

## **BRANY IRB - Guidance for Use of Short Form Consents**

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1. **What is the difference between the *short form consent* and *long form consent*?**

The ***short form consent*** explains what the elements of consent are, and states that these elements were explained to the subject/LAR.

The ***long form consent*** contains all the elements of consent (required by §46.116/§50.25) and explains each one in detail as it pertains to the study in question.

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2. **When should *short form consent* be used?**

- When the language of the potential subject to be enrolled was not anticipated (i.e., the subject's language was not listed on your BRANY application as an anticipated language).



- If there is a translation pending for the language in question (Please speak with the IRB staff if short form is applicable)

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### 3. When can **short form consent** be used?

The short form should be used once to enroll the subject in question.

**You must thereafter pursue a written translation of the English long form consent for this subject (see # 7). If needed more than once, please contact BRANY IRB staff for further details.**

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### 4. How is **short form consent** requested?

After completing **steps a – c below**, login to *IRBManager* (BRANY IRB's web portal) and complete the xForm called [03-Short Form Consent Request](#). The xForm will prompt you to confirm you have addressed the items below.

- a. Confirm that your organization/institution policy does not prohibit the use of **short form consent**. **If not prohibited, then:**
- b. Speak with your study sponsor contact (if applicable) to ensure that all subject materials can be made available or are able to be translated into the unanticipated language. **If the study sponsor says yes, then:**
- c. Complete the xForm called [03-Short Form Consent Request](#).

**Note: If the short form consent document is needed within 24-48 hours from the time requested, please contact BRANY IRB staff to ensure that the short form consent document is available in the language needed.**

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### 5. What is the process for using **short form consent**?

- a. Obtain the most current BRANY IRB-approved **English long form consent**, which will be read to the potential subject, and the **short form consent in the unanticipated language**.
  - The subject will use the **short form consent** as a guide to ensure that all the elements of the informed consent required by §46.116/§50.25 have been presented and discussed.

- b. Have a member of the research team who is fluent in the subject's language or a translator **read the English long form consent** to the subject/representative.

**Note: A family member or a friend cannot serve as a translator.**

- c. A **witness\*** must be present for the consenting process to attest that the information in the short consent form, summary, and any other information provided was explained to, and apparently understood by, the subject/representative, and that consent was freely given.

**\* Who can be the witness?**

- A person who is conversant in the potential subject's language.
- Examples: the interpreter, a family member, or other person.

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**6. Who should sign which document?**

**Short form consent**

- Subject/ subject's legally authorized representative
- Witness

**English long form consent**

- Witness
- Person obtaining consent
- Any other signatures required by your institution's policy

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**7. Does the English long form consent need to be translated into the subject's language?**

**YES** - BRANY staff will work on obtaining a translation of the English **long form consent** in the subject's language.

**Note: BRANY IRB policy requires that you re-consent the subject using the translated long form consent once available.**

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8. **Will I receive an approval letter from BRANY IRB for the *short form consent*?**

**NO** - No approval letter will be issued. Within 24-48 hours of receiving the x-form, an email will be sent to you with the requested translated short form. If needed earlier, please contact BRANY IRB Staff.

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9. **Do I need a translated HIPAA Form?**

**YES** - The translated HIPAA Authorization form in the requested language will be included in the email sent to you by BRANY IRB along with the translated short form consent.

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10. **In what languages is *short form consent* available?**

- |                        |                |
|------------------------|----------------|
| 1. Akan (Ghana)        | 15. Japanese   |
| 2. Albanian            | 16. Korean     |
| 3. Arabic              | 17. Polish     |
| 4. Bengali             | 18. Portuguese |
| 5. Simplified Chinese  | 19. Punjabi    |
| 6. Traditional Chinese | 20. Russian    |
| 7. Creole              | 21. Sinhalese  |
| 8. Farsi               | 22. Sonineke   |
| 9. French              | 23. Spanish    |
| 10. Gaujarati          | 24. Tibetan    |
| 11. Ghana (Akan)       | 25. Turkish    |
| 12. Greek              | 26. Vietnamese |
| 13. Indonesian         |                |
| 14. Italian            |                |

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11. **What if the language needed is not available?**

Please contact BRANY IRB staff.

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