

Research Advertisement Requirement G003

Reference:

SOP Current: Section 5

SOP Future: WVU OHRP SOP 027

1 Protocol Application Submission

The protocol application submission should include the following:

- The advertisement(s) described in the protocol application.
- Upload the final printed ad, flyer, or audio/videotape with the protocol submission.
- Obtain IRB approval for changes to approved advertising materials.

2 Required Elements of Research Advertisements

- Clearly state that advertisement is for participation in a Research Project.
- State the purpose of the research.
- Summarize the eligibility criteria.
- Provide the benefits to the participant, if applicable.
- Indicate the time and participation commitment.
- Indicate the location of the research.
- Provide the name, address/email, and the department of the Principal Investigator (PI).
- Provide a contact person and phone number.
- Indicate that WVU IRB approval or acknowledgement (as appropriate) is on file.
- Do not imply a certainty of a favorable outcome or other benefits beyond the information contained in the consent document and the protocol.
- Do not include exculpatory language.
- Do not emphasize compensation by using a larger, bold, or different color font.

3 Advertisements – Research Involving Drugs, Devices, or Test Articles

- Do not make claims either explicitly or implicitly that the drug, biologic, or device was safe or effective for the purposes under investigation.
- Do not make claims either explicitly or implicitly that the drug, biologic, or device was known to be equivalent or superior to any other drug, biologic, or device.
- Use terms such as “investigational new treatment,” “investigational new medication,” or “investigational new drug.”
- Do not promise “free medical treatment,” when the intent is to indicate that participants will not be charged for their participation in the research.
- If a placebo is used, clearly state that some participants may receive a placebo.