New Study Submission Guidance
Avera Institutional Review Board (IRB)

1. Application for Approval of Research Involving Human Subjects (IRB form # FO-301A Version 4.0 (found on IRB Website: [http://www.aver.org/avera/about/services/irbhome.aspx](http://www.aver.org/avera/about/services/irbhome.aspx))

2. Current research protocol including a version date

3. Current Investigator’s Brochure with version date (if applicable)

4. Copy of FDA Form 1572 signed and dated by Principal Investigator (if applicable)

5. Proposed Informed Consent Document with current version date
   - All blanks must be filled in (except signature blocks)
   - HIPAA Authorization information must be included in Informed Consent document or a stand-alone HIPAA authorization may be used.

6. Electronic copy (Microsoft Word Format) of the proposed Informed Consent Document emailed to irb@aver.org if health science or Oncirb@aver.org if oncology related.

7. Proposed Patient Information (instructions, diaries, etc.) (if applicable)

8. Other Supporting Materials (i.e. sample of any proposed advertising) (if applicable)


Please call Jovette Van Hoorn or Sandra Ellenbolt if you have any questions regarding the IRB.

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