1.0 POLICY

1.1 Background.

1.1.1 Federal regulations require the recruitment methods for human subjects research to minimize the possibility of coercion or undue influence.

1.1.2 Payment arrangements among sponsors, organizations, investigators, and others referring research participants may place participants at risk of coercion or undue influence or may cause inequitable selection.

1.1.2.1 Finder’s fees are payments from the investigator or sponsor to a person who refers a potential participant.

1.1.2.2 Recruitment bonuses are payments from the sponsor to an investigator or organization based on the rate or timing of recruitment. For example, a sponsor may contract to pay a fixed fee for each participant or promise an additional payment if more than a certain number are enrolled in the first week or the site has the highest enrollment at the end of the month.

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that in recruiting human subjects for research no attempt shall be made to make the potential participant feel obligated or unduly pressured to participate in the research.

1.2.2 All advertising or other recruitment material shall be submitted by the investigator and must be reviewed and approved by the IRB. Flyers and other advertising materials will be marked as approved by the IRB before distribution or posting. Letters and e-mails to potential participants will be submitted to the IRB for review and approval prior to mailing.

1.2.3 As a general rule the UA IRB does not favor use of finder’s fees or recruitment bonuses but will consider them if allowed by the sponsor or if a compelling case can be made for their use. Investigators shall describe any plan for use of finder’s fees and recruitment bonuses, the rationale, and the measures taken to avoid their abuse by finders/recruiters and to avoid coercion of prospects.
1.2.4 When screening for eligibility is part of the recruitment process, investigators shall submit screening scripts, consent documents that cover screening procedures, and descriptions of how personal or sensitive information about persons will be handled and safeguarded.

1.2.5 The University of Alabama allows research under its purview to provide incentives or remunerate individuals who participate in research projects. The incentive or remuneration is to be presented as “in appreciation of your time and effort” and not as “payment”. NIH considers “payment” to mean fee for service and to decrease the voluntary nature of research participation. The IRB will review the nature, amount, and schedule of any proposed incentive or remuneration to determine that it is fair and not an undue inducement to participate.

1.2.5.1 Remuneration for participation in research should be reasonable and the amount should be comparable to other research projects involving similar time, effort, and inconvenience.

1.2.5.2 If financial remuneration is a major reason for participation, and the research presents minimal risk to the participants, the IRB may approve remuneration sufficient to engage participants.

1.2.6 Incentives or remuneration should accrue as the study progresses and, if the study is not completed in one session, should not be contingent upon the completion of the entire study. Unless it creates an undue inconvenience or a coercive practice, incentives or remuneration to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.

1.2.7 The IRB may approve research that includes a proposed bonus for completion if it determines that the bonus will not unduly induce participants to stay in the study when they otherwise would have withdrawn. All information concerning incentives, remuneration, or bonuses including amount and schedule should be set forth in the application and in the consent document.

1.2.8 **Raffles or lotteries are illegal under Alabama law** and will not be allowed as a recruitment incentive or study benefit.

1.3 Objective.

1.3.1 Implementation of this policy will ensure that recruitment methods do not interfere with the equitable selection of research subjects and do not impair the process of informed consent.

1.4 Responsibility.

1.4.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Office of Research Compliance, IRB chairs and members, members of the Council of Associate Deans for Research, investigators, and faculty supervisors of student research.
2.0 PROCEDURE

2.1 The investigator must include in the IRB application all recruitment material (letters, newspaper ads, flyers, email messages, radio or television spots, etc.), all details of any finders’ fees or recruitment bonuses, and all screening information to the IRB for review and approval before its use (GUIDANCE: IRB Application Guide).

2.2 IRB will review information provided by the Investigator using FORM: IRB Checklist for Reviewers and Investigators and make a determination of whether the materials used in recruiting human subjects are fair and accurate, allow for informed consent, and that the payments or other remuneration befits the nature of the research burden placed on those subjects.

2.3 The IRB will review materials used in direct advertising and their mode of communication. The IRB will review the final copy for printed and audio/videotaped advertisements.

2.4 In reviewing recruitment material the IRB will review advertising to assure that the advertising:

2.4.1 Is not unduly coercive and does not promise a certainty of cure beyond what is outlined in the consent and the protocol,

2.4.2 Makes no claims, either explicitly or implicitly, that the drug, biologic, device or other research procedures are safe or effective for the purposes under investigation, or that the test article or other research procedures are known to be equivalent to or superior to any other drug, biologic, device, or procedure,

2.4.3 Does not use terms such as “new treatment,” “new medication” or “new drug” without explaining that the test article or the research procedures are investigational or experimental,

2.4.4 Does not promise “free medical treatment,” when the intent is only to say subjects will not be charged for taking part in the investigation,

2.4.5 Does not emphasize remuneration or incentives by using such means as large font or bold type, although it may state that subject will receive a certain sum or item.

2.4.6 Does not include exculpatory language.

2.4.7 FDA-regulated research does not include compensation for participation in a trial offered by a sponsor to involve a coupon good for a discount on the purchase price the product once it had been approved for marketing.

2.4.8 The IRB will determine if the advertisement is limited to information necessary for prospective subjects to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements:

2.4.8.1 Name(s) and address(es) of the investigator and/or research facility,
2.4.8.2 Condition under study and/or the purpose of the research,
2.4.8.3 Criteria to be used to determine eligibility for the study,
2.4.8.4 A brief list of participation benefits, if any (e.g., a no-cost health examination),
2.4.8.5 Time or other commitment required of participants,
2.4.8.6 Location of the research,
2.4.8.7 Person or office to contact for further information.

2.5 Flyers and other advertising materials must be marked as approved by the IRB before distribution or posting.

2.6 The IRB will determine if eligibility for incentives or remuneration occurs only at completion of normal study participation or previous to that condition.

2.7 The IRB will make a determination as to whether the item or amount, method and timing:

2.7.1 Unduly influence the prospect to participate,

2.7.2 Are reasonable relative to the particulars of the study, and

2.7.3 Are reasonable relative to the particular population being recruited.

2.8 The IRB will evaluate handling and protection of any sensitive or Protected Health Information about prospective participants.

2.8.1 A simple statement that confidentiality will be maintained will not suffice.

2.8.2 Issues that will be considered by IRB include the following: What happens to personal information if the caller ends an interview or hangs up? If data are gathered by a marketing company, are names or other information sold to others? Are names of non-eligibles maintained in case they would qualify for another study? Are readable copies of records shredded or put out for trash?

2.8.3 The IRB may seek external consultation about the appropriateness of recruitment strategies or content for various cultural groups.

2.9 The Research Compliance Specialist will notify the investigator of the board’s approval or request for modification of recruiting materials as part of the letter sent to investigators following IRB review.

2.10 Once approved, investigators must submit any subsequent changes in recruiting strategies or informational content to the board for review and approval on FORM: Modification of an Approved Protocol.

3.0 REFERENCES

3.1 45 CFR §46.111 (a)(3)
3.2 45 CFR 46 §116
3.3 45 CFR 17.92
3.4 21 CFR §50.20
3.5 21 CFR §56.111(a)(3)
3.6 OHRP Guidance on Written Institutional Review Board Procedures
3.8 FDA guidance on Recruitment, Media, and Compensation is found at www.fda.gov/oc/ohrt/irbs/toc4.html
3.9 DoD: Dual Compensation Act, 24 U.S.C 301, DoD 3216.2, para.4.4.4; SECNAVIST 3900.39D, para.6a(6)
3.10 DOJ: 28 CFR 512.11 (4,5)

4.0 RELATED SECTIONS

4.1 GUIDANCE: IRB Advertising Guidelines
4.2 POLICY: Appropriate and Equitable Selection of Subjects
4.3 POLICY: Protection of Human Research Participants’ Privacy and Confidentiality
4.4 GUIDANCE: IRB Application Guide
4.5 GUIDANCE: Templates(2): Informed Consent for Medical and Non-Medical Studies
4.6 GUIDANCE: Department of Defense Regulations for Human Subjects Research
4.7 FORM: IRB Checklist for Reviewers and Investigators