# 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. In addition, this policy describes the requirements for the RSRB to evaluate the consent process when approving research as the Reviewing IRB.

## 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.

- The informed consent requirements in this policy do not preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective.
- Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe).

## 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.

3.2. *Written or In Writing* – Writing on a tangible medium (e.g., paper) or in an electronic format.

3.3. *Electronic Informed Consent (eConsent)* – is an electronic platform for facilitating the informed consent process. It is a computer-based system to disclose the necessary consent elements and document consent, like traditional paper documentation. eConsent may include multimedia components designed to aid the consenting process. It can also be used as a method to evaluate comprehension of the study, with questions built into the eConsent process. When eConsent is used, the consent process can occur in-person or remotely. Not all eConsent systems contain the ability to document legally effective signatures.

3.4. *Legally authorized representative* - An individual authorized to consent on behalf of a prospective subject. Federal regulations (45 CFR 46.116 and 21 CFR 50.20) defer to state law for persons authorized to provide such consent. Per New York State law, another

individual is legally authorized to consent on behalf of a prospective adult subject for the subject's participation in research under the following categories:

3.4.1. A health care agent and proxy (authorized under New York Public Health Law, Article 29-C)

3.4.2. A guardian appointed under the Mental Hygiene Law, Article 81

3.4.3. An individual appointed by the prospective subject under an Advance Directive for Medical Research Participation (research proxy)

3.4.4. In certain instances, a family member or close friend, according to Article 29-CC (Family Health Care Decision Act) or other relevant law.

## 4. References

4.1. HHS 45 CFR 46.116; HHS 45 CFR 46.117; FDA 21 CFR 50.20; FDA 21 CFR 50.24; FDA 21 CFR 50.25; FDA 21 CFR50.3(k) and 56.102(j); New York State Law Article 24-A Section 2442
FDA Guidance for IRBs, Clinical Investigators, and Sponsors: Informed Consent
FDA Guidance – IRB Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations (Dec. 2023)
FDA Guidance, April 2013 – Exception from Informed Consent Requirements for Emergency Research
FDA Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable
NIH Policy for Issuing Certificates of Confidentiality

4.2. Policy 404 Criteria for Approval of Research
Policy 504 IRB Reliance and Collaborative Research
Policy 601 Research Involving Children
Policy 602 Research Involving Pregnant Persons, Human Fetuses and Neonates
Policy 603 Research Involving Prisoners
Policy 604 Research Involving Adults with Decisional Impairment
Policy 605 Research Involving FDA Regulated Drugs, Biologics, and Supplements
Policy 606 Research Involving FDA Regulated Devices
Policy 607 Emergency Use of Investigational Drugs, Biologics, and Medical Devices
Policy 608 Research Involving Genetic Testing and Gene Transfer
Policy 609 Research Supported by the Department of Defense
Policy 702 HIPAA Privacy Rule
Policy 703 Recruitment and Subject Payment

4.3. Guideline for Informed Consent
Guideline for Using REDCap for Electronic Informed Consent (eConsent)
Guideline for Research Involving HIV Testing

Guideline for Research Involving Repositories

4.4. 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. See section 6.7 for a detailed description of the consent requirements when working with vulnerable populations (i.e., pregnant persons, minors, prisoners, etc.)

5.1.2. Section 6.8 describes each of the required elements of the consent process [HHS 45 CFR 46.116, FDA 21 CFR 56.111].

5.2. When the RSRB is the Reviewing IRB, 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, when reviewing modifications to research, and when reviewing reportable new information as appropriate.

5.3. When the RSRB is the Relying IRB, the RSRB is responsible for reviewing the consent form(s) to ensure compliance with institutional review requirements described in *Policy 504 IRB Reliance and Collaborative Research*.

## 6. General Requirements for Informed Consent

6.1. The Investigator must obtain legally effective informed consent of the subject, or the subject's legally authorized representative, before involving a human subject in research.

6.1.1. The Investigator must begin the consent form with a concise and focused presentation of key information that will assist the subject, or subject's legally authorized representative, in understanding the reasons why one might or might not want to participate. This must be organized and presented in a way that facilitates comprehension.

6.2. The Investigator must provide a description of the process for obtaining and documenting informed consent and provide all consenting documents to the Reviewing IRB for review and approval.

6.2.1. All required elements and applicable additional elements of consent, as well as additional institutional and regulatory considerations, listed in Sections 6.3 – 6.7

below, must be included unless a waiver or alteration of informed consent (Section 8) or waiver of documentation of consent (Section 9) is requested by the Investigator.

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

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

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

6.3.1. An introduction that indicates the **study involves research**; explanation of the **purpose** of the research; the **expected duration** of the subject's participation; and a **description of study procedures** which includes the **identification of research procedures** as well as those that are investigational or standard of care procedures.

6.3.2. A description of any reasonably foreseeable **risks or discomforts** to the subject

6.3.3. A description of any **benefits** to the subject or to others which might reasonably be expected from the research.

6.3.4. Appropriate **alternatives** (procedures or course of treatment), if any, that might be advantageous to the subject (not applicable if the only alternative is not to participate).

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

6.3.6. For research involving more than minimal risk, indication whether any **compensation or medical treatment** will be provided if injury occurs.

6.3.7. **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.

6.3.8. A statement that **participation is voluntary**; **refusal to participate involves no penalty or loss of benefits** to which subject is otherwise entitled, and the subject **may discontinue participation at any time** without penalty or loss of benefits.

6.3.9. If there is **collection of identifiable private information or identifiable biospecimens**, one of the following statements must be included regarding **future use of information and/or biospecimens**:

- Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if applicable.

- The subject's information or biospecimens collected as part of the research will not be used or distributed for future research studies, even if the identifiers are removed.

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

6.4.1. 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).

6.4.2. Circumstances under which the subject's **participation may be terminated** by the Investigator without regard to the subject's, or the subject's legally authorized representative's, consent.

6.4.3. **Additional costs** to the subject to participate.

6.4.4. **Consequences of subject withdrawal** from the study, including procedures for withdrawal that may be necessary to protect the subject's safety.

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

6.4.6. Approximate **number of subjects** in the study.

6.4.7. Statement that subject's biospecimens (even if identifiers are removed) may be used for **commercial profit**, including whether subject will or will not share in this commercial profit.

6.4.8. Statement whether **clinically relevant research results** (including individual results) will be disclosed to the subject, and if so, under what conditions.

6.4.9. If research involves biospecimens, whether the research will (if known) or might include **whole genome sequencing**.

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

6.5.1. A statement that the test article is "investigational" or "not FDA-approved".

6.5.2. 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.

6.5.3. Description of any plans for randomization.

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

6.5.5. For applicable FDA-regulated research, a statement regarding study registration at ClinicalTrials.gov.

6.5.6. Conditions for which the study team would be unblinded to the treatment allocation, such as a serious adverse event (i.e., breaking the code).

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

6.5.8. 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.

6.6. The Investigator will include the following additional elements of informed consent required by the University of Rochester:
- 6.6.1. HIPAA Authorization, if applicable (see *Policy 702 HIPAA Privacy Rule*)
- 6.6.2. A statement that subjects will be given a copy of the consent form, if the consent is written.
- 6.6.3. Identification of the entity sponsoring the study, for sponsor-initiated studies.
- 6.6.4. Whether subjects are paid, and if so, the amount of payment and how/when payments are made.
- 6.6.5. If using email or text messaging communication, a statement regarding the purpose the mode(s) of communication, as well as the security risks.
- 6.6.6. A disclosure statement regarding any financial conflicts of interest, for both the Investigator and the University, as applicable.
- 6.6.7. Additional information as indicated in the RSRB Consent Form Template(s).

6.7. For additional consent issues and considerations pertaining to vulnerable research populations and special types of study procedures, Investigators should refer to the following policies and guidelines, as applicable:
- 6.7.1. *Policy 601 Research Involving Children*
- 6.7.2. *Policy 602 Research Involving Pregnant Women, Fetuses and Neonates*
- 6.7.3. *Policy 603 Research Involving Prisoners*
- 6.7.4. *Policy 604 Research Involving Adults with Decisional Impairment*
- 6.7.5. *Policy 608 Research Involving Genetic Testing and Gene Transfer* and the *Consent for Genetic Testing Template Language*
- 6.7.6. *Policy 609 Research Supported by the Department of Defense*
- 6.7.7. *Guideline for Research Involving HIV Testing*
- 6.7.8. *Guideline for Research Involving Repositories* (for research involving specimen or data banking)

6.8. When the RSRB is the Reviewing IRB, the RSRB will review the protocol materials 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 [HHS 45 CFR 46.116, FDA 21 CFR 56.111]:
- 6.8.1. The Investigator will obtain legally effective consent from the subject, or subject's legally authorized representative.
- 6.8.2. The consent process provides sufficient opportunity for the subject, or subject's legally authorized representative, to discuss and consider whether to participate, and minimizes the possibility of coercion or undue influence.

6.8.3. The information communicated to the subject, or subject's legally authorized representative, is provided in a language understandable to the subject or representative.

6.8.4. The subject, or subject's legally authorized representative, is provided with information that a reasonable person would want to have in order to make an informed decision whether or not to participate and provided an opportunity to discuss that information.

6.8.5. The consent form begins with a presentation of key information that will assist the subject, or subject's legally authorized representative, in understanding the reasons why one might or might not want to participate.

6.8.6. The consent form as a whole is presented with sufficient detail relating to the research which facilitates the subject's or subject's legally authorized representative's understanding of the reasons why one might or might not want to participate.

6.8.7. 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, or appears to release, the Investigator, Sponsor, University, or its agents from liability for negligence.

## 7. Documentation of Informed Consent when the RSRB is the Reviewing IRB

7.1. Documentation of informed consent must be obtained using one of the following methods:

7.1.1. A written consent form approved by the RSRB, bearing a current RSRB watermark, with the first page printed on UR letterhead that is signed by the subject, or subject's legally authorized representative [45 CFR 46.117(b)(1) and 21 CFR 50.27(b)(1)] before any research procedures may begin, unless a waiver of documentation of consent has been granted, when allowed (see Section 9).

- The RSRB will consider when the signature of the person obtaining consent is required or when other documentation can be used to document the signature of the person obtaining consent.

7.1.2. The RSRB may approve the use of an eConsent process. IRB approval for eConsent must be obtained prior to its implementation. The following requirements must be documented:

- The consent process (including all components described in Section 6.8 above) and mechanism of authentication is clearly described in the protocol.
- The use of electronic signatures is legally valid within the jurisdiction where the research is to be conducted.
- If FDA-regulated research, the electronic format of consent must be on a 21 CFR 11 compliant platform. **Note: UR REDCap is not part 11 compliant**.

7.1.3. A short form written consent form [45 CFR 46.117(b)(2) and 21 CFR 50.27(b)(2) which states that all elements of consent (see Section 6) were presented verbally to the subject, or subject's authorized representative, and key information was presented first to the subject before other information, if any, was provided.

- The RSRB will approve a written summary of what is to be said to the subject. The full version of the consent form, inclusive of all applicable elements described in Section 6 is often utilized as the written summary.
- Consent utilizing a short form written consent must be obtained and documented ***before*** any research procedures begins.
- Signature and date by the subject, or subject's authorized representative on the current, RSRB watermarked short form.
- Signatures and date of a witness who observed the consent process on both the current, RSRB watermarked short form and the summary document.
- Signature and date of the person obtaining consent is required on the current RSRB watermarked summary document.

7.2. When obtaining consent (whether written or electronic), the Investigator is responsible for giving the subject, or subject's authorized representative, adequate opportunity to read the consent form and ask questions before it is signed. The form may, alternatively, be read to the person providing consent.

7.3. After written documentation of consent is obtained (whether written or electronic), 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 (see Section 8). This also applies to use of short form written consent, in which case a copy of both the short form and the summary document must be provided.

7.3.1. If the consent document includes HIPAA Authorization, a signed copy must be provided.

## 8. Waiver or Alteration of Informed Consent Requirements when the RSRB is the Reviewing IRB

8.1. 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 8.1.1 or 8.1.2 below [45 CFR 46.116(f)(3)], or 8.1.3 below for FDA-regulated research [*FDA Guidance, July 2017 – IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects*]:

8.1.1. The research meets all of the following criteria:

- The research involves no more than minimal risk to the subjects.

- The research could not practicably be carried out without the waiver or alteration.
- If the research involves use of identifiable private information or identifiable specimens, the research could not practicably be carried out without using such information or specimens in an identifiable format.
- The waiver will not adversely affect the rights and welfare of the subjects, and
- When appropriate, the subjects will be provided with additional pertinent information after participation.

8.1.2. The research is to be conducted by or under the approval of state or local government officials, the research could not practicably be carried out without the waiver or alteration, and the research is designed to study, evaluate, or otherwise examine:

- Public benefit or service programs
- Procedures for obtaining benefits or services under those programs
- Possible changes in or alternatives to those programs or procedures or
- Possible changes in methods or levels of payment for benefits or services under those programs.

8.1.3. The research is FDA-regulated and meets all of the following criteria:

- The clinical investigation involves no more than minimal risk [as defined in 21CFR50.3(k) or 56.102(j)] to the subjects.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- The clinical investigation could not practicably be carried out without the waiver or alteration, and
- When appropriate, the subjects will be provided with additional pertinent information after participation.

## 9. Consent Exception for Screening, Recruiting or Determining Eligibility of Prospective Subjects when the RSRB is the Reviewing IRB

9.1. The RSRB may approve a consent exception, whereby an Investigator may obtain information or biospecimens strictly for the purposes of screening, recruiting, or determining eligibility of prospective subjects without informed consent of the prospective subject or subject's legally authorized representative, provided the RSRB finds and documents that the research meets the criteria of 9.1.1 or 9.1.2 below [45 CFR 46.116(g)]:

9.1.1. The investigator will obtain such information through verbal or written communication with the prospective subject or legally authorized representative or

9.1.2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

9.2. Following screening, recruitment or determination of eligibility (as applicable), the Investigator must obtain legally effective informed consent of the subject, or the subject's legally authorized representative (as described in Section 6), ***prior*** to conducting further study procedures.

## 10. Waiver of Documentation of Informed Consent when the RSRB is the Reviewing IRB

**Note: For FDA-regulated research, the RSRB may only waive documentation of informed consent under Section 10.1.2 below.**

10.1. The RSRB may waive the requirement to obtain a signed consent form provided the RSRB finds and documents that the research meets one of the criteria below, as applicable:

10.1.1. 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)].

10.1.2. 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)], or

10.1.3. If the subjects are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to the subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

10.2. If the RSRB waives the requirement for documentation of informed consent, the RSRB may require the Investigator to provide subjects with a written description of the study (see Consent Form Templates for sample Information Sheets).

## 11. Requirements for FDA Regulated Research Requiring Special Consideration when the RSRB is the Reviewing IRB

11.1. 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 RSRB Consent Template.

11.2. 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 RSRB Consent Template.

11.3. For FDA-regulated emergency research requiring waiver of informed consent [FDA 21 CFR 50.24], refer to the *Guideline for Informed Consent*.

11.4. 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 subjects. Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable).

## 12. Informed Consent for Deception Research when the RSRB is the Reviewing IRB

12.1. 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 8). Further justification for a waiver of documentation of consent may also be required, if applicable (see Section 10).

12.2. The Investigator must provide the consent documents that will be utilized before the study procedures begin (see RSRB Consent Form Templates), as well as those used at the conclusion of participation (i.e., Consent to Data Use; Debriefing Form). See the *Guideline for Informed Consent*.

## 13. Use of Non-English Consent Forms when the RSRB is the Reviewing IRB

13.1. Enrollment of non-English speaking subjects (one or more) requires that the consent document and any relevant subject-facing materials, must be translated into a language understandable to the subject, and RSRB approved prior to use. A translator declaration form is required by the RSRB when translated documents are used (see RSRB Consent Form Templates).

13.1.1. The Investigator must determine that the lack of English proficiency will not affect a subject's ability to make an informed and voluntary decision to participate in the study, or the ability to report problems or adverse events, when considering whether enrollment of the non-English speaking subjects is appropriate.

13.1.2. The RSRB may permit the use of a short form (See Section 7.1.2), in conjunction with the English consent form, for conducting a verbal 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). See the *Guideline for Informed Consent* when proposing the use of a short form.

13.1.3. 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 completed materials, must be translated into the language understandable to the subject, and RSRB approved prior to use.

**14. Certificates of Confidentiality**

14.1. Certificates of Confidentiality (CoC) are automatically issued by the National Institutes of Health (NIH) for NIH-funded research, according to the NIH Policy for Issuing Certificates of Confidentiality, to protect identifiable research information from forced legal disclosure. NIH will also consider requests for Certificates for non-federally funded research.

14.1.1. 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).

14.2. The Biomedical Consent Form template and the Non-Biomedical Consent Form template provide standard language to include in the informed consent document for NIH funded research or when a CoC is issued.

**15. Posting of Clinical Trial Consent Forms**

15.1. The awardee or funding agency of a clinical trial that receives federal funding must post one IRB-approved consent form used to enroll subjects on a publicly available federal website, www.clinicaltrials.gov [45 CFR 46.116(h)] (see *Guideline for Informed Consent*).

15.1.1. If the funding agency determines that certain information should not be made publicly available on the federal website (e.g., confidential commercial information), such funding agency may permit or require redactions to the information posted.

15.2. The consent form must be posted on the federal website after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject, as required by the protocol.

**Originator/Authors:**

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

**Appendices:**

None

**Revision History:**

06/2018: Section 2 added exceptions to the scope; Section 4 added hyperlinks; added language throughout for Reviewing versus Relying IRB; Section 12 revised per NIH CoC policy; additional administrative and editorial changes throughout for clarifications and relevance to regulations and current practice.

01/2019: Updates for Revised Common Rule (Section 2, Section 3.2 added, Section 5.1.1, Section 6.1.1 added, Section 6.3.9 added, Sections 6.4.7-6.4.9 added; Sections 6.8.4-6.8.6 added, Section 7.1.1 and 7.1.2, Section 8.1.1, Section 9.1.3 added, Section 14 added); Sections 10.1 – 10.4 moved as a new section; editorial changes throughout; remove T. Gommel as signatory

12/2024: Revised definitions; additional Resources to Section 4; added Section 9; additional administrative and editorial changes throughout for clarifications, relevance to regulations, and current practice. Updated signatories.

**Supersedes Date:**

01/21/2019

**Approved By:**

Signed by:
Elizabeth Kipp Campbell
Signer Name: Elizabeth Kipp Campbell
Signing Reason: I approve this document
Signing Time: 12/6/2024 | 12:09:52 PM EST
4320CFA25932487490F5DFB28FCC7D7C

Elizabeth Kipp Campbell — 12/6/2024 | 12:10:06 PM EST
Associate Vice President for Human Subject Protection — Date

Signed by:
Wendy Duncan
Signer Name: Wendy Duncan
Signing Reason: I have reviewed this document
Signing Time: 12/6/2024 | 2:55:34 PM EST
49FD24DE79D54EC6838597 94C6848D96

Wendy Duncan — 12/6/2024 | 2:55:37 PM EST
Director, Research Subjects Review Board — Date