Recruitment and Media Advertising	RSP.027.00
Effective Date	May 2016
Last Revision/Review	July 26, 2023

1. Purpose/Scope

Purpose: The SOP provides information regarding IRB oversight of and allowable practices in recruitment of human subjects for research study.

Scope: All Burrell faculty, staff and students involved in human subjects research

2. Related Policy/Authority

3. Faculty/Staff Responsibilities

Responsible Official(s)- Authorized Institutional Official for Research, IRB, Principal Investigator

4. Definitions/Abbreviations

45 CFR 46

5. Procedural Steps

5.1 **Guidance:** When direct advertising is to be used in the recruitment of research subjects, the Principal Investigator shall seek IRB approval. It is recommended that the investigator seek such IRB input in advance of final preparation of recruitment materials to avoid excess expense necessitated by having to edit or revise recruitment materials after final production has occurred. This may be accomplished through the review of scripted material or drafts of printed material. Upon completion of preparation of the final version, the P.I. shall submit the recruitment to the IRB for review and approval.

5.2 **Recruitment Material Content:** No claims should be made, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic, or device. Such representation would not only be misleading to subjects but would also be a violation of regulations concerning the promotion of investigational drugs and of investigational devices. Advertising for recruitment into investigational drug, biologic, or device studies should not use terms such as “new treatment”, “new medication”, or “new drug” without explaining that the test article is investigational. A phrase such as “receive new treatments” may lead study subjects to believe they will be receiving a new FDA-approved product or a newly improved product of substantiated worth. Advertisements should not promise “free medical treatment”, when the intent is only to say subjects will not be charged for taking part in the investigation. Advertisements may state that subjects will be paid, but should not emphasize the payment, nor the amount to be paid, by such means as larger or bold type. To do so could be understood by the IRB to represent coercive advertising. Generally, any advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest.

When appropriately worded, the following items may be included in advertisements.

1. The name and address of the clinical investigator and/or research facility;
2. The condition under study and/or the purpose of the research;
3. A summary of the criteria used to determine eligibility for the study;
4. A brief list of participation benefits, if any (e.g., a no-cost health examination);
5. The time or other commitment required of the subjects; and
6. The location of the research and the name of contact to obtain information.

5.2 **Use of Receptionist Scripts for Office Staff:** The first contact prospective study subjects make is often with a receptionist or study coordinator who follows a script to determine basic eligibility for the specific study. The IRB should assure that the procedures followed adequately protect the rights and welfare of the prospective subjects. The P.I. shall assure that the office staff have been appropriately trained with respect to interacting and determining basic eligibility of prospective subjects.

In some cases, personal and sensitive information is gathered about the individual. The IRB should have assurance from the P.I. that the information will be appropriately handled, by describing the specific protocol for securing this information. A simple statement such as "confidentiality will be maintained" does not adequately inform the IRB of the procedures that will be used. Appropriate information provided for IRB review include but may not be limited to:

1. What happens to personal information if the prospective subject ends the interview?
2. Are there other data gathered by a marketing company or study recruiter? If so, are names, etc. sold to others?
4. What happens to prospective subject information if they do not qualify for the study? Are names of non-eligible subjects maintained in case they would qualify for another study? If so, then are the subjects informed that their information will be kept in a database? Can the subjects opt out of having their information included in such a database?
3. Are paper copies of records shredded or are readable copies put out as trash? The acceptability of the procedures would depend on the sensitivity of the data gathered, including personal, medical, and financial.

5.3 **IRB Responsibilities:** When direct advertising is to be used in the recruitment of research subjects, the IRB should review the information contained in the advertisement and the mode of its communication, to determine that the procedure for recruiting subjects is not coercive and does not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

The IRB shall review the final copy of printed advertisements to evaluate the relative size of type used and other visual effects. When advertisements are to be taped for broadcasts, the IRB shall review the final audio/video tape. The IRB may review and approve the wording (script) of the advertisement prior to taping to preclude re-taping because of inappropriate wording. The review of the final taped message prepared from IRB-approved text may be accomplished through expedited procedures. The IRB should caution investigator(s) to obtain IRB approval of message text prior to taping, to avoid excess expense necessitated by a requirement to re-tape an ad because of inappropriate wording.

6. Reports/Charts/Forms/Attachments/Cross References

7. Maintenance

Reviewed annually by Office of Research.

8. Signature

Approved by	8/9/2023
Assistant Dean for Research	Date

9. Distribution List

Internal/External

10. Revision History

Revision Date	Subsection #	Summary of Changes	New/Cancellation/ Replacement Procedure? (if applicable)	Approval Date
7/26/23		Converted from May 2016 policy		8/9/2023