



ASENTRAL™ IRB

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.

- 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).
- Study Application Form along with:
 - 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
- 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 exemp.
- Study Protocol with signed Protocol Signature Page.
- Informed Consent(s) with hard copy and electronic file of Microsoft Word compatible. Compensation schedule attachment.
- Proposed Subject Information (*if any*).
- Copy of the signed Form FDA 1572 (if applicable).
- Signed copy of Investigator Statement if no Form FDA 1572 is required.
- Satellite Site Application(s) for each site listed in section #3 of the Form FDA 1572 (if applicable).
- Shipping & Invoicing Information Form.

- 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.
- Curriculum vitae (CV) of the Principal Investigator and all Sub-Investigators (CVs must be current within 1 year, include any medical license information and be signed and dated). Massachusetts sites please include the Massachusetts Research Registration Number from the Department of Public Health for the PI.
- Investigator Financial Disclosure Form (available at www.asentralirb.com).

Please compile all of the requested materials and information listed above and forward to the following address:

Asentral, Inc. IRB
15 Main Street
Suite 203
Salisbury, MA 01952

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.