**Toolkit 16.360 (HRP-507) Template Short Form Consent and Instruction**

**INSTRUCTION**

This Toolkit Item 16.360 (HRP-507) - Template -Short Form Consent outlines steps to be followed when using the Short Form Method to enroll non-English speaking subjects in research. Learn the details about enrolling non-English speaking subjects in research at <https://research.rutgers.edu/faculty-staff/compliance/human-research-protection/hrpp-guidance-topics>. [**NOTE:** When Surrogate Consent is required (i.e., enrolling an adult represented by a surrogate to make decisions on their behalf), use of a short form consent is not permitted per NJ State Statute 26:14.1-14.5 Access to Medical Research Act. Instead, translation of the long form consent into the language of the Surrogate must occur.]

**STEP 1**

Choose the non-English Short Form Consent appropriate to the research from the translated Short Form Non-English Templates available at <https://research.rutgers.edu/faculty-staff/compliance/human-research-protection/toolkit>.

**STEP 2**

Add the following information at the beginning of the translated template chosen. Be sure to translate the title of the study into the appropriate language for the non-English speaking person to understand.

**Header:** Use your Department Letterhead & Rutgers Logo

**Title:** Title

**Protocol No.:** [PRO# assigned by eIRB+]

**Sponsor:** Name

**Investigator:** Name

 Address

 City, State, Zip Code

 Country

**Daytime Phone Number:** Phone Number

The text below reflects the English language version of the informational elements included in the non-English Short Form. **[NOTE: Do not change any of the text in the translated Short Form.]**

**CONSENT TO TAKE PART IN A RESEARCH STUDY**

You are being asked to participate in a research study.

Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; (v) how confidentiality will be maintained.

When applicable, the investigator will present key information to you before presenting other information.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; (vii) how many people will be in the study, (viii) use of your biologic specimens for commercial profit, (ix) whether you will be told about your research results, (x) whether the research might include whole genome sequencing (xi) information about the research has been or will be submitted for inclusion in a clinical trial registry, and (xii) future research use of your information or biologic specimens.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact the research team at the phone number above any time you have questions about the research.

You may contact the IRB at (phone number) if you have questions about your rights as a research subject or what to do if you are injured.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

**STEP 3**

Choose the appropriate signature block from the choices below. Cut/paste your choice(s) to the bottom of the translated short form consent you will use to enroll non-English speaking subjects. Be sure to translate the text within the Signature Block.

Here are some things to know about documenting consent when using the Short-Form:

* The subject must sign & date the short form written in the appropriate non-English language and be provided a copy of the short form, as well as the orally presented English language Consent Long Form approved by the IRB.
* A witness to the consent process, who may not be the member of the research team obtaining consent, must sign & date the non-English Short Form and the orally presented IRB-approved English Consent Long Form.
* When both parents must permit a child’s participation in research, add an additional signature line as seen in the Signature Block for Parental Permission. [Delete highlighted instructional text in the Signature Block.]
* When assent\* of a child will be sought and documentation of assent—subject signature—will be obtained using the short form, add a signature line where it appears in Signature Block for Parental Permission. [Delete highlighted instructional text in the Signature Block.] *[\*Assent is an affirmative agreement by an individual not capable of giving legally valid consent, such as a child who has not reached the age of majority.]*
* The investigator or study team member obtaining consent (and assent if applicable) must sign and date the orally presented English IRB-approved Consent Long Form.
* The consent process, presence of interpreters and/or witnesses, and non-English language of the subject, must be appropriately documented on the orally presented IRB-approved Consent Long Form and in the research record.

**ADULT CONSENT**

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| **Subject**Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**Witness**Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ |

**PARENTAL PERMISSION**

**Parent or Legal Guardian\***

Parent or Legal Guardian Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:

\*Ensure individuals who are not parents can demonstrate their legal authority to serve as guardian.

If both parents must permit the child’s enrollment in research, add a 2nd permission line. If not, delete:

Parent Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

If documentation of child assent is by having the child (the subject of the research) sign this Short-Form Consent with the parent, add the following signature line:

**Subject**

Subject’s Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Witness**

Witness Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_

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