|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Inline image 2 | CHECKLIST: Human Research Consent Meeting Audit -  Interview/Questionnaire | | | | |
| NUMBER | DATE | AUTHOR | APPROVED BY | PAGE |
| HRP-743 | 12/1/2018 | B. Hansen | J. Thomas | 1 of 3 |

With this audit approach, the interview or questionnaire is completed by the participant, guardian or LAR immediately following the consent meeting.

|  |  |
| --- | --- |
| **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 audit: Interview / Questionnaire
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 reconfirmed at time of audit**

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:

**INTERVIEW/QUESTIONNAIRE**

Interview/questionnaire items specific to the type of study and the purpose of the audit are utilized. The question list is provided to the study team in advance of the audit.