POLICY

1. Purpose
   This policy describes the requirements for Investigators to appropriately obtain informed consent and document the consent process, including requests for waivers or alterations of the consent process, and the requirements for the RSRB to evaluate the consent process when approving research.

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. Informed Consent – An ongoing process of information exchange that takes place between the potential subject and the Investigator, which begins at the time the potential subject initially learns about the research and continues throughout the course of the study.

4. References
   4.1. HHS 45 CFR 46.116; HHS 45 CFR 46.117; FDA 21 CFR 50.20; FDA 21 CFR 50.25; New York State Law Article 24-A Section 2442
   4.2. Policy 404 Criteria for Approval of Research;
        Policy 601 Research Involving Children;
        Policy 604 Research Involving Adults with Decisional Impairment;
        Policy 703 Recruitment Materials and Subject Payment;
        Guideline for Informed Consent
   4.3. RSRB Protocol Templates;
        RSRB Consent Form Templates

5. Responsibilities
   5.1. Investigators have a legal and ethical obligation to ensure the following in regard to informed consent in accordance with federal regulations HHS 45 CFR 46.116, FDA 21 CFR 50.20, NYS Law Article 24-A Section 2442, institutional policies, and the Guideline for Informed Consent:
      5.1.1. That prospective subjects have sufficient knowledge and comprehension of the elements of informed consent to enable them to make an informed decision whether or not to participate in research;
      5.1.2. That all consent documents and relevant subject completed forms are translated into the language understandable to the study population when enrolling non-English speaking subjects.
      5.1.3. In addition to 5.1.1 and 5.2.1 above, for research involving adults with decisional impairment, to allow participation in research if a legally authorized
representative is delegated according to Policy 604 Research Involving Adults with Decisional Impairment;

5.1.4. In addition to 5.1.1 and 5.2.1 above, for research involving children, to allow permission for a child to participate in research according to Policy 601 Research Involving Children.

5.2. The RSRB is responsible for determining whether the research satisfies the criteria for approval relevant to the process for obtaining informed consent, as well as the criteria for approval relevant to appropriate documentation of consent, according to federal regulations, Policy 404 Criteria for Approval of Research, and the Guideline for Informed Consent when reviewing protocol materials at the time of initial and continuing review, and when reviewing amendments to research.

6. Requirements
6.1. The Investigator must include a description of the process for obtaining and documenting informed consent in the study protocol and provide all consenting documents to the RSRB for review and approval, according to the Guideline for Informed Consent.

6.1.1. All required elements and applicable additional elements of consent listed in Sections 6.3 – 6.6 below must be included, unless a waiver or alteration of informed consent (Section 7) or waiver of documentation of consent (Section 8) is requested by the Investigator.

6.1.2. Recruitment methods and materials are considered part of the informed consent process and must be submitted to the RSRB (see Policy 703 Recruitment Materials and Subject Payment).

6.1.3. RSRB Protocol Templates and RSRB Consent Form Templates are available to researchers to help ensure required elements and standard institutional language is incorporated into the documents.

6.2. The Investigator will include the following basic elements of informed consent required by federal regulations HHS 45 CFR 46.116(a) and, for FDA regulated studies 21 CFR 50.25(a).

6.2.1. An introduction that indicates the study involves research;
6.2.2. An explanation of the purpose of the research;
6.2.3. A description of study procedures, which includes identification of research procedures, as well as those that are investigational or standard of care procedures.
6.2.4. The expected duration of subject’s participation;
6.2.5. A description of any reasonably foreseeable risks or discomforts of participation;
6.2.6. A description of any benefits to the subject or to others which might reasonably be expected from the research;
6.2.7. Any appropriate **alternatives** or course of treatment that might be advantageous to the subject (not applicable if the only alternative is not to participate);

6.2.8. For research involving greater than minimal risk, indication whether any **compensation for injury and medical treatment** will be provided if injury occurs;

6.2.9. Description of the extent to which **confidentiality of records** identifying the subject will be maintained;

6.2.10. **Contact persons** for questions about the research, whom to contact in the event of a research-related injury, and whom to contact for questions about subject’s rights;

6.2.11. A statement that **participation is voluntary**;

6.3. The Investigator will include the following additional elements of informed consent, as applicable to the study [HHS 45 CFR 46.116(b) and FDA 21 CFR 50.25(b)]:

6.3.1. Approximate **number of subjects** in the study;

6.3.2. A statement that the treatment or procedure may involve **unforeseeable risks** to the subject (or to the embryo or fetus, if the subject is or may become pregnant);

6.3.3. Circumstances under which the subject’s **participation may be terminated** by the Investigator without regard to the subject’s wishes;

6.3.4. **Additional costs** to the subject to participate;

6.3.5. **Consequences of subject withdrawal** from the study, including what will happen to the data that has been collected about the subject and procedures for withdrawal that may be necessary to protect the subject’s safety;

6.3.6. A statement that significant **new findings** which may relate to the subject’s willingness to continue participation will be provided to the subject.

6.4. For **FDA regulated research**, the Investigator will apply the following additional elements of informed consent, when applicable:

6.4.1. A statement that the test article is “investigational” or “not FDA-approved”;

6.4.2. No claims may be made which state or imply, directly or indirectly, that the test article is safe or effective for the purpose(s) under investigation or that the product is in any way superior to another product;

6.4.3. Description of any plans for randomization;

6.4.4. Description of any plans for use of placebo and the probability of the subject receiving the test article or the placebo;

6.4.5. For applicable FDA regulated research, a statement regarding study registration at ClinicalTrials.gov;

6.4.6. Conditions for breaking the code, if the study is blinded;

6.4.7. For phase I studies, disclosure that the purpose of the research includes examining the safety and toxicity of the test article;

6.4.8. For phase II and phase III studies, the consent document must disclose that the purpose of the research includes examining the test article for safety and efficacy.
6.5. The Investigator will include the following additional elements of informed consent required by the RSRB, as applicable to the study:

6.5.1. HIPAA Authorization, if applicable (see Policy 702 HIPAA Privacy Rule);

6.5.2. A statement that subjects will be given a copy of the consent form, if the consent is written (when the consent includes HIPAA Authorization, it must be a signed copy);

6.5.3. Identification of the entity sponsoring the study, for sponsor-initiated studies;

6.5.4. The amount of payment and how/when payments are made;

6.5.5. A disclosure statement regarding any financial conflicts of interest, for both the Investigator and the University;

6.5.6. Additional information as indicated in the applicable Consent Form Template.

6.6. For additional consent issues and considerations pertaining to vulnerable research populations and special types of study procedures, Investigators should also refer to the following policies and guidelines, as applicable:

6.6.1. Policy 601 Research Involving Children

6.6.2. Policy 602 Research Involving Pregnant Women, Fetuses and Neonates

6.6.3. Policy 604 Research Involving Adults with Decisional Impairment

6.6.4. Policy 608 Research Involving Genetic Testing and Gene Transfer and the Consent for Genetic Testing Template Language

6.6.5. Guideline for Research Involving HIV Testing

6.6.6. Guideline for Research Involving Repositories (for research involving specimen or data banking)

6.7. The RSRB will review the protocol and ROSS application to evaluate the consent process and ensure that it is adequate and meets the criteria for approval according to Policy 404 Criteria for Approval of Research, and other policies as applicable, including but not limited to the following determinations when applicable:

6.7.1. The Investigator will obtain legally effective consent from the subject, or subject’s legally authorized representative;

6.7.2. The consent process provides sufficient opportunity for the subject, or subject’s legally authorized representative, to consider whether to participate;

6.7.3. The consent process minimizes the possibility of coercion or undue influence;

6.7.4. The information communicated to the subject, or subject’s legally authorized representative, is provided in a language understandable to the subject or representative;

6.7.5. The information communicated to the subject, or subject’s legally authorized representative, doesn’t include exculpatory language through which the subject or representative is made to waive, or appear to waive, any legal rights;

6.7.6. The information communicated to the subject, or subject’s legally authorized representative, doesn’t include exculpatory language through which the subject or
representative releases, or appears to release, the Investigator, Sponsor,
University, or its agents from liability for negligence.

6.8. Documentation of informed consent must be obtained using a written consent form
approved by the RSRB, and must be signed by the subject, or subject’s legally
authorized representative [21 CFR 50.27(a) and 45 CFR 46.117(a)] before any research
procedures may begin, unless a waiver of documentation of consent has been granted
by the RSRB (see Section 8).

6.8.1. The RSRB requires the signature of the person obtaining consent when using a
written consent form.

6.8.2. When appropriately justified, obtaining documentation of consent by facsimile
may be permitted by the RSRB. The consent must be presented verbally to the
subject, or subject’s legally authorized representative, and the signed document
returned to the Investigator by facsimile before any research procedures may
begin. The original signed document must be presented to the Investigator and
filed in the Investigator’s study file.

6.9. After consent is obtained, the person signing consent (i.e., subject or subject’s legally
authorized representative) must receive a copy of the entire consent document, unless a
waiver or alteration of informed consent has been granted by the RSRB (see Section 7).
If the consent document includes HIPAA Authorization, a signed copy must be
provided.

7. Waiver or Alteration of Informed Consent Requirements

Note: For FDA regulated research, waiver of the requirements for obtaining informed
consent is not permitted, except as noted in Sections 7.3, 7.4 and 7.5.

7.1. The RSRB may waive or alter some or all requirements for obtaining informed consent,
provided the RSRB finds and documents that the research meets the criteria of 7.1.1 or
7.1.2 below [45 CFR 46.116(b)]:

7.1.1. The research meets all of the following criteria:
- The research involves no more than minimal risk to the subjects,
- The waiver will not adversely affect the rights and welfare of the subjects,
- The research could not practicably be carried out without the waiver, and
- When appropriate, the subjects will provided with additional pertinent
  information after participation.

7.1.2. The research could not practicably be carried out without the waiver or alteration,
the research is to be conducted by or under the approval of state or local
government officials, and the research is designed to study:
- Public benefit or service programs,
- Procedures for obtaining benefits or services under those programs, or
- Possible changes in methods or levels of payment for benefits or services under those programs.

7.2. For FDA-regulated research, the requirements for obtaining informed consent for expanded access of investigational drugs or devices in the clinical treatment of patients are outlined in Policy 605 Research Involving FDA Regulated Drug, Biologics, and Supplements and Policy 606 Research Involving FDA Regulated Devices. Refer also to the ‘Consent for Treatment’ template on the RSRB Consent Form Templates website.

7.3. For FDA-regulated research, the exceptions to informed consent requirements for emergency use of a test article are outlined in Policy 607 Emergency Use of Investigational Drugs, Biologics, and Medical Devices. Refer also to the ‘Consent for Emergency Use’ template on the RSRB Consent Form Templates website.

7.4. For FDA-regulated emergency research requiring waiver of informed consent [FDA 21CFR50.24], refer to the Guideline for Informed Consent.

7.5. For FDA-regulated in vitro diagnostics (IVD) device investigations, it is possible in certain circumstances to conduct research without informed consent using leftover specimens, as long as the subject cannot be identified and where results of the investigational test are not communicated to or otherwise associated with the identified subject (Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable).

8. Waiver of Documentation of Informed Consent

Note: For FDA regulated research, the RSRB may only waive documentation of informed consent under Section 8.1.2 below.

8.1. The RSRB may waive the requirements for documentation of informed consent provided the RSRB finds and documents that the research meets one of the criteria below, as applicable:

8.1.1. That the only record linking the subject and the research is the consent document and the principal risk is potential harm from breach of confidentiality [45 CFR 46.117(c)], or

8.1.2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context [45 CFR 46.117(c) and 21 CFR 56.109(c)].
8.2. The Investigator may be required by the RSRB to provide subjects with a written description of the study (see Consent Form Templates for sample Information Sheets).

9. Informed Consent for Deception Research

9.1. The Investigator must provide an adequate description and rationale for the procedures to be conducted, in addition to fulfilling the requirements for an alteration of informed consent (see Section 7) or waiver of documentation of consent (see Section 8).

9.2. The Investigator must provide the consent documents that will be utilized before the study procedures begin (see RSRB Consent Form to Procedures Template), as well as those used at the conclusion of participation (see RSRB Consent Form to Data Use Template). See the Guideline for Informed Consent.

10. Use of Non-English Consent Forms

10.1. The Investigator must determine if the lack of English proficiency will negatively affect a subject’s ability to participate in the study (e.g., understand and follow directions, ability to report problems or adverse events) when considering whether enrollment of the non-English speaking subject is appropriate.

10.2. If the Investigator anticipates enrolling even one non-English speaking subject, the full consent form, and any relevant subject materials, must be translated into a language understandable to the subject and RSRB approved prior to use.

10.3. Use of Short Forms – The RSRB may permit the use of a short form, in conjunction with the English consent form, for conducting an oral presentation of informed consent when an Investigator needs to unexpectedly enroll a subject who does not read and/or speak English (e.g., when clinical care or treatment is part of the research).

10.3.1. The short form may only be used for the initial presentation of informed consent and to obtain the subject’s consent to participate. Once the subject is enrolled, the informed consent, and any relevant subject materials, must be translated into the language understandable to the subject and RSRB approved prior to use.

10.3.2. The Investigator should follow the steps outlined in the Guideline for Informed Consent when proposing the use of a short form.

11. Certificates of Confidentiality

11.1. A certificate of confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation.
11.2. **Certificates of Confidentiality** (CoC) are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information from forced disclosure.

11.2.1. Certificates do not protect against voluntary disclosures by the subject or researcher; however, those disclosures must be specified in the consent document (e.g., evidence of child abuse or a subject’s threatened violence to self or others).

11.3. Certificates may be applied to biomedical, behavioral, clinical, or other research, and may be issued for both federally and non-federally funded research.

11.4. The Certificate of Confidentiality Template language on the RSRB Consent Forms Templates website provides standard language to include in the informed consent document when a CoC is applied to a study.
Originator/Authors:
Emily Flagg, Senior Regulatory Specialist

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Approved By:

K. A. O'Donoghue
Director, OHSP

T. L. Gommel
Director, RSRB

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