The purpose of this review tool worksheet is to provide support for a member of the IRB, HRPP or designee when observing the consent process of a research participant. This worksheet does not need to be retained, but observations can be used as examples or findings in any letter sent to the Principal Investigator.

|  |  |
| --- | --- |
| IRB Number |  |
| Name of Person Completing Worksheet |  |
| Date Worksheet Completed |  |

**Note: If the potential research participant does not provide permission for a member of the IRB or HRPP staff to be present for the consent process, then their wishes prevail.**

1. **Consent form Documentation** (check if yes):

|  |  |
| --- | --- |
|  | 1. Is informed consent obtained from each subject prior to the start of any study procedures? |
|  | 1. Is the IRB approved consent form (approval stamp on the consent form) used to consent each subject? |
|  | 1. Is the original dated and signed consent form on file for each subject? |
|  | 1. Did all consented subjects receive a copy of their signed and dated consent form? |

1. Where are signed consent forms kept for this study?
2. What is the process to assure the study team is using the IRB currently approved consent form?
3. How does the study team know they are using the IRB currently approved form?
4. Who presents the consent form to the individuals?

**2. Consent Observation Checklist**

1. Who is administering the consent? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
   1. Are they authorized to do so by the PI Yes No
   2. Is the delegation to obtain consent documented? Yes No
2. Location: Where is the consent Process Occurring: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
3. Is a Study Code or ID Number of Subject being assigned? Yes No
4. Are the following key elements part of the consenting of a potential study participant (other issues may also be needed):
   1. Is the consent form the most recent IRB-approved version?  Yes  No
   2. Does the consenter mention that the study involves “research?”  Yes  No
   3. If the study involves an unapproved agent (i.e., not FDA approved),   
      does the consenter explain this?  Yes  No
   4. Does the consenter discuss/summarize or allow the subject time to read about and question the consenter regarding the following:
      1. Study purpose  Yes  No
      2. Randomization  Yes  No  NA
      3. Blinding  Yes  No  NA
      4. Study Procedures and interventions  Yes  No
      5. Risks  Yes  No
      6. Benefits  Yes  No
      7. Alternatives  Yes  No  NA
      8. Confidentiality and/or HIPAA authorization  Yes  No
      9. Cost and any compensation  Yes  No  NA
      10. PI contact information for study related questions or concerns  Yes  No
      11. IRB contact information to discuss any concerns about   
          human subject rights Yes  No
      12. Voluntary nature of study (right to refuse/withdraw without   
          affecting individual’s present or future care)  Yes  No
      13. Research-related injury compensation and pregnancy issues   
          (if appropriate)  Yes  No  NA
      14. Does the consenter solicit and sufficiently answer questions?  Yes  No
5. Does the consenter communicate using understandable language and avoid using scientific jargon that the subject clearly did not understand?  Yes  No
6. Is the consent form properly signed and dated?  Yes  No
7. Is a copy of the signed consent form (and HIPAA authorization when applicable) given to the participant?

Yes  No

1. Is the consenting “environment” suitable?  Yes  No
2. Did the consenter spend sufficient time obtaining informed consent?  Yes  No

**Additional Comments (provide a brief explanation for each “No”):**