

## GUIDELINE FOR INFORMED CONSENT

Informed consent is a basic ethical obligation for researchers and is required by federal regulation. Informed consent is a process, beginning with the initial steps of recruitment (see OHSP [Guideline for Recruitment Methods and Materials](#)) and continues as the study progresses. As such, RSRB review of informed consent methods and materials is essential to ensure the consent process provides sufficient opportunity for the potential subject to consider whether to participate and minimizes the possibility of coercion or undue influence. For the RSRB to adequately make a review determination the Investigator must: 1) include a process for consent in the protocol that addresses the questions within the RSRB [Protocol Templates](#), 2) include appropriate consent documents that contain the information requested in the [Consent Form Templates](#), and 3) upload the appropriate consent documents in the RSRB on-line review system. This document supplements OHSP Policy 701 Informed Consent to provide additional guidance to Investigators.

### Table of Contents:

1. [Purpose and General Requirements of Informed Consent](#)
2. [What to Consider For Obtaining and Documenting Informed Consent](#)
3. [Required Basic Elements of Consent](#)
4. [Additional Elements of Consent](#)
5. [Requirements for Deception Research](#)
6. [Use of Non-English Consent Forms \(Short Form\)](#)
7. [Certificates of Confidentiality](#)
8. [Emergency Research Waiver of Consent \(21 CFR 50.24\)](#)
9. [Informed Consent – The Document](#)
10. [Informed Consent - The Process](#)
11. [Consent Documents – Initial RSRB Review](#)
12. [Informed Consent – RSRB Expectations and Investigator Responsibilities](#)
13. [Informed Consent – Activities After RSRB Approval](#)
14. [Addressing Errors in Obtaining or Documenting Informed Consent](#)
15. [Posting of Clinical Trial Consent Forms](#)
16. [Additional Resources](#)

## 1. **Purpose and General Requirements of Informed Consent**

- a) The purpose of the consent form is to provide a written source of information regarding the research, and is a mechanism to document that a subject has consented to participate in the research. The consent form serves as a baseline of information for initial presentation and discussion with the prospective subject and is a resource for the subject to reference during the study.
- b) Only RSRB approved Investigators and study team members listed on the RSRB application may obtain consent, unless the IRB-approved protocol or department policy puts additional restrictions on who may obtain consent. All individuals conducting research, including obtaining consent, must be trained according to [Policy 201 Education Program](#) through the Research Education [Human Subjects Training](#) program.
- c) RSRB approval is required for any consent materials **prior to use**, including, but not limited to:
  - Consent documents
  - Assent/Permission documents
  - Information sheets
  - Cover sheets or other supplemental consent materials
  - Oral scripts
  - Short forms
- d) Informed consent must be obtained before any research procedures may begin.
- e) Documentation of informed consent must be obtained before any research procedures may begin, unless a waiver of documentation of consent has been granted by the RSRB.
  - Waivers of documentation of consent may alter the consent procedures, such as providing an information letter.
- f) 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.
- g) Subjects are considered “enrolled” in a study once consent is obtained. In studies where a screening/selection process is needed, it may be necessary to obtain a separate consent for the screening in addition to the main study consent. In either case, the process should be clearly described in the protocol.
- h) After consent is obtained, the subject (or subject’s legally authorized representative), must receive a copy of the entire consent document (if the consent document includes HIPAA Authorization, the copy must be signed), and **the entire signed original** document is retained in the Investigator’s study file.

[\[Table of Contents\]](#)

## 2. **What to Consider when Obtaining and Documenting Informed Consent**

The amount of information that needs to be presented both in writing (i.e., the consent document and related materials) and orally is directly related to the risk that the study presents, the complexity of the research procedures, and the subject population.

- a) In order to provide an adequate description of the informed consent process in the protocol, the following should be considered by the Investigator and included in the protocol and consent materials submitted to the RSRB, as appropriate to the study design:

- Identification of the person(s) who will conduct the consent process;
- Identification of the person(s) who will provide consent or permission/assent (e.g., subject, parent/guardian, child, legally authorized representative);
- Information communicated to the potential subject such that adequate information is provided to allow for an informed decision about participation in the study;
- When non-English speaking subjects may be included in research, the language used by those obtaining consent and the language understood by the potential subjects (or legally authorized representative);
- If an auditor, witness, and/or translator are to be used, an explanation of their function, when they are required (e.g., consenting, study visits), as well as who qualifies to act as an auditor/witness/translator;
- A process for the Investigator and study team to facilitate the potential subject's understanding of the information;
- Provisions to provide adequate opportunity for the potential subject to ask questions and to consider whether to participate;
- The process for determining subject comprehension of the study (e.g., use of assessment tool, documentation in visit note);
- The process for minimizing undue influence on subject participation, especially when the study will include vulnerable populations such as children or decisionally impaired adults;
- The criteria for data retention when a subject withdraws from the study, such as:
  - Data collected until the point of withdrawal remains part of the study database and may not be removed,
  - Whether the subject will be offered the opportunity to provide continued follow-up data if the subject withdraws only from the interventional portion of the study (e.g., outcome information), the mechanism to ensure the subject gives consent to this limited participation, and indication that, if consent is not given, only data collected until the point of withdrawal will be used.
- Whether there will be any waiting period between the first discussion about the study with the potential subject and obtaining consent;
- The process for obtaining documentation of the potential subject's voluntary agreement to participate (unless RSRB grants a waiver of documentation of consent), or the process used for obtaining permission of the legally authorized representative, if applicable;
- Explanation as to how consent will be documented and how the forms will be stored (e.g., medical chart, electronic health record, school records);
- The process for providing information to the subject as the study progresses, as necessary.

[\[Table of Contents\]](#)

### 3. **Required Basic Elements of Consent**

Although each research study is unique in design, study population, and risk level, the federal regulations and the RSRB require that all consent forms contain the following required elements, unless a waiver or alteration of the informed consent process has been approved by the RSRB:

- a) Key Information - a concise and focused presentation of key information that will most likely assist the subject, or subject's legally authorized representative, in understanding the reasons why one might or might not want to participate.
- b) An introduction that indicates the **study involves research**;
- c) An explanation of the **purpose** of the research;
- d) A **description of study procedures**, which includes **identification of research procedures**, as well as those that are investigational or standard of care procedures;
- e) The **expected duration** of subject's participation;

- f) A description of any reasonably foreseeable **risks or discomforts** of participation;
- g) A description of any **benefits** to the subject or to others which may reasonably be expected from the research;
- h) Any 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);
- i) For research involving greater than minimal risk, indication whether any **compensation and medical treatment** will be provided if injury occurs;
- j) Description of the extent to which **confidentiality of records** identifying the subject will be maintained;
- k) **Contact persons**
  - Study team - for information about the research, to address any concerns during study conduct, to report research events, and possible research-related injury
  - RSRB – to allow subjects to voice concerns about the research, about their rights as a research subject, and if the subject is unable to get in touch with the study team.

*Note: It is important for study teams to have a method for handling subject calls about the research and to respond in a timely manner.*
- l) 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; and,
- m) If there is **collection of identifiable private information or identifiable biospecimens**, one of the following statements 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.

[\[Table of Contents\]](#)

#### 4. **Additional Elements of Consent**

The following additional elements of informed consent are required by federal regulations and the RSRB, as applicable to the study, unless a waiver or alteration of the document has been approved by the RSRB:

- Additional elements required by federal regulations:
  - a) 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);
  - b) 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 (e.g., side effects of a study drug are too severe, the sponsor terminates the study);
  - c) **Additional costs** to the subject to participate (e.g., hospitalization, cost of testing or transportation to and from the research site);
  - d) **Consequences of subject withdrawal** from the study and procedures for withdrawal that may be necessary – include whether any adverse health or welfare effects may be anticipated (e.g., the need to taper a drug treatment), or whether additional tests may be needed to help ensure the safety of the subject after withdrawal, and consequences of withdrawal are not intended to coerce the subject into continuing participation;

- e) A statement that significant **new findings** which may relate to the subject’s willingness to continue participation will be provided to the subject (e.g., if findings of a data & safety monitoring board raise safety concerns, new toxicities develop).
  - f) Approximate **number of subjects** in the study, to provide subjects the risk exposure/context in which the study takes place, or to inform subjects if these numbers may pose a risk to privacy;
  - g) 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;
  - h) Statement whether **clinically relevant research results** (including individual results) will be disclosed to the subject, and if so, under what conditions; and,
  - i) If research involves biospecimens, whether the research will (if known) or might include **whole genome sequencing**.
- Additional elements required for FDA regulated research:
- a) A statement that the test article is “investigational” or “not FDA-approved”;
  - b) 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;
  - c) Description of any plans for randomization (e.g., one in two, like flipping a coin; or, one in four like drawing numbers from a hat);
  - d) Description of any plans for use of placebo and the probability of the subject receiving the test article or the placebo;
  - e) Conditions for breaking the code, if the study is blinded;
  - f) For applicable FDA regulated research, a statement regarding study registration at [ClinicalTrials.gov](https://www.clinicaltrials.gov) – to determine if registration applies, refer to the [clinical trials fact sheet](#);
  - g) For phase I studies, disclosure that the purpose of the research includes examining the safety and toxicity of the test article;
  - h) 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.
- Additional elements required by the RSRB:
- a) HIPAA Authorization, if applicable (see *Policy 702 HIPAA Privacy Rule*);
  - b) 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);
  - c) Identification of the entity sponsoring the study, for sponsor-initiated studies;
  - d) The amount of payment and how/when payments are made;
  - e) A disclosure statement regarding any financial conflicts of interest, for both Investigator and University;
  - f) Other elements as indicated in the applicable [Consent Form Template](#).

[\[Table of Contents\]](#)

## 5. **Requirements for Deception Research**

The RSRB recognizes that some otherwise ethically acceptable social/psychological research cannot be conducted with a complete description of its purpose; so some information must be temporarily withheld and an altered informed consent process is necessary. The [Consent Form Templates](#) website contains “Consent to Procedures” and “Consent to Data Use” template forms.

- a) Protocol Requirements – The Investigator should address the following points in the protocol, as applicable:
  - Rationale for scientific validity of the research,
  - Consideration of comparative efficacy of alternative procedures,

- Assurance that deception would not influence subjects' willingness to participate,
  - Procedures for removing any harm through debriefing,
  - Assurance that the deception doesn't create inappropriate invasions of privacy,
  - Procedures for handling data when the subjects do not consent for their information to be used as part of the research.
- b) Consent to Procedures – Prior to beginning study procedures and data collection, subjects must have the opportunity to read and respond to as much information about the study as possible. This consent should not be used as part of the deception, therefore, should not include untruthful information. Any missing information should not put the subject at increased risk of harm or discomfort. This consent should include, at minimum, the following information:
- Study title,
  - Investigator name(s), department, contact information,
  - What subjects will be asked to do,
  - Any risks associated with study activities,
  - Any payment for participation,
  - Opportunity to withdraw at any time without penalty,
  - Opportunity to ask questions and get answers,
  - Signature and date of the subject and person obtaining consent, unless a waiver of documentation of consent has been approved by the RSRB.
- c) Consent to Data Use – At the conclusion of participation, it is important that the researcher disclose to the subject that deception occurred as part of the research and be given the opportunity to consent to allow the data to be used, or to withdraw from the study. Subjects must have an opportunity to read and respond to additional information regarding the actual purpose of the research. This consent should include, at minimum, the following information:
- Study title,
  - Investigator name(s), department, contact information,
  - Full disclosure of the deception/actual purpose of the study,
  - Opportunity to withdraw at any time without penalty,
  - Opportunity to ask questions and get answers,
  - A statement noting that a form of deception was used in the study,
  - A statement regarding data use (e.g., “I give my permission for the Investigators to use the data I provided in this study. If I do not give my permission, I understand that the data I provided will be destroyed.”).

[\[Table of Contents\]](#)

## **6. Use of Non-English Consent Forms (Short Form)**

When the Investigator anticipates enrolling even one non-English speaking subject, the consent form, and any relevant subject materials (e.g., consent forms, recruitment materials, surveys, questionnaires, subject completed assessments) must be translated into a language understandable to the subject (i.e., the subject's primary language) and RSRB approved prior to use. However, the RSRB may permit the use of a short form for obtaining consent when an Investigator needs to unexpectedly enroll a non-English speaking subject (e.g., when clinical care or treatment is part of the research)

The short form may only be used to initially obtain the subject's consent to participate. Once the subject enrolls in the study, the consent, and any relevant subject materials (e.g., surveys, questionnaires, subject completed assessments), must be translated into the subject's primary language and RSRB approved prior to use. Once the documents have been translated, a modification should be submitted to



provide the RSRB with the translated documents (including a completed translator's declaration and the CV of the translator). Once approved the translated documents should be provided to the subject.

The RSRB has several translated short forms, as well as a Translator Attestation, under the [Consent Form Templates](#) on the RSRB website. An English version of the short form is also included with the RSRB consent templates, which may be used to translate into the subject's primary language.

a) Submit a Modification (Expedited review is permitted)

The modification must include a short form written consent document in the subject's primary language, and must include, at minimum, the following information:

- Title of the study,
- A statement that the study's (English) consent form was presented orally to the subject/subject's legally authorized representative,
- The purpose, risks, benefits and alternatives (if any) of participation,
- A statement that participation is voluntary and the subject can withdraw at any time,
- A statement that the subject was given a copy of the (English) consent form and of the short form,
- Name, signature line, and date for the subject/ subject's legally authorized representative,
- Attestation, signature line, and date for the witness.

b) When Using the Short Form, the following must be considered:

- The English-version of the written consent states the elements of disclosure required by regulations have been presented orally to the subject or the subject's authorized representative.
- The written summary or the English-version of the written consent embodies the basic and required additional elements of disclosure.
- There is an **adult** witness to the oral presentation of the short form who is conversant in both English and the subject's primary language. The witness must be unaffiliated with the research and it is best if the witness is a fluent professional. **It is best if the witness is not a family member.**
- The translator should not be the same person as the witness.
- The subject or the subject's authorized representative will sign and date the translated short form.
- The witness will sign both the translated short form and the English-version of the written consent.
- The person obtaining consent will sign the English-version of the written consent.
- Copies of the translated short-form and the English-version of the consent will be given to the subject or the subject's authorized representative.
- Both the original signed translated short-form and the signed full English version are to be kept in the research records with other signed consent forms.

[\[Table of Contents\]](#)

## 7. Certificates of Confidentiality

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

NIH will also consider requests for Certificates for non-federally funded research. More information regarding Certificates of Confidentiality may be found on the [NIH Certificates of Confidentiality](#) website.

[\[Table of Contents\]](#)

## 8. **Emergency Research Waiver of Consent (21 CFR 50.24)**

If an Investigator proposes FDA regulated research requiring emergency waiver of informed consent, refer to *Policy 704 Exception from Informed Consent Requirements for Emergency Research*. When the RSRB is the Reviewing IRB, the Investigator must complete the *Justification for Emergency Waiver of Informed Consent and Community Consultation/Public Disclosure Plan*. This document will be used in conjunction with the RSRB Reviewer Guide for the RSRB and the Institution to evaluate the feasibility and regulatory requirements of conducting the research. If an Investigator would like to pursue this type of research, contact the RSRB Director for additional information.

[\[Table of Contents\]](#)

## 9. **Informed Consent – The Document**

The consent documents are meant to act as the foundation for the exchange of information between the Investigator, study team, and potential subjects. The document should be written and presented in a manner that is clear and understandable\* to the study population. It should provide potential subjects with enough information so that they can make an informed decision about whether to participate in the study. Subjects must also have the opportunity to ask questions and have their questions answered prior to making that decision.

\*Understandable also pertains to the language commonly spoken by the subject population. Investigators who anticipate enrolling even one subject who only speaks a language other than English need to translate the entire consent form (and any other recruitment or subject completed materials) into that language. This translation may be done after the English form has been approved, but translated forms must be approved by the RSRB before use.

The RSRB [Consent Form Templates](#) provide instruction, as well as standard language to assist Investigators in developing consent documents that comply with federal regulations and University and OHSP policies and guidelines. In addition, the templates may be used in conjunction with sample language for various topics provided in the [Consent Document Sample Language](#) guide.

### a) Points to Consider When Developing Consent Documents

- Information in the consent form must agree with the study plan/protocol. It's not uncommon for protocols to go through a number of revisions before and after submission to the RSRB. Some protocol revisions may require modification to the consent form (e.g., the number/kind of tests); therefore, with each revision ensure the protocol and consent are consistent (e.g., not 3 tests in the consent and 4 in the protocol).
- Use suggested font types of Times New Roman or Arial and **font size of at least 12 point**. Consent forms for elderly subjects and those with visual impairments may benefit from even larger type. Keep the font type, style, and size consistent throughout the document.
- The footer should include:
  - Page numbering (e.g., 1 of 6),
  - The STUDY number, and
  - The version date – when entering the date in the footer, manually type in the date rather than selecting “Insert Date” from the footer toolbar. Using “Insert Date” will



automatically update the footer each time the document is opened resulting in incorrect version dates.

- Maintain a space in the bottom right hand footer of at least 1.25" x 1.25" to provide space for watermarking approved documents.
- Aim for a 6th-8th grade reading level. Most word processors can generate reading level scores. Although some study designs or diseases under study may, by nature, lead to consent documents written at a higher reading level, use of the following may aid in producing a document with a lower reading level.
  - Replace scientific, medical and technical terms with lay terms. See 'Plain Language Resources' under [Additional Resources](#) for thesauruses and health literacy toolkits.
  - Subheadings and white space to improve readability in long forms.
  - Keep words to 3 syllables or less. Keep sentences short, simple and direct. Keep paragraphs short, conveying one procedure/risk/etc. per paragraph/bullet.
  - Pictures, lists, bullets, tables and charts to help clarify complex schedules, study designs, and procedures. When using graphics ensure that they are
    - easy to understand,
    - have captions,
    - reproduce well,
    - are appropriately located and
    - are meaningful to the subject.
- The project title in the consent form may be the actual title used in the RSRB application and grant/contract, or, if it helps the subject understand the study, it may be simplified (as long as it isn't incorrect or misleading).
- Write as if you were talking to the subject in a conversational tone in 2nd person narrative, e.g., "you are being asked to...", rather than about the subject in 3rd person objective, e.g., "he/she will be asked to...". Use active rather than passive voice and keep pronoun usage consistent through the document. For example, rather than saying:
  - A pregnancy test will be administered to you/the subject will be given...  
...say:
  - You will have a pregnancy test.
- Do not use, "I understand that..." This terminology can be coercive, implying a level of understanding the subject may not have.
- Use the term "subject" instead of "participant" or "patient".
- For clinical trials, use "study doctor" or "study investigator" instead of "principal investigator".
- Use the term "payment" instead of "compensation".
- List/Describe study procedures in a logical order (start at the beginning; end at the end).
- Use consistent terminology throughout the document. Spell out all abbreviations and acronyms when first used. Clearly define any scientific, medical or legal words.
- Consider providing a summary of highlights or supplemental "quick reference guide" with consent documents that are lengthy and potentially overwhelming.
- When creating multiple consent documents for one study (e.g., an adult consent, legally authorized representative permission form, parental permission form and age-appropriate assents) consider combining the consent and permission documents. This can be accomplished by stating in the consent heading "If you are the parent of a child or the legally authorized representative of an adult subject who may be enrolled in this study, the use of the word 'you' in this form refers to the subject."

#### b) Preventative Action Measures

The following should be considered when developing and using consent documents throughout the course of a study:

- Incorporate electronic letterhead directly onto the 1st page of all consent documents submitted to the RSRB so the RSRB approved document(s) is ready to print and use. This eliminates the extra step of having to print documents on letterhead.
- Only the Principal Investigator needs to be identified at the top of the first page on the consent form. The more Investigators/study team members listed in the heading, the more likely the need to revise the document when there are changes to the study team members. The more consent form revisions the greater likelihood, that an outdated/incorrect version of the form will be used when obtaining consent.
- Do not include a space for subject initials on each page of the document. This is not a requirement and leads to compliance problems if the subject misses a page. Initials should only be used for indicating participation in optional procedures.
- Do not include a witness signature, unless necessary. OHRP and FDA only require a witness signature when a short form is used to document consent. For studies where witness signatures are necessary to include, it is best practice to address in the study protocol whether this is mandatory or optional. If optional, the protocol should indicate circumstances in which this should be completed.
- Develop a process for:
  - Maintaining copies of the current, approved, RSRB watermarked (when applicable) consent forms for use.
  - Destroying outdated copies of consent forms.
  - Ensuring that the signature page (including name, signature, date and any optional checkboxes) is completed at the time of consent/before the subject leaves the visit.
  - Providing subjects with a signed copy of the document.

[\[Table of Contents\]](#)

## **10. Informed Consent - The Process**

The consent document is a description of what will be communicated to potential subjects. The process not only includes reviewing and signing the consent document, but may also include the following:

- Recruitment materials
- Oral instructions or explanations
- A question and answer period
- Assessing subject understanding
- Providing adequate time for the subject to review the form and consider their participation
- Providing new findings or study updates as appropriate throughout the study
- Periodic re-affirmation or re-consent as appropriate throughout the study

As part of the review process, the RSRB will evaluate the consent process outlined in the study protocol to ensure that the process is adequate given the nature of the study. In developing the consent process in the protocol, the following should be considered:

- Setting: Generally speaking consent discussions should occur in a private setting where your conversation won't be overheard by others (this is particularly important when dealing with topics that are sensitive in nature). It's also important to consider how the setting may affect the discussion. For example, if study information is being presented in a classroom setting there may be additional elements of peer pressure and inattentiveness to deal with.
- Timing: The consent process should be completed well in advance of any study intervention or procedure to give the subject sufficient opportunity to consider participation. It may take

several meetings/discussions before the potential subject not only understands the study but, for those recently diagnosed with a new disease or disorder it may also require additional time to understand the new information and what alternative treatment options may be available.

- Minimizing Undue Influence: Vulnerable populations such as minors and students are particularly susceptible to influence from authority. Healthcare providers have tremendous influence over patients within their clinical practice. Potential subjects may be too trusting of their healthcare providers and provide consent without a true understanding of what the study entails. Potential subjects may not want to antagonize healthcare providers by refusing to participate in a study. In these cases, it may be appropriate to consider delegating the consent responsibility to someone else on the study team.
- Use additional aids (videos, brochures, etc.) to explain study procedures and supplement the information provided in the consent document.
- Ask open-ended questions to potential subjects to assess their understanding of the study (e.g., “In your own words, tell me...what the study is about; what will happen to you if you decide to be in the study; what risks might you experience; what other options do you have.”).
- Discuss the study in the presence of “personal advisors” (friends/family members) who may aid in the subject’s decision making process, with the permission of the potential subject.

[\[Table of Contents\]](#)

## **11. Consent Documents – Initial RSRB Review**

Once the consent document has been submitted to the RSRB with the initial application, it will be reviewed by the RSRB Specialist, Chair or Vice Chair and, depending on the level of risk, the convened board. The document will be reviewed to ensure that it is understandable and consistent with the protocol and application. Any RSRB-required changes will either be described in writing or provided directly in a tracked document.

- In reviewing tracked documents, be sure to review and accept each change and address any miscellaneous comments or questions noted directly in the document. Once all of the necessary revisions have been made and the tracked changes accepted, review the document for any additional grammatical or formatting errors.
- A clean, unmarked version of the document should be uploaded into the RSRB application for review by the RSRB.
  - If a tracked copy of the document is going to be provided, upload the tracked document when submitting the response to the RSRB.
- When you receive notification that your study has been approved by the RSRB, the RSRB approved consent documents are available in the online review system in the ‘Documents’ tab. These are the approved forms that should be printed and used for purposes of consent. Refer to the [Click® IRB: Study Staff Manual](#) under “Find Approved Study Documents” for additional guidance.

[\[Table of Contents\]](#)

## 12. **Informed Consent – RSRB Expectations and Investigator Responsibilities**

Expectations concerning the process for obtaining and documenting informed consent are the same regardless of the risk level of the study. In order to comply with federal regulations, University and OHSP policies and guidelines, the responsibilities of the Investigator are outlined in the RSRB approval letters. These letters indicate that Principal Investigators are responsible for ensuring compliance with [Policy 901 Investigator Responsibilities](#) and reporting any unanticipated problems involving risks to subjects or others according to [Policy 801 Reporting Research Events](#). Investigators are also responsible for maintaining all RSRB approved materials, including all approved pages of the signed consent form for at least 3 years after the research is completed and closed with the RSRB (6 years protected health information was collected as part of the research), or for a longer term if required by FDA regulations or other contractual agreements.

*Practically speaking, what does this mean?*

- a) How Consent is Obtained: The RSRB expects that consent will be obtained in the manner indicated in the RSRB approved application and protocol, and that any changes to the procedures will be submitted for RSRB approval by means of a modification request.

Here are some examples:

- If the study eligibility criteria state that subjects must be able to consent for themselves, a relative or friend cannot sign the consent on behalf of the subject.
  - If the protocol indicates that only English speaking subjects will be enrolled, consent cannot be obtained from an individual who doesn't speak or read English.
  - If the study involves two different populations and two separate consent documents for each population (e.g., patients with illness and healthy controls), the proper consent for each specific subject population must be used.
  - If the protocol states that the Principal Investigator will obtain consent and no other study team members, then only the Principal Investigator may sign consent as the person obtaining consent.
- b) How Consent is Documented (Signed): The following guidance will help ensure proper documentation of consent:
- Unless the requirement for the subject's signature has been waived by the RSRB through a waiver of documentation of consent, make sure the consent form is signed and dated. Signatures are required from the subject (or subject's representative) and from the person obtaining consent. The person obtaining consent should sign the form on the same day as the subject. Signature dates separated by days may prompt auditors and the RSRB to question compliance with the consent process. If it is anticipated that the signature dates of the subject and person obtaining consent will consistently be different (e.g., when obtaining written consent via mail after a telephone discussion), this should be described in the protocol.
  - Make sure the first page of the consent document is on department letterhead. It is recommended that consent/recruitment documents be submitted to the RSRB with the first page on electronic letterhead; however if this is not possible, the first page of the document should be printed on letterhead after approval and before it is presented to potential subjects.
  - Make sure that any checkboxes on the form (e.g., indicating interest in optional, additional testing, or future studies) are completed.
  - Make sure that any witness signature blocks are completed. Generally speaking, it is expected that only individuals unaffiliated with the research will act as witnesses. If a

witness is optional or required only in certain circumstances, this should be clarified in the protocol.

- Remember that anyone obtaining consent must have completed [human subjects training](#) and must be approved by the RSRB according to study team members listed in the RSRB application. If, during the study, additional individuals will obtain consent, submit a modification to the RSRB adding these individuals to the list of study team members. This modification must be RSRB approved before the added study team member obtains consent.
  - The RSRB expects that the original signed consent be maintained in the study file by the Investigator and that a complete copy of the consent form is provided to the subject (if HIPAA Authorization is included in the consent document, it must be a signed copy). Failure to keep these records may lead auditors/RSRB to question whether valid consent was obtained.
  - To help ensure confidentiality, store the consent forms in a secure manner (in a locked file cabinet, for example). **The Investigator must maintain control over the original, signed consent form(s).** If a copy needs to be uploaded into the electronic health record, a copy of the signed form should be used.
  - DON'T sign or date the consent form for the subject (or the subject's representative). Signed consent documents should be reviewed by the person obtaining consent prior to providing a copy to the subject to ensure it is complete.
  - DON'T use a signature stamp in place of an original signature for the person obtaining consent.
  - DON'T white out, cross out or otherwise change any part of the RSRB approved consent form. Any revisions to the content of the consent form must be submitted as a modification for RSRB review and approval.
    - It is acceptable for the person obtaining consent to use the back of forms/other white space to note questions the subject or family members asked, etc. as a way to document the consent conversation.
    - Any changes to a signature or the dates for corrections, etc., should be initialed and dated by the person making the change at the time the change is made. In addition, include a reason for the change, e.g., error or typo.
  - Consider documenting the consent process for each subject in the progress note/case history. While federal guidelines do not specify that further documentation is required beyond that of signing/dating the consent form, FDA guidance under Good Clinical practice specific to clinical trials and FDA regulations under Investigational New Drug Application state that “the case history for each individual shall document that informed consent was obtained prior to participation in the study” (21CFR312.62[b]). Therefore, although contextual documentation of how and when the consent process occurs is not required for all studies, it is recommended as best practice. Documentation of any re-consent should also be included in the study file.
- c) Using the Current RSRB Watermarked Consent: The RSRB places a watermark on each page of the approved consent (and recruitment) document, as applicable, indicating the approval date and expiration date, when applicable.

Points to consider:

- The watermarked consent is the version the RSRB approved and the only one the University recognizes as valid. To locate the watermarked documents in the Click IRB system, refer to the [Click® IRB: Study Staff Manual](#) under “Find Approved Study Documents”:

- Review the consent document before presenting it to the potential subject. Make sure the date on the consent form indicates the current version.
- Each time the consent form is modified or the study is renewed, file one copy of the previous version in the study file, but destroy any unsigned copies to help ensure that only the current copies are available to the study team members and presented to potential subjects. Note that it is best practice to download the consent document from the Click IRB online review system to ensure the most currently approved version is used.

[\[Table of Contents\]](#)

### **13. Informed Consent – Activities After RSRB Approval**

#### a) Storage of Consent Documents

- As noted above, and per [Policy 901 Investigator Responsibilities](#), Investigators are responsible for maintaining all approved pages of the signed consent forms for at least 3 years after the research is completed and the RSRB file is closed (6 years if HIPAA authorization is required), or for a longer term if required by FDA regulations or other contractual agreements. In storing consent documents, keep the following points in mind:
  - **The Investigator must maintain control over the original, signed consent forms while at the University of Rochester**, but ultimately signed consent documents are under the custody of the department. If the Investigator leaves the institution, the original signed consents must remain at the University of Rochester.
  - Designate one specific area to store all original copies of signed consent documents to decrease the chance of losing the documents.
  - Store the signed documents in chronological order to aid in finding the last signed consent documents required for continuing review.
  - Consider maintaining a link between the consent document and subject number. In the event of an audit, it is important to be able to link signed consent documents to study data. Ideally study teams should keep an enrollment log separate from the study database.
  - Keep a blank approved copy of all RSRB approved consent documents in the study file. This should be done at the time of every approval.

#### b) Modifications to Consent Documents

- Revisions may be as minor as an updated Investigator telephone number or as major as the addition of a new investigational arm. Whatever the nature of the change, RSRB review and approval is required before the change may be implemented.
- Consider whether current/past subjects will need to be informed of the change and potentially re-consented. Changes that are minor and do not affect subject participation (e.g., formatting, editorial or study team member changes) may not require notification and/or re-consent. A change to telephone numbers for contact information may need to be communicated. Likewise, when more substantial changes are made, such as adding an additional procedure, changing subject payment, new information emerges that may affect subject's willingness to participate), the information needs to be communicated to subjects.
- Changes may be communicated orally or in writing via an information sheet/letter, a consent addendum, or a revised consent form, depending on the nature of the change, but the content of the notification must be approved by the RSRB. Any oral communications should be documented in the subject's study file.

#### c) Continuing Review of Consent Documents

- At the time of continuing review, the RSRB requests a complete (all pages) copy of the consent signed by the last subject enrolled. If the study has more than 1 approved consent document,



a copy of the last signed form for **EACH** type of approved consent document should be submitted. The printed name and signature of the subject (or subject's legally authorized representative) and witness, if applicable, should be blanked out **on the copy submitted**, *not on the original*, to protect subject privacy. Do not obscure the subject's (or witness', if applicable) written date of consent nor the name, signature and date of the person obtaining consent. The RSRB reviews the document(s) to determine the following:

- The first page is on letterhead.
- Each page contains the current RSRB watermark (when applicable).
- Signatures and dates are appropriately provided.
- The person obtaining consent was approved by the RSRB.
- The entire, correct consent version was used.

d) Re-Consenting Subjects

- Throughout the course of the study, it may be necessary to re-consent subjects, as determined by the study team, or the RSRB. Circumstances in which re-consent would be required include, but are not limited to, the following:
  - Substantial changes are made to the study (e.g., changes in risks or study procedures), or new information emerges regarding study participation.
  - The RSRB board or chair determines that re-consent is required after an incident of non-compliance has been reported.
  - A minor that originally provides assent with parental permission and subsequently turns 18 during the course of study participation must give consent in order to continue participation.
  - A subject originally enrolled with the permission of a legally authorized representative regains capacity during the course of study participation must give consent in order to continue study participation.
  - A subject that initially provides consent for participation and subsequently loses capacity over the course of a study, permission from a legally authorized representative would then be required to allow for continued participation (given that the protocol includes provisions for this as part of the consent activities).
- In the event that a subject needs to be re-consented, ensure that only the most recently approved RSRB consent document is used and that the current date is used to document the date of re-consent (not the date prior consent was obtained). Ensure that the re-consent is documented in the study records.

[\[Table of Contents\]](#)

#### **14. Addressing Errors in Obtaining or Documenting Informed Consent**

Errors in obtaining and documenting informed consent occur, and are typically either self-identified by the study team, found at the time of an external audit, at the time of an OHSP Quality Improvement review, or when the RSRB reviews the last signed consent documents submitted with the continuing review. Common errors include:

- Using the incorrect form – an outdated version of the document or the wrong document for the study population (e.g., using a written assent versus the oral script for a subject 12 years of age or under).
- Not printing the first page of the document on letterhead, or not using an approved version of the document.
- Consent obtained by individuals who have not been approved by the RSRB, or study team members without human subject training or their training has expired.

- Hand written cross outs, additions or other revisions on the consent document.
  - Initiating study procedures prior to obtaining consent.
  - Not checking boxes or initialing for optional procedures or contact for future research.
- Typically errors are minor and may be remediated through a variety of actions depending on the circumstance. Regardless of the circumstance, the error must be reported to the RSRB. Errors can be reported using either of the following mechanisms: 1) Submit a Report of New Information in the online review system, or 2) at the time of completing the continuing review form, do not check the question "All problems that require prompt reporting to the IRB have been submitted" and summarize the errors in the Comments section. If there are reporting questions, consult the RSRB regarding the appropriate mechanism to use.
- When errors are reported, the RSRB will review the event and determine if the remediation plan is appropriate. Corrective actions may include:
- Notification to the subject(s).
  - Re-consent of the subject(s).
  - Documenting the error in a note to file
    - Notes to file are meant to provide additional information or clarification to study documents maintained in the study file and to explain any discrepancies or missing/incomplete data. To be valuable, the note to file should explain the discrepancy, the action taken to correct the discrepancy, and the preventative action adopted to prevent similar discrepancies in the future.
  - De-identification of the data.
  - Exclusion of the data.
- Although errors in obtaining and documenting informed consent are typically minor, if the Investigator does not adhere to federal regulations and/or University policy regarding informed consent, then the Investigator has failed to obtain a legally effective informed consent.

NOTE: Failure to obtain legally effective informed consent may be considered serious non-compliance under federal regulations and repeated failures may be considered continuing non-compliance (see [Policy 802 Non-Compliance in Human Subjects Research](#)). Both serious non-compliance and continuing non-compliance must be reported to federal authorities according to the [Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance, UPIRTSO](#).

[\[Table of Contents\]](#)

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

The revised Common Rule requires that for any clinical trial obtaining federal funding, one IRB-approved consent form used to enroll subjects must be posted on a 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 (see [Policy 701 Informed Consent](#)). Two publicly available federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule, have been identified: [ClinicalTrials.gov](#) and a docket folder on [Regulations.gov](#) ([Docket ID: HHS-OPHS-2018-0021](#)). For additional information and instruction refer to the HHS website regarding [Clinical Trial Informed Consent Posting](#).

[\[Table of Contents\]](#)

## 16. Additional Resources

- a) OHRP & FDA
  - [The Belmont Report](#)
  - [OHRP Informed Consent Guidance](#)
  - [OHRP Informed Consent FAQs](#)
  - [OHRP Informed Consent Tips](#)
  - [OHRP Video – General IC Requirements](#)
  - [FDA – A Guide to Informed Consent](#)
  - [FDA/ICH E6 Good Clinical Practice – Consolidated Guidance](#)
  
- b) Plain Language Thesauruses & Health Literacy Tools
  - Agency for Healthcare Research and Quality – [Informed Consent and Authorization Toolkit for Minimal Risk Research](#)
  - CDC – [Simply Put: A Guide for Creating Easy-to-Understand Materials](#)
  - Program for Readability in Science & Medicine ([PRISM](#)) [Readability Toolkit](#)
  - URMC Miner Library - [Health Literacy Toolkit](#)

[\[Table of Contents\]](#)