**Consent Guidance 6/3/19**

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|  | **“Standard” Consent** | **Assent – Children** | **Surrogate Consent – Temporarily Impaired Adults** | **Subjects Physically Unable to Sign** | **Non-English Speaking Subjects** |
| **Is IRB approval specific to this population required\*?** | No | Yes | Yes | No | Yes |
| **What consent forms do I need?**Note: The OHR-8B is sometimes used in place of the OHR-8. | Consent Form (OHR-8) | Consent Form (OHR-8) and Assent (can be combined with consent form or separate) | Consent Form (OHR-8) and Surrogate Consent Form Signature Pages (OHR-8B) | Consent Form (OHR-8)  | English and Translated Consent Forms (OHR-8) **OR** English Consent Form (OHR-8) and Translated Short Form (OHR-8S) |
| **What people need to be present?** | See Consent Signatories Guidance document | See Consent Signatories Guidance document | See Consent Signatories Guidance document | See Consent Signatories Guidance document | See Consent Signatories Guidance document |
| **What else do I need to know?**\*IRB approval is always required. This question is asking if the IRB specifically has to approve the inclusion of a certain population. The IRB does this by approving the IRB submission, including the consent documents, which describe the intended population. |  | Is also used for individuals with impaired decision making capacity.The form and the discussion are simplified.Assent must always be done with consent.Children 7 – 17 should be given the opportunity to assent.Older children (late teens) can use the consent form as an assent form if appropriate. | The surrogate consent form replaces the consent form signature page.The surrogate consent form gives the priority of the surrogates.If able, the patient can assent at the same time.If the patient later becomes able, assent of consent should be obtained. | Used for patients who are physically unable to sign e.g. paralyzed, not mentally unable.The patients name and date of signature may be written in by someone else.Include the following note on the signature page: The subject is physically unable to sign the consent form. All pages of the consent form were reviewed with the subject, who voluntarily consented to participate in this study. | There are several translated OHR-8S on the IRB website.After a patient is consented using the short form process, the full consent form should be translated and approved by the IRB. The subject is then provided with the translation (which should be documented).In both cases, a translator, who is present for the entire consent discussion and available throughout the study, is required. |

**Consent Signatories Guidance**

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| **CONSENT SIGNATORIES** | **Regular Consent** | **Surrogate Consent (Use OHR-8B as signature page)** | **Assent (Always used with parent / guardian consent)** | **Parent / Guardian Consent (Used with assent)** | **Subject is Physically Unable to Sign** | **Subject is Illiterate (Full consent form is presented verbally)** | **Subject is Blind (Must use braille consent or reading device)** | **Short Form Process – English Speaking Subjects** |
| **Short Form** | **Summary** |
| **Subject** | X |  | X |  | X (Makes Mark if Possible) | X | X | X |  |
| **Person Conducting Consent Interview (May be the Investigator)** | X | X |  | X | X | X | X |  | X |
| **Investigator** | X | X |  | X | X | X | X |  | X |
| **Impartial Witness (May not be study personnel)** |  |  |  |  | X | X | X | X | X |
| **Parent / Guardian / Legal Representative / Surrogate** |  | X |  | X |  |  |  |  |  |

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| **CONSENT SIGNATORIES** | **Translations – Full Consent Form** | **Translations – Short Form Process - Investigator / Study Personnel Does Not Speak Other Language** | **Translations – Short Form Process - Investigator / Study Personnel Speaks Both Languages and Acts as the Translator** |
|  | **Investigator / Study Personnel does not speak other language** | **Investigator / Study Personnel speaks both languages and acts as the translator** | **Short Form** | **Summary** | **Short Form** | **Summary** |
| **Subject** | X | X | X |  | X |  |
| **Person Conducting Consent Interview (May be the Investigator)** | X | X |  | X |  | X |
| **Investigator** | X | X |  | X |  | X |
| **Impartial, Bilingual Witness (May not be study personnel)**  | X | X | X | X | X | X |
| **Translator** | XA translator is needed but doesn’t sign unless also acting as the impartial witness. |  | XA translator is needed but doesn’t sign unless also acting as the impartial witness. | XA translator is needed but doesn’t sign unless also acting as the impartial witness. |  |  |