Informed Consent Process

Human Research Protections Office (HRPO)

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Understanding the Consent Process

The consent process is more than obtaining a signature on a form—it's an ongoing process of information exchange that includes:

- Recruitment materials
- Verbal instructions
- Question/answer sessions
- Efforts to enhance participant understanding before and after *voluntary* consent

The Principal Investigator (PI) and research team must ensure each research participant voluntarily gives informed consent before participating in research activities, unless the IRB grants a waiver. The consent document should serve as the foundation for meaningful exchange between investigator(s) and participant.

Note: "Consent form" includes assent forms and HIPAA Authorization forms.

Essential Do's and Don'ts

DO:

1. Process requirements:
    - ✓ Become familiar with essential consent form elements and signature requirements
    - ✓ Train all research staff as listed in the IRB application on IRB-approved consent process
    - ✓ Verify investigator and/or research team member(s) obtaining consent have IRB approval
    - ✓ Ensure process executed matches IRB approved process, including storage location
    - ✓ Sign all materials (consent, assents, HIPAA Authorizations) as applicable
    - ✓ Obtain consent from minor participants once they turn 18
    - ✓ Provide a signed copy to the participant
2. Environment and Approach
    - ✓ Approach participants with respect and positive attitude
    - ✓ Use private area free of interruptions
    - ✓ Review each section of consent form with participant
    - ✓ Actively inquire about questions
    - ✓ Check understanding using open-ended questions or teach-back method
    - ✓ Allow sufficient time for participant to read, including taking form home to read and discuss with family members

DON'T:

- × Rush the process
- × Use medical jargon or language not easily understood
- × Exert undue pressure on participant or family members
- × Minimize concerns
- × Assume no questions if none are asked
- × Begin procedures before consent form signing

Using *Current* IRB-Approved Forms

DO:

- ✓ Use consent templates from IRB website for most current required and sample language
- ✓ Update forms for study procedure changes and/or identify new risks
- ✓ Obtain IRB approval **before** using revised forms
- ✓ Get re-consent on IRB-approved revised versions as required
- ✓ Print *currently* approved forms from PRIS3M as needed
- ✓ Procedure in place to verify correct IRB-approved versions are in use

DON'T:

- × Use expired/outdated forms
- × Alter IRB approved forms (e.g., adding signature lines, changing dates) without IRB approval

Form Completion Requirements

DO:

1. Verification Steps
    - ✓ Check to make sure <u>all sections</u> are completed, including the participant writing the date they are signing the form
    - ✓ Verify no missing pages
    - ✓ Confirm ink is used
    - ✓ Ensure simultaneous signing/dating between participant and the research team member
    - ✓ Sign on original, make copy for participant
    - ✓ Maintain <u>original</u> signed form in research records
    - ✓ Use sticky tabs to indicate signature pages

2. Signature Requirements
    - ✓ Verify person obtaining consent signs and dates the consent form themselves
    - ✓ Allow participants to make marks on signature line if capable of providing consent, but not capable of signing the form. Document explanation in consent process note-to-file.
    - ✓ Document LAR is the parent or guardian for a child
    - ✓ Document who is signing as LAR for an adult with diminished capacity
    - ✓ Follow LAR Guidelines for adult capacity determinations

DON'T:

- × Leave sections and questions incomplete
- × Confuse initials with checkmarks
- × Fix participant's errors (instead, write a consent process note that documents the oversight)
- × Enter dates for participants; they must write it themselves
- × Forge signatures or alter date of signatures
- × Ignore ambiguous dates; if needed, explain them in consent process note to file (example: "Ju" may mean June or July)
- × Obtain unauthorized signatures
- × Create new lines on forms or have someone sign outside of an approved signature line
- × Leave LAR relationship undocumented (i.e., describe relationship to participant)

Documentation Requirements

Use a consent process note-to-file (a signed and dated consent process note) when:

- Waiver of written consent has been obtained and using **verbal** consent
- Working with decision-impaired participants
- Recruiting non-English speakers
- Conducting in-patient studies to capture time of consent, if required

For when process differs from IRB approved consent process

Document:

- How consent was obtained and differed from the approved process
- Abnormalities that might occurred when obtaining consent (e.g., why there is more than one consent form for participant, why the participant signed on a different day than study team member if not expected)

For Verbal Consent

- Verify IRB approval
- Maintain consent documentation log
- Record consent timing
- Document materials provided

For Parental Permission

1. Obtain written parental permission for all studies involving children

- Get permission from at least one parent/guardian for minimal risk research or research with direct benefits
- Obtain permission from both parents/guardians for research with greater than minimal risk and no direct benefits
- Verify legal responsibility for care and custody when only one parent provides permission

2. Document assent properly

- Use child-friendly documents limited to one page when possible
- Create age-appropriate and study-specific forms
- Ensure forms treat children respectfully while conveying essential information

3. Follow age-appropriate assent procedures

- Give all children ages 7-17 the opportunity to assent
- Allow children 15-17 to sign the parental permission form for assent
- Consider assent capabilities of children under 7 on individual basis

DON'T:

- × Assume failure to object equals assent
- × Proceed without required parental permissions based on risk level
- × Use the same assent form for all age groups
- × Ignore individual's child's cognitive and emotional maturity
- × Waive parental permission without IRB approval
- × Skip assent for children who can meaningfully participate
- × Proceed without both parents' permission when required for higher risk research
- × Ignore state or local laws regarding consent
- × Use complex language in child assent forms
- × Proceed without documenting parental legal authority when required

For Decisionally-Impaired Participants

Document:

1. Capacity Assessment
   - How capacity was determined
   - Extent of cognitive impairment
   - Comprehension level
   - Decision-making capacity
2. LAR information
   - Whether LAR was asked to act on behalf of participant
   - How LAR was determined
   - Assent process if applicable
   - Periodic reassessment of capacity plans, if applicable (i.e., in populations where capacity to consent can improve or fluctuate)

Non-English Speaking Participants

Standard Process:

1. Requirements
   - Read non-English speaking participant guidelines
   - Use certified/qualified translator
   - Submit Certificate of Translation to IRB
   - Get IRB approval for translated materials
   - Ensure witness fluent in participant's language is present for consent discussion and study activities
   - Document process thoroughly
2. Short Form Process (when applicable):
   - Follow short form guidance
   - Use translated short form
   - Provide written summary that meets the required elements of informed consent (the IRB approved English version of consent document may serve as the summary)
   - Verify whether the interpreter will also be able to serve as witness before starting consent process. If not, identify another person to act as witness.
   - Ensure witness to oral translation of full consent form is present and fluent in both languages (English and non-English language of participant)
   - Obtain signature from participant (or the participant's LAR) on short form

- Obtain signatures from the Interpreter/Witness on short form document ***and*** summary
- Confirm summary is signed by the study team member obtaining consent
- Ensure participant was given copies of both the short form document and written summary of what was presented orally
- Detailed note-to-file written of the consent process, signed and dated

Error Management

When Errors Occur:

1. Immediate Response:

- Write signed/dated note-to-file
- Determine if the error is reportable to the IRB and/or reportable to the sponsor
- Contact IRB with questions
- Report as appropriate to IRB/sponsors

2. Error Correction:
   - Same day: Person who made error cross out the error with single line, date, initial
   - Later discovery: Usually require repeating the signature process on a new form (re-consent)
     - Prefer in-person re-consent, especially if the consent form contains health or other sensitive information
     - Re-consent timing should occur prior to any research activities/events take place

DON'T:

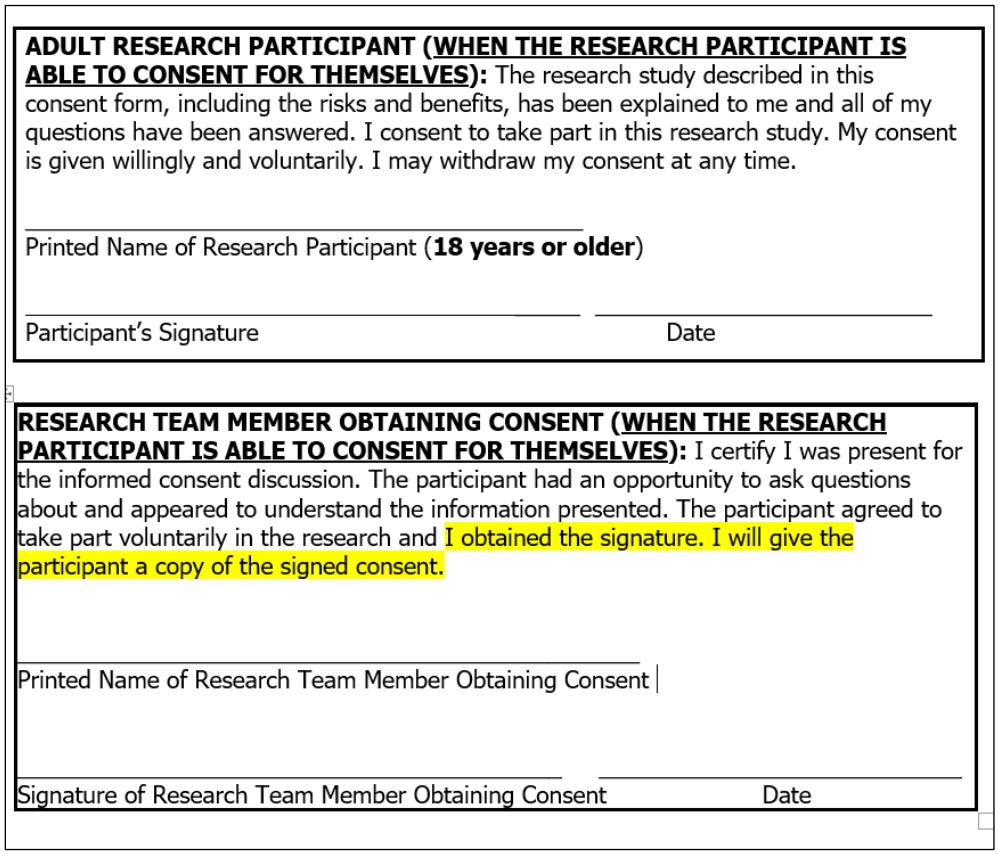
- × Make any corrections on the form itself if it cannot be corrected by the person who made the error on the same day of consent process
- × Use white out
- × Obscure original entries
- × Back date
- × Fabricate information
- × Delay filing signed documents in the designated secure location
- × Assume research team knows the consent process and what was done

Remember: If it isn't documented, it didn't happen!

This document provides comprehensive guidance for the consent process. Contact the IRB office with any questions or clarifications needed.

Consent Signature Box Examples

Participant (Adult) Able to Consent Example: The IRB allows the signed consent form to serve as documentation that the consent process occurred, but recommends a consent process note also be written to capture notable details such as who was present, etc.



ADULT RESEARCH PARTICIPANT (WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES): The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time.

_____

Printed Name of Research Participant (**18 years or older**)

_____ _____

Participant's Signature Date

RESEARCH TEAM MEMBER OBTAINING CONSENT (WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES): I certify I was present for the informed consent discussion. The participant had an opportunity to ask questions about and appeared to understand the information presented. The participant agreed to take part voluntarily in the research and I obtained the signature. I will give the participant a copy of the signed consent.

_____

Printed Name of Research Team Member Obtaining Consent

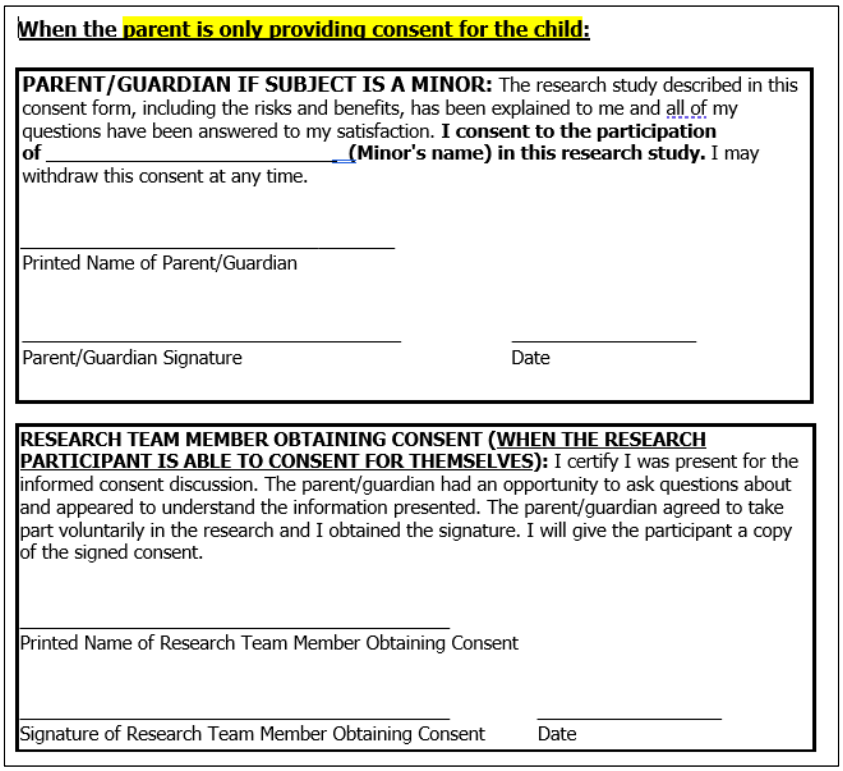
_____ _____

Signature of Research Team Member Obtaining Consent Date

CONSENT SIGNATURES:

- **Research Participant Box** must always be completed unless the participant is incapable of giving consent, cannot read, or is physically unable to sign the form. Separate boxes are provided for these exceptions.
- **Person Obtaining Consent Box** must always be completed.
- **Signatures must be obtained/documented on the same date, prior to enrollment.**
- **Participants or their LAR** must receive a signed copy of this consent form.

Parental Permission Example: Ensure *all applicable lines* are completed (including second parent if required). Verify requirements in IRB approved application.



When the parent is only providing consent for the child:

PARENT/GUARDIAN IF SUBJECT IS A MINOR: The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered to my satisfaction. **I consent to the participation of _____(Minor's name) in this research study.** I may withdraw this consent at any time.

_____
Printed Name of Parent/Guardian

_____ _____
Parent/Guardian Signature Date

RESEARCH TEAM MEMBER OBTAINING CONSENT (WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES): I certify I was present for the informed consent discussion. The parent/guardian had an opportunity to ask questions about and appeared to understand the information presented. The parent/guardian agreed to take part voluntarily in the research and I obtained the signature. I will give the participant a copy of the signed consent.

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____
Signature of Research Team Member Obtaining Consent Date

It is important to note the following criteria when creating parental permission signature boxes:

- Research not involving greater than minimal risk in accordance with 45 CFR 46.404 where signed parental permission must be obtained from one parent

- Research involving greater than minimal risk with the prospect for direct benefit in accordance with 45 CFR 46.405 where signed parental permission must be obtained from one parent

- Research involving greater than minimal risk without the prospect for direct benefit in accordance with 45 CFR 46.406 where signed parental permission must be obtained from both parents
    - Unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for care and custody of child

When both the parent and child are in the study:

RESEARCH SUBJECT AND PARENT WHEN SUBJECT IS A MINOR: The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered to my satisfaction. **I consent to the participation of _____(Minor's name) in this research study. I also consent to my own participation in this research.** I may withdraw this consent at any time.

_____
Printed Name of Parent/Guardian/Subject

_____ _____
Parent/Guardian/Subject Signature Date

RESEARCH TEAM MEMBER OBTAINING CONSENT (WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES): I certify I was present for the informed consent discussion. The participant/parent/guardian had an opportunity to ask questions about and appeared to understand the information presented. The participant/parent/guardian agreed to take part voluntarily in the research and I obtained the signature. I will give the participant a copy of the signed consent.

_____
Printed Name of Research Team Member Obtaining Consent

_____ _____
Signature of Research Team Member Obtaining Consent Date

When both the child is 15-17 and is signing the main consent form:

RESEARCH TEAM MEMBER OBTAINING CONSENT (WHEN THE RESEARCH PARTICIPANT IS ABLE TO CONSENT FOR THEMSELVES): The research study described in this form, including the risks and benefits, has been explained to me and all of my questions have been answered to my satisfaction. I agree to take part in this research study. My assent is given willingly and voluntarily. I may withdraw my assent at any time. I will receive a signed copy of this form.

_____
Printed Name of Minor Research Subject

_____ _____
Signature of Minor Research Subject Date

LAR Consent Example: Carilion Clinic HRPO has a 5-step guide for LAR consent process.

PLEASE COMPLETE ALL 5 STEPS PRIOR TO ENROLLMENT WHEN THE ADULT POTENTIAL PARTICIPANT IS DETERMINED TO HAVE ABSENT, DIMINISHED, OR FLUCTUATING CAPACITY TO CONSENT:

IRB APPROVAL OF THE CONSENT PROCESS IS REQUIRED.

STEP 1

Certification of Incapacity to Make an Informed Decision

☐ **Category 1: I certify that the patient is unconscious or experiencing a profound impairment of consciousness due to trauma, stroke, or other acute physiological condition and is therefore incapable of making an informed decision.** (For this category, **only** the physician caring for the patient **must certify below in Box #1.)**

Comments:

OR

☐ **Category 2:** (Use this category if the patient does not meet Category 1.) **I certify that the patient is incapable of making an informed decision. The patient is unable to understand the nature, extent or probable consequences of the proposed research or is unable to make a rational evaluation of the risks and benefits of alternatives to the proposed research.** (The physician caring for the patient must certify below in **Box #1. ALSO**, a second physician or clinical psychologist **not** otherwise currently involved in the treatment of the patient **must certify below in Box #2.)**

Comments:

(Box 1) CAT. 1 and 2: Physician caring for the patient	**(Box 2) CAT. 2 ONLY:** Physician or clinical psychologist **not** involved in the treatment of the patient
_____ (Print Name of Physician#1)	_____ (Print Name of Physician#2 or Clinical Psychologist)
_____ (Signature)	_____ (Signature)
_____ (Date)	_____ (Date)

STEP 2

THE IRB APPROVED RESEARCH TEAM MEMBER MUST COMPLETE THIS SECTION PRIOR TO ENROLLMENT:

Certification of identification of a health care agent or a surrogate who is the legally authorized representative (LAR) (choose correct statement by marking with an X; complete the second statement if chosen):

____ I certify that I have verified that the legally authorized representative of the patient/research participant is a health care agent, who has been appointed by the patient/research participant under a written advance directive as defined in §54.1-2982, executed by the prospective participant, provided the advance directive authorizes the agent to make decisions regarding the prospective participant's participation in human research. I will place a copy of the advance directive in the research file.

OR

____ I certify that I have been unable to identify a health care agent appointed by the patient/research participant. I have determined that the legally authorized representative of the patient/research participant is the surrogate who is the first available surrogate health care decision maker for the research participant under Virginia law. The relationship of the surrogate, listed in decreasing order of priority, to the research participant is (**check the correct relationship**):

☐ the legal guardian of a prospective participant,
☐ the spouse of the prospective participant, except where a suit for divorce has been filed and the divorce decree is not yet final,
☐ an adult child of the prospective participant,
☐ a parent of the prospective participant when the participant is an adult,
☐ an adult brother or sister of the prospective participant, or
☐ any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective participant to such participant's participation in the particular human research.

I certify this person has been found to be incapable of giving informed consent by clinician(s) and the appropriate category was selected/signed (**STEP 1**). I have identified the health care agent or surrogate who is the LAR. (**STEP 2**)

_____
Printed Name of Research Team Member

_____ _____
Signature of Research Team Member Date

STEP 3

LEGALLY AUTHORIZED REPRESENTATIVE MUST COMPLETE WHEN THE PARTICIPANT IS INCAPABLE OF GIVING INFORMED CONSENT:

The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study. The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered to my satisfaction. I consent to the participation of the research participant for this research study. To my knowledge, participation would not conflict with the individual's religious or personal beliefs. I may withdraw this consent at any time.

_____
Printed Name of Legally Authorized Representative

_____ _____
Legally Authorized Representative's Signature Date

_____
Printed Name of Research Participant

STEP 4

PERSON OBTAINING LAR CONSENT MUST COMPLETE: I certify I was present for the informed consent discussion. The legally authorized representative (LAR) had an opportunity to ask questions and appeared to understand the information presented. The LAR voluntarily agreed for the person noted above to take part in the research and I obtained his/her signature. I will give the LAR a copy of the signed consent.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

STEP 5:

THE PRINCIPAL INVESTIGATOR OR EQUALLY QUALIFIED SUB-INVESTIGATOR MUST SIGN AND DATE BELOW TO ATTEST THAT THE LAR CONSENT PROCESS WAS CONDUCTED AND DOCUMENTED CORRECTLY (STEPS 1 – 4 above).

_____
Printed Name

_____ _____
Signature Date

Error correction example: Error correction should be made on the same day by the person who made the error. Cross out the error with single line, date, and initial.

Robert Smith, MD	~~05-01-15~~ 05-01-14 RAS
Signature of Consenting Research Team Member	**Date**
Robert Smith, MD	
First Name / Last Name *Credentials*	
Printed Name of Consenting Research Team Member	

Witness example: Witness is required when participant or LAR cannot read.

TO BE COMPLETED BY WITNESS TO THE CONSENT PROCESS WHEN PARTICIPANT OR LEGALLY AUTHORIZED REPRESENTATIVE CANNOT READ:
I was present during the consent process. The material in the consent form was read to the research participant. Consent was given voluntarily.

_____
Printed Name of Research Participant

_____
Printed Name of Witness to Consent Process
(This person cannot be part of the study team)

_____ _____
Signature of Witness to Consent Process Date

OR

Witness is required by sponsor or protocol. If included in the consent process, it must be completed for all participants in study.

WITNESS TO SIGNATURE (ONLY If required by sponsor or protocol, REMOVE IF NOT REQUIRED): As an impartial third party, I witnessed the authorization process and the participant's signature on this form. I confirm that this entire form was read to the participant named above. The participant voluntarily agreed to be in this study.

_____
Printed Name of Witness

_____ _____
Witness' Signature Date

Non-English Speaking Participant Signature Box Examples: Signature boxes on the consent forms are dependent upon procedure for obtaining and documenting informed consent for research subjects who do not read, speak, or understand English.

Interpreter Signature Boxes when Consent Documents are Translated:

Interpreter Signature

My signature below confirms that the information in the full English consent form has been fully explained to the potential subject in their language, and all their questions have been answered.

_____

Interpreter Name (print)

_____ _____

Interpreter's Signature **Date**

Firma del Intérprete

Mi firma abajo confirma que la información en el formulario completo del consentimiento en inglés ha sido explicada en su totalidad, al posible participante, en su idioma y que se han respondido todas las preguntas.

_____

Nombre del Intérprete (en letra de molde)

_____ _____

Firma del Intérprete **Fecha**

OR SHORT FORM

Short Form Consent Process Boxes:

Witness Signature (Non-English Short Form Consent Process When Interpreter is Affiliated with the Study):

My signature below confirms that an oral presentation of the full English consent form was conducted in the subject's language. Consent was freely given by the subject.

_____

Witness Name (print)

_____ _____

Witness Signature **Date**

Firma del Intérprete

Mi firma abajo confirma que se realizó una presentación oral del formulario completo de consentimiento en inglés en el idioma del participante. El consentimiento fue otorgado libremente por el participante.

_____

Nombre del Testigo (letra de molde)

_____ _____

Firma del Testigo **Fecha**