral, Inc. IRB
10 Mulliken Way
Newburyport, MA 01950

The Board will send all original correspondence to the Principal Investigator. Upon written request, Asentral IRB will provide a copy of the approval documentation directly to the Sponsor/CRO/SMO managing the study.