POLICY

1. Purpose
   Document the mechanism for RSRB review and approval of research study recruitment materials, as well as the methods for subject payment, to ensure the fair and equitable selection of subjects, and to minimize the possibility of coercion or undue influence.

2. Scope
   This policy applies to all human subject research conducted or supported by employees or agents of the University of Rochester (UR), the RSRB, and the RSRB office.

3. Definitions
   3.1. Recruitment Materials – Material potential subjects will see or hear that is used as part of the recruitment process, including web sites, flyers, posters, newspaper ads, television or radio ads, brochures, doctor-to-patient or Investigator-to-subject letters, social media ads (e.g., Facebook, Twitter), or any other material used as a recruitment method.

   3.2. Recruitment Methods – The means used to identify potential research subjects, or to draw potential research subject’s attention to research, including but not limited to identification through records and recruitment materials.

4. References
   4.1. Policy 404 Criteria for RSRB Approval of Research
   4.2. Guideline for Recruitment Materials and Subject Payment; Guideline for Payment to Subjects to Recruit Other Subjects; University of Rochester Policy on Enrollment Incentive Payments by or to University Clinical Trial Researchers

5. Requirements
   5.1. Investigators must adequately describe all recruitment methods and plans for subject payment (including amounts and schedule for payments) in the protocol (see RSRB Protocol Templates) and the Research Subject Review Board on-line submission system (ROSS).

   5.1.1. Subject payments, if applicable, must also be included in the consent form (see RSRB Consent Forms Templates) and must be consistent with the information presented in the protocol and the ROSS application.

   5.2. Investigators must submit all recruitment materials, as defined under Section 3.2 above, to the RSRB at the time of initial submission of the protocol. Recruitment materials and payment methods must meet the standards outlined within the Guideline for Recruitment Materials and Subject Payment.

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the OHSP shared network.
5.2.1. Recruitment materials directed at prospective subjects must be limited to the information needed to determine their eligibility and interest (see Guideline for Recruitment Materials and Subject Payment).

5.3. Investigators must submit any recruitment materials and plans for subject payment that are developed or revised after initial RSRB approval to the RSRB as a protocol amendment for RSRB approval prior to implementation.

5.4. The RSRB will review the following to ensure consistency between all application materials, including the protocol and consent form(s):
   5.4.1. The information contained in the advertisement.
   5.4.2. The mode of its communication.
   5.4.3. The final copy of printed advertisements.
   5.4.4. The final audio or video taped advertisements (Note: The finalized script that will be used for audio or video materials is acceptable for purposes of RSRB submission, review and approval.).

5.5. The RSRB will review recruitment materials provided in the protocol and the ROSS application to ensure that materials:
   5.5.1. Do not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the protocol and consent document(s).
   5.5.2. Do not include exculpatory language.
   5.5.3. Do not emphasize payment or the amount to be paid (e.g., use of larger or bold type font).
   5.5.4. Do not promise “free treatment” when the intent is only to say subjects will not be charged for taking part in the research.
   5.5.5. For FDA-regulated research:
     - Do not make claims about the drug, biologic, or device under study that are inconsistent with FDA labeling.
     - Do not use terms such as “new treatment”, “new medication”, or “new drug” without indicating that the test article is investigational
     - Do not allow compensation to a subject that includes a coupon or discount on purchase price of the product once it is approved for marketing

5.6. The RSRB will review payment information to determine that:
   5.6.1. The amount of payment and method and timing of disbursement is neither coercive nor presents undue influence (e.g., payment should be prorated for completed visits rather than a one-time payment for completing the entire study).
   5.6.2. Any payment to peer recruiters is appropriate in accordance with the Guideline for Payment to Subjects to Recruit Other Subjects.
5.6.3. Payment is not contingent upon the subject completing the entire study, as applicable to the study design.

5.6.4. Any payment made as a bonus for completing the study is not so large as to unduly influence subjects to stay in the study when they may have otherwise withdrawn.

5.6.5. All information regarding payment, including amount and payment schedule, is included in the consent form.

5.7. The RSRB will approve recruitment materials and subject payment methods after considering the items listed under Section 5.4 through 5.6 above, and in accordance with Policy 404 Criteria for RSRB Approval of Research.

5.8. Recruitment incentive payments or enrollment bonuses from the Sponsor to the Institution or the Investigator are followed in accordance with the University of Rochester Policy on Enrollment Incentive Payments by or to University Clinical Trial Researchers.
Originator/Authors:
Emily Flagg, Senior Regulatory Specialist

Appendices:
None

Revision History:
None

Supersedes Date:
Not Applicable

Approved By:

______________________________
Kelly A. O'Donoghue
Director, OHSP
10/28/2014

______________________________
Tiffany L. Gommel
Director, RSRB
10/28/2014