**REVIEWER CHECKLIST: CRITERIA REQUIRED FOR IRB APPROVAL OF A HUMAN RESEARCH STUDY**

Study #:

Reviewer:

**45 CFR 46.111 and 21 CFR 56.111**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | The study can be approved only if the IRB determines the study meets ALL the required criteria. | Yes | No | N/A |
| 1 | **Risks to subjects are minimized*** Procedures are consistent with sound research design and do not unnecessarily expose subjects to risk.
* Study utilizes procedures already performed for diagnosis/treatment -- when appropriate.
 |[ ] [ ] [ ]
| 2 | **Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.** |[ ] [ ] [ ]
| 3 | **Selection of subjects is equitable*** Inclusion/exclusion criteria are adequate
* Research purpose and setting are appropriate
* Recruitment process is fair
* Special Requirements for vulnerable populations are addressed
 |[ ] [ ] [ ]
| 4 | **Informed consent will be sought for each subject or waived** * Note: No waivers allowed on FDA regulated studies
 |[ ] [ ] [ ]
| 5 | **Informed consent will be documented or documentation waived** * Note: No waivers allowed on FDA regulated studies
 |[ ] [ ] [ ]
| 6 | **Provisions for data and safety monitoring of collected data are adequate** |[ ] [ ] [ ]
| 7 | **Provisions to protect privacy of subjects are adequate** |[ ] [ ] [ ]
| 8 | **Provisions to maintain confidentiality of data are adequate**  |[ ] [ ] [ ]
| (b) | **Vulnerable/Special populations are adequately protected by additional safeguards.*** Consider vulnerability to undue influence, impaired decision-making, and economically or educationally disadvantaged
 |[ ] [ ] [ ]
|  | **Submitted Documents are Consistent*** IRB application, local protocol, consent form, and recruitment scripts are consistent with each other
 |[ ] [ ] [ ]
|  | **Outcome – Full Board** | [ ] Approve | [ ] Require Modifications | [ ] Return to Full Board Committee/Table |
|  | Continuing review Period | [ ] 12 Months | [ ]  \_\_\_ Months | [ ] Minimal Risk (CR by Expedited Review) |
|  | **Outcome – Expedited** | [ ] Approve | [ ] Require Modifications | [ ] Send to Full Board Committee |
|  | Frequency of Review | [ ] CR/12 Months | [ ] Administrative**/**24 Months |  |
|  |  | If CR is requested, please state reason:  |

**ELEMENTS OF CONSENT CHECKLIST**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Following are the REQUIRED elements of consent. | Yes | No | N/A |
|  | Language Is Understandable To Subject (8th Grade Reading Level) |[ ] [ ] [ ]
|  | No Exculpatory Language (Does Not Waive Rights) |[ ] [ ] [ ]
|  | Key Information (Reasons Why One Might Or Might Not Want To Participate) |[ ] [ ] [ ]
|  | Statement Study Involves Research |[ ] [ ] [ ]
|  | Statement That Participation Is Voluntary |[ ] [ ] [ ]
|  | Statement That Refusal To Participate Will Not Result In Penalty Or Loss Of Benefits |[ ] [ ] [ ]
|  | Statement That Subjects May Withdraw At Any Time With No Penalty |[ ] [ ] [ ]
|  | Explanation Of Purpose Of Research |[ ] [ ] [ ]
|  | Accurate & Complete Description Of Procedures (Identify Which Procedures Are Experimental) |[ ] [ ] [ ]
|  | Expected Duration Of Participation |[ ] [ ] [ ]
|  | Description Of Compensation To Participant |[ ] [ ] [ ]
|  | Description Of Reasonable Foreseeable Risks Or Discomforts To Participant |[ ] [ ] [ ]
|  | Description Of Benefits To Participant |[ ] [ ] [ ]
|  | Statement Describing The Extent To Which Privacy And Confidentiality Will Be Maintained |[ ] [ ] [ ]
|  | Explanation Of Medical Treatment Which Are Available If Injury Occurs (More Than Minimal Risk Only) |[ ] [ ] [ ]
|  | Explanation Of Who To Contact For Questions About The Research |[ ] [ ] [ ]
|  | Explanation Of Who To Contact For Information About Subjects Rights (IRB Contact Information) |[ ] [ ] [ ]
|  | Explanation Of Who To Contact In The Event Of A Research Related Injury |[ ] [ ] [ ]
|  | Statement That Data Will/Will Not Be Used In Future Research Studies |[ ] [ ] [ ]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Additional Elements, if applicable | Yes | No | N/A |
|  | Disclosure of Appropriate Alternative Procedures or Courses of Treatment |[ ] [ ] [ ]
|  | Statement that Treatment May Involve Risks that are Currently Unforeseeable |[ ] [ ] [ ]
|  | Anticipated Circumstances By Which Participant May Be Terminated |[ ] [ ] [ ]
|  | Additional Costs to Subjects |[ ] [ ] [ ]
|  | Consequences of Subject’s Decision to Withdraw |[ ] [ ] [ ]
|  | Statement that Significant New Findings that May Impact Subject’s Willingness to Participate will be Provided |[ ] [ ] [ ]
|  | Approximate Number of Subjects |[ ] [ ] [ ]
|  | Statement if Subject’s Biospecimens Will/Will Not be Used for Commercial Profit |[ ] [ ] [ ]
|  | Statement Regarding Whether Clinically Relevant Research Results will be Disclosed to Subjects |[ ] [ ] [ ]
|  | If Research Involves Biospecimens, Whether whole Genome Sequencing Will Occur |[ ] [ ] [ ]
|  | Clinical Trials.gov Statement (All Clinical Trials) |[ ] [ ] [ ]
|  | Certificate of Confidentiality Language (All NIH Funded Studies Plus Those Applying for CoC.) |[ ] [ ] [ ]
|  | GINA Language Included (If Study Involves Genetic Analysis) |[ ] [ ] [ ]
|  | Financial Interest Disclosure |[ ] [ ] [ ]
|  | Radiation Risk Language |[ ] [ ] [ ]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | HIPAA Authorization, if applicable | Yes | No | N/A |
|  | Contains WSU-Approved Template Language |[ ] [ ] [ ]
|  | If yes, PI and proper Covered Entity referenced, purpose customized, PHI listed, signature line includes authorization language |[ ] [ ] [ ]
|  | If no, check all the following in non-template authorization language: |  |  |  |
|  | Proper Covered Entity is Named (e.g., Miami Valley, Premier Health, Wright State Physicians) |[ ] [ ] [ ]
|  | Name(s) of persons authorized to request authorization (e.g., PI Name and his/her study team) |[ ] [ ] [ ]
|  | Description of PHI to be created, used or disclosed in a specific and meaningful manner |[ ] [ ] [ ]
|  | Description of purpose of requested use or disclosure (e.g., study title and overall study purpose) |[ ] [ ] [ ]
|  | Statement of authorization expiration date or event |[ ] [ ] [ ]
|  | Names of individuals, organizations, to whom PI can share subject’s PHI with including covered entity officials, IRB, Sponsor |[ ] [ ] [ ]
|  | Place for subject or LAR signature and date. If one signature for both consent and authorization, certification language includes subject giving “authorization” as well as consent. |[ ] [ ] [ ]
|  | Statement of the subject’s right to revoke authorization and how to do so (e.g., mailing address or email) and if there are any consequences for revoking authorization. |[ ] [ ] [ ]
|  | Statement explaining whether non-research treatment, payment, enrollment, or eligibility of benefits can be conditioned on authorization. In addition, whether a subject can still participate in research study if they don’t provide authorization. |[ ] [ ] [ ]
|  | A statement of the potential risk that PHI will be re-disclosed by the recipient and no longer protected by the Privacy Rule. This may be a general statement that the Privacy Rule may no longer protect health information disclosed to the recipient. |[ ] [ ] [ ]
|  | Non-template authorization is written in plain language. |[ ] [ ] [ ]