|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Inline image 2 | CHECKLIST: Human Research Consent Meeting Audit -  Observation | | | | |
| NUMBER | DATE | AUTHOR | APPROVED BY | PAGE |
| HRP-742 | 12/1/2018 | B. Hansen | J. Thomas | 1 of 9 |

This tool is designed for observation of *live* or *recorded* consent meetings.

|  |  |
| --- | --- |
| **Protocol Title** |  |
| **Principal Investigator/Faculty Advisor** | Name: |
| Department: |
| Telephone Number: |
| Email Address: |
| **Student Investigator** | Name: |
| Current Academic Status (Student, Fellow, Resident): |
| Department: |
| Telephone Number: |
| Institutional Email Address: |
| **Primary Contact** | Name: |
| Department: |
| Telephone Number: |
| Email Address: |
| **Person Obtaining Consent** | Name: |
| **IRB Study Number** |  |
| **Audit Date(s)** |  |
| **Date of Consent Meeting (if different than Audit Date)** |  |
| **Consent Meeting ID Number** |  |
| **RNI Number** | To be determined |
| **Auditor** | Name: |
| Telephone Number: |
| Email Address: |

**GENERAL INFORMATION – to be completed prior to consent meeting**

1. Reason for Review: For-cause / Routine / Other

Comment:

1. Type of observation: Live / Recorded
2. Person providing consent (circle one): Adult Participant / LAR / Parent(s) / Legal Guardian(s) / Child
3. Participant category:
   1. Adult capable of providing consent
   2. Adult not capable of providing consent, able to provide assent
   3. Adult not capable of providing consent or assent
   4. Child capable of providing consent
   5. Child capable of providing assent
   6. Child not capable of providing assent
4. The IRB-approved protocol requires that assent be obtained from adults unable to provide consent as follows:
   1. All participants
   2. Some participants, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   3. None of the participants.

1. Language/literacy/communication considerations (circle all that apply)
   1. Does not speak English
   2. Not able to read/write/speak
   3. Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Type of consent meeting: Initial / Re-consent
3. Comment/s on General Information:

**COMPLIANCE – to be confirmed prior to consent meeting and re-confirmed onsite**

1. Y / N The consenter is on the IRB-approved list of people who will obtain consent for this study.

1. Y / N The participant meets the inclusion parameters of the study, per the consenter.

1. Y / N / NA If applicable, the guardian or LAR who will be present has the legal authority to provide consent on behalf of the participant.
2. Y / N Form/s and tools being used are the most current IRB-approved version/s.
3. Comment/s on Compliance:

**BASIC ELEMENTS – The consenter explained:**

1. Y / N That the study involves **“research”**.

Comment:

1. Y / N The **purpose** of the study.

Comment:

1. Y / N The study **procedures / design**.

Comment:

1. Y / N / NA Which, if any, procedures are **experimental**.

Comment:

1. Y / N The **duration / time commitment** of participation.

Comment:

1. Y / N The possible **risks** of participation.

Comment:

1. Y / N The possible **benefits** of participation.

Comment:

1. Y / N / NA If applicable, **alternative procedures / treatments**.

Comment:

1. Y / N Measures taken to protect **confidentiality** and limits to confidentiality.

Comment:

1. Y / N / NA If applicable, **compensation**.

Comment:

1. Y / N / NA If applicable, what would happen if there were **injury/harm** to the participant during the study.

Comment:

1. Y / N **Contact information** for questions and concerns.

Comment:

1. Y / N The **voluntary** nature of participation. The participant’s right to **withdraw** at any time.

Comment:

1. Y / N / NA If applicable, that the study involves a **non-FDA approved agent.**

Comment:

**ADDITIONAL ELEMENTS – The Consenter explained:**

1. Y / N / NA The research may involve **risks that are currently unforeseeable**.

Comment:

1. Y / N / NA Circumstances under which the researcher might decide that **the participant cannot continue** to be in the study and/or that the **entire study might end before it is complete**.

Comment:

1. Y / N / NA Any **additional costs** to the participant.

Comment:

1. Y / N / NA **Consequences of withdrawal** and **procedures** for orderly termination of participation.

Comment:

1. Y / N / NA Significant **new findings will be shared** with participant (or parent/guardian or LAR) during course of the study.

Comment:

1. Y / N / NA The **approximate number** of participants in the study.

Comment:

**PROCESS**

1. Y / N The participant (or parent/guardian or LAR) was provided with a **copy of the Consent Form in advance** of the consent discussion, per the consenter.

Comment:

1. Y / N The consenting **environment** was suitable (e.g., private, reasonably comfortable).

Comment:

1. Y / N The consenter used **understandable language** and avoided medical terms/scientific jargon.

Comment:

1. Y / N The consenter encouraged the participant to ask **questions**.

Comment:

1. Y / N The consenter sufficiently **answered questions** asked by the participant.

Comment:

1. Y / N The consenter spent **sufficient time** obtaining consent.

Comment:

1. Y / N The participant (or parent/guardian or LAR) **seemed to understand** the information being presented.

Comment:

1. Y / N / NA The consenter checked for **understanding** and assessed **comprehension** (e.g., utilized the “teach back” method).

Comment:

**DECISION**

1. Y / N The participant (or parent/guardian or LAR) **agreed to enroll** in the study.

Comment:

*If “no”, this audit is complete. If “yes”, continue.*

**DOCUMENTATION**

1. Y / N The **Consent Form (or Summary, if applicable)** was properly signed and dated.

Comment:

1. Y / N / NA If the **Short Form** was utilized, it was properly signed and dated.

Comment:

1. Y / N / NA **Assent** was properly documented per the IRB-approved protocol (e.g., noted in signature block).

Comment:

1. Y / N / NA If HIPAA authorization is required, the **HIPAA Form** was properly signed and dated.

Comment:

1. Y / N / NA If an **impartial witness** was present, the name of the witness was printed on the consent document.

Comment:

1. Y / N The **participant (or parent/guardian or LAR) was** **given signed copies** of the Consent Form and, if applicable, additional forms (HIPAA, Assent, Short Form)

Comment:

**FINAL ASSESSMENT**

1. **Y / N Was the information in the Consent Form (and any other written information) thoroughly explained to, and apparently understood by, the participant (or parent/guardian or LAR)? IF NO: the consent is not valid. The prospective participant may not be entered in research unless and until any corrective action required is completed and the participant is re-consented.**
2. **Y / N Was informed consent freely given by the participant (or parent/guardian or LAR)? IF NO: the consent is not valid. The prospective participant may not be entered in research unless and until any corrective action required is completed and the participant is re-consented.**

FOR LIVE OBSERVATION ONLY:

1. Y/N If “no” to either of the above: is immediate verbal feedback and corrective action possible/appropriate, such that valid consent could be obtained?
2. Y/N If immediate verbal feedback and corrective action is possible and appropriate, was it conducted? IF YES: return to items 49 & 50.
3. Comments on Final Assessment and, if applicable, immediate corrective action:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SPECIAL CIRCUMSTANCES:**

**Capacity to Consent, Child Assent, Participant Does Not Speak English, Participant Unable to Read/Write/Talk**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**A. Capacity to Consent**

*Determination of Capacity*

1. Y / N / NA The consenter administered the appropriate validated tool to assess capacity.

Comment:

1. Y / N / NA An independent assessor was utilized.

Comment:

1. Y / N / NA The participant was determined to have the capacity to consent.

Comment:

*If “yes”, follow standard procedure. If “no”, proceed to questions below:*

1. Y / N The IRB approved inclusion of adult participants who do not have the capacity to consent.

Comment:

*If “no”, the individual cannot be enrolled at this time. If “yes”, proceed to questions below:*

*Legally Authorized Representative (LAR)*

1. Y / N The participants’ LAR was present.

Comment:

*If “no”, the individual cannot be enrolled at this time. If “yes”, proceed to questions below:*

1. Y / N The consenter explained the role of the LAR using understandable language.

Comment:

1. Y / N The LAR appeared to understand their role.

Comment:

1. Y / N The LAR was provided with the LAR brochure.

Comment:

*Assent/Dissent (see IRB requirement re: assent noted in General Information)*

1. Y / N The participant was able to provide assent.

Comment:

1. Y / N / NA If the participant was able to provide assent, an assent form was used.

Comment:

1. Y / N / NA If the participant was not able to provide assent, an information sheet was provided.

Comment:

**B. Child (7-18 years Old) / Legal Guardian**

1. Y / N The child was able to provide assent.

Comment:

1. Y / N / NA If the child was able to provide assent, an assent form was used.

Comment:

1. Y / N / NA If the child was not able to provide assent, an information sheet was provided.

Comment:

**C. Participant Does Not Speak English – Majority of Participants Speak EnGLISH**

1. Y / N A short form in language understandable to the participant(or parent/guardian or LAR)was used.
2. Y / N The information in a written summary (i.e., English consent form) was provided using an interpreter.
3. Y / N The participant, guardian or LAR read the short form OR the interpreter read the short form to the participant, guardian, or LAR.
4. Y / N An impartial witness who speaks both English and a language understandable to the participant, guardian or LARwas present for the entire consent meeting.

Comment:

*Note: If enrolled using short form:*

1. *Short form should be signed by participant and witness.*
2. *Summary (usually English consent form) should be signed by witness and consenter.*
3. *Copies of short form and summary should be provided to participant.*
4. *The translator (if impartial) may serve as the witness.*
5. *The name of the witness should be printed on the consent document.*

**D. Participant Does Not Speak English – Majority of PArticipants DO NOT Speak EnGLISH**

1. Y / N The consent form translated into a language understandable to the participant, guardian or LARwas used.
2. Y / N An interpreter was used to interpret the entire meeting.

Comment:

1. Y / N An impartial witness who speaks both English and a language understandable to the participant, guardian, or LARwas present for the entire consent meeting.

Comment:

**E. Participant Not Able to Read / Write / Talk**

1. Y / N An impartial third party witnessed the entire consent meeting.

Comment:

1. Y / N The consenter documented on the Consent Form the method used for communication.

Comment:

1. Y / N / NA The consenter documented on the Consent Form the specific means by which the participant communicated their decision about participation.

Comment:

*Note: If enrolled, Consent Form should be signed by the impartial third party.*