

<b>University of Rochester</b>	<b>Office for Human Subject Protection</b>		
	<b>Research Subjects Review Board</b>		<b>Effective Date: 12/10/2021</b>
	<b>Recruitment and Subject Payment</b>		<b>Policy 703</b>
			<b>Version: 2.1</b>

## POLICY

### 1. Purpose

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

The [University of Rochester's mission](#) values diversity and inclusivity. The University of Rochester is an institution devoted to teaching, research, and service. In the context of our commitment to being more inclusive and diverse, we can apply these skills to the continuing work of transforming our environment in ways that enable greater participation, enhance human dignity, eliminate prejudice and discrimination, and improve the quality of life for everyone.

### 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* – Information potential subjects will see or hear that is used as part of the research recruitment process, including but not limited to web sites, flyers, posters, newspaper ads, television or radio ads, brochures, doctor-to-patient or Investigator-to-subject letters, and social media ads (e.g., Facebook, Twitter).
- 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, in-person discussion, and use of recruitment materials.

### 4. References

- 4.1. [FDA Payment and Reimbursement to Research Subjects Information Sheet](#)
- 4.2. [Policy 404 Criteria for RSRB Approval of Research](#)
- 4.3. [Guideline for Recruitment Methods and Materials](#);
- 4.4. [Guideline for Subject Payments](#);
- 4.5. [Material Guideline for Payment to Subjects to Recruit Other Subjects](#) (Peer Recruiters);
- 4.6. [University of Rochester Policy on Enrollment Incentive Payments by or to University Clinical Trial Researchers](#)
- 4.7. [Guideline for Notification of RSRB Determinations](#)

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## 5. Requirements

- 5.1. Investigators must provide the Reviewing IRB a complete description of all recruitment methods and plans for subject payment (including amounts and schedule for payments). Refer to the [RSRB Protocol Templates](#) for guidance.
  - 5.1.1. Subject payment(s), if applicable, must also be included in the consent form (see [RSRB Consent Forms Templates for guidance](#)) and must be consistent with the information provided in the protocol materials submitted to the Reviewing IRB.
  - 5.1.2. When there is a payment discrepancy between subjects performing the same activities (not all subjects receive the same) Investigators must provide a justification in the protocol.
  
- 5.2. Investigators must submit all recruitment materials, as defined under Section 3.2 above, to the Reviewing IRB for review and approval prior to implementation, either at the time of initial submission, or as an amendment. Recruitment materials and payment methods must meet the standards outlined within the *Guideline for Recruitment Methods and Materials* and *Guideline for Subject Payment* as well as the *FDA Payment and Reimbursement to Research Subjects Information Sheet*.
  - 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 Methods and Materials*).
  
- 5.3. 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](#).

## 6. Responsibilities When the RSRB is the Reviewing IRB

- 6.1. The RSRB will review the following recruitment information to ensure consistency between all application materials, including the protocol and consent form(s):
  - 6.1.1. The information contained in the advertisement.
  - 6.1.2. The method of communication.
  - 6.1.3. The final version of printed advertisements.
  - 6.1.4. 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.).
  
- 6.2. The RSRB will review recruitment methods and materials to assess whether selection of subjects is equitable and inclusive, when appropriate. The following information provided by the Investigator will be considered:
  - 6.2.1. Purpose of the research;

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- 6.2.2. Setting in which the research will be conducted;
  - 6.2.3. Whether prospective subjects will be vulnerable to coercion or undue influence;
  - 6.2.4. Eligibility (inclusion/exclusion) criteria;
  - 6.2.5. Subject recruitment and enrollment procedures; and,
  - 6.2.6. Influence of payments to subjects, if applicable.
- 6.3. The RSRB will review recruitment materials to ensure that materials:
- 6.3.1. Do not state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the protocol and consent document(s).
  - 6.3.2. Do not include exculpatory language.
  - 6.3.3. Do not emphasize payment or the amount to be paid (e.g., use of larger or bold type font).
  - 6.3.4. Do not promise “free treatment” when the intent is only to say subjects will not be charged for taking part in the research.
  - 6.3.5. For FDA-regulated research:
    - 6.3.5.1. Do not make claims about the drug, biologic, or device under study that are inconsistent with FDA labeling.
    - 6.3.5.2. Do not use terms such as “new treatment”, “new medication”, or “new drug” without indicating that the test article is investigational.
    - 6.3.5.3. 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.
- 6.4. The RSRB will review payment information to determine that:
- 6.4.1. 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).
  - 6.4.2. Any payment to peer recruiters is appropriate in accordance with the *Guideline for Payment to Subjects to Recruit Other Subjects (Peer Recruiters)*.
  - 6.4.3. Payment accrues as the study progresses and is not contingent upon the subject completing the entire study, as applicable to the study design.
  - 6.4.4. Any payment made as a bonus for completing the study is reasonable and not so large as to unduly influence subjects to stay in the study when they may have otherwise withdrawn.
  - 6.4.5. All information regarding payment, including amount and payment schedule, is included in the consent form.
- 6.5. The RSRB will approve recruitment materials and subject payment methods after considering the items listed under Section 6.1 through 6.4 above, and in accordance with *Policy 404 Criteria for RSRB Approval of Research*.
- 6.5.1. For multi-site research, the RSRB may approve template recruitment materials under the main protocol and allow each participating site to enter site-specific information without additional approval.

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- 6.6. The RSRB will notify the Investigator of approved recruitment materials according to the *Guideline for Notification of RSRB Determinations*.

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**Originator/Authors:**

Emily Flagg, Senior Regulatory Specialist  
Ann Marie Scorsone, Senior Regulatory Specialist

**Appendices:**

None

**Revision History:**

06/2018: Remove “Materials” from policy name; Sect 1 revise the purpose; Sect 4 add hyperlinks and addition of new Guideline for Subject Payments; Sect 5.2.2 added regarding multi-site research; Sect 6.2 added to be current with AAHRPP standards; language throughout for Reviewing versus Relying IRB; additional administrative for clarification and to accurately reflect current practice.  
10/2021: Added policy statement regarding diversity; Sect 5.1.2 added regarding payment discrepancies; Editorial and administrative updates; Signatories updated

**Supersedes Date:**

06/19/2018

**Approved By:**



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Stephen Dewhurst  
Institutional Official and Vice President for Research

12/16/2021

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Date



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Kelley A. O'Donoghue  
Director, OHSP

12/10/2021

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Date