“(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, [handicapped or, DHHS] mentally disabled persons, or economically or educationally disadvantaged persons” 45 CFR 46.111, 21 CFR 56.111

The Institutional Review Board (IRB) shall determine that selection of subjects is equitable. In assessing the selection of subjects for a research study, the IRB considers the following factors:

- Whether selection of subjects meets regulatory requirements and/or whether the selection of subjects meets ethical principles as outlined in the Belmont Report
- Purpose of the research
- Requirements of the proposed study design
- Setting in which research would be conducted
- Subjects’ susceptibility to risk
- Whether prospective subjects would be vulnerable to coercion or undue influence
- Likelihood that the proposed benefits will be realized by the subjects
- Practicability of the proposed research
- Fairness and equitability of the proposed research design, including inclusion and exclusion criteria
- Subject recruitment and enrollment procedures
- The amount and timing of payments to subjects, including whether recruitment processes, advertisements, and payment arrangements affect the equitable selection of subjects
- Influence of payments to subjects
- Whether someone is receiving payment for recruiting subjects

**Recruitment**
Subjects should not feel obligated or in any way pressured to participate in the research study. Subjects should be provided with an accurate description of the research and should not be given false promises. The potential research subject’s wishes shall
govern and if s/he indicates that s/he does not want to participate, his/her wish must be respected.

Payment of Subjects
Prizes/awards given to subjects based on chance (e.g., entering into a drawing) should be limited to $100.00 or less and must comply with lottery laws (e.g., State of Michigan).

There is no cash limit on awards/reimbursement that all subjects receive. However, compensation to subjects should never be so high as to constitute an undue influence to participate in research (e.g., accept a risk that they would not otherwise accept), and should generally be limited to nominal amounts, e.g., reimbursement for out-of-pocket expenses and time. Payments to subjects must also comply with state and federal laws (e.g., tax reporting, Internal Revenue Service).

If any type of payment will be offered (e.g., compensation, incentives), the payment amount, proposed method, and timing of distribution will be evaluated during the review of the study to assess the appropriateness. The assessment will include the following considerations:

- The payment amount, method, and timing of distribution:
  - Will not unduly influence the subject to participate in a research study or accept a research risk in which he or she would otherwise decline
  - Are reasonable based upon the complexities and inconveniences to subjects of the study
  - Are reasonable based upon the particular subject population
- For multiple visits or assessments, the credit for payment accrues as the study progresses and is not contingent upon the subject completing the entire study
- Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn
- All information concerning payment, including the amount and schedule of payments, is set forth in the consent form

The following types of payments by the sponsor to investigators, research staff, or those referring research subjects are prohibited:

- Payments in exchange for referrals of potential subjects (i.e., finder’s fees).
- Payments designed to accelerate recruitment that are tied to the rate and timing of enrollment (i.e., bonus payments).

The guidance provided by the U.S. Food and Drug Administration (FDA) Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators – 1998 Update is also used in the review of payment amount, method and timing for studies to which FDA policies and procedures apply.

- “Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study.
- Unless it creates undue inconvenience or a coercive practice, payment 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. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.

- While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn.
- All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.”

Advertisements
If advertisements are proposed to be used, the IRB reviews the following:

- Information contained in the advertisement
- Mode of its communication
- Final copy of printed advertisement
- Final audio/video taped advertisement
- Advertisements posted on websites

If investigators would like to use advertisements in their recruitment practices, the advertisements must be limited to information prospective participants need to determine their eligibility and interest, such as:

1. The name and contact mechanism of the investigator, study team, or research facility
2. The purpose of the research or condition under study
3. In summary form, the criteria that will be used to determine eligibility for the study
4. Straightforward and truthful description of the risks and/or benefits to the subject from participation in the study
5. The location of the research or research facility and the person or office to contact for further information
6. Time or other commitment required of subjects

Advertisements may not:

- Include IRB endorsement of research studies either in recruitment materials or consent forms
- Include exculpatory language
- Emphasize the payment or amount to be paid, by such means as larger or bolder type
- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent form and the research study
- Promise “free treatment” when intent is only to say subjects will not be charged for taking part in the investigation

In addition to the above criteria, the following recommendations from guidance provided by the FDA Information Sheets: Guidance for Institutional Review Boards and Clinical Investigators – 1998 Update are followed for research to which FDA regulations and policies apply:
• “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 the agency's regulations
concerning the promotion of investigational drugs [21 CFR 312.7(a)] and of investigational
devices [21 CFR 812.7(d)].
• 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" leads study
subjects to believe they will be receiving newly improved products of proven 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 or the amount to be paid,
by such means as larger or bold type.
• Generally, the FDA believes that 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. It
should be noted, however, that the FDA does not require inclusion of all of the listed items.
  o the name and address of the clinical investigator and/or research facility;
  o the condition under study and/or the purpose of the research;
  o in summary form, the criteria that will be used to determine eligibility for the study;
  o a brief list of participation benefits, if any (e.g., a no-cost health examination);
  o "the time or other commitment required of the subjects; and
  o the location of the research and the person or office to contact for further
    information.”

Advertisements for research regulated by the FDA may not:
• Make claims, either explicitly or implicitly, about the drug, biologic, or device under
investigation that are inconsistent with FDA labeling
• Use terms such as "new treatment," "new medication," or "new drug" without
explaining that the test article is investigational
• Allow compensation for participation in a trial offered by a sponsor to include a
coupon good for a discount on the purchase price of the product once it has been
approved for marketing

Additional Considerations
For research studies subject to the requirements of the U.S. Department of Defense
and the U.S. Department of Justice, see the following sections of the Human Research
Protection Program Manual:
2-2-A U.S. Department of Defense
2-2-C U.S. Department of Justice