**IRB Protocol Review Sheet for Convened Initial Review**

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Number: | 2016B0567 | **PI:** | Miller |

|  |  |  |
| --- | --- | --- |
| **DETERMINATIONS** |  | **CONSENT/HIPAA (check all that apply)** |
|  |  |  |  |  |
|  | Approved |  |  | No Waivers, Alterations, or LAR Consent |
|  |  |  |  |  |
| x | Requires Modifications – \*provide comments |  |  | Waiver of Consent |
|  |  |  |  |  |  |
|  | Deferred – \*provide comments |  |  | Alteration of Consent |
|  |  |  |  |
|  | Disapproved – \*provide comments |  | x | Waiver of Consent Documentation |
|  |  |  |  |
|  |  |  | Waiver of Parental Permission |
|  |  |  |  |
| **POPULATIONS (check all that apply)** |  |  | Alteration of Parental Permission |
|  |  |  |  |  |
| x | No Special Populations |  |  | Waiver of Parental Permission Documentation |
|  |  |  |  |  |
|  | Approval for Pregnant Women/Fetuses |  |  | Waiver of Assent |
|  |  |  |
|  | Approval for Children |  |  | Consent by Legally Authorized Representative |
|  |  |  |  |
|  | Approval for Prisoners |  |  | Waiver of HIPAA Research Authorization |
|  |  |  |  |  |
|  | Approval for Adults with Decisional Impairment |  |  | Partial Waiver of HIPAA Research Authorization |
|  |  |  |  |  |
|  | Approval for Non-English Speaking Subjects |  |  | Alteration of HIPAA Research Authorization |
|  |  |  |  |  |
|  | Approval for Non-Viable Neonates |  |  |  |
|  |  |  |  |  |
|  | Approval for Neonates of Uncertain Viability |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **LEVEL OF RISK** |  | **NONCOMPLIANCE (check all that apply)** |
|  |  |  |  |  |
| x | Minimal risk |  | x | N/A |
|  |  |  |  |  |
|  | Greater than minimal risk |  |  | Unsubstantiated |
|  |  |  |  |  |
|  |  |  |  | Minor (not serious, not continuing) |
|  |  |  |  |  |
| **NEXT REVIEW DATE** |  |  | Serious |
|  |  |  |  |  |
| x | One year |  |  | Continuing |
|  |  |  |  |
|  | Other – specify: |  |  | Refer to IRB Investigative Committee |
|  |  |  |  |  |
|  |  |  |  | Refer to another university review process |
|  |  |  |  |  |
|  |  |  | Determination pending/ Further information required |
|  |  |  |  |
|  |  |  | Corrective actions(s) required – \*provide comments |

**\*COMMENTS/MODIFICATIONS:**

|  |
| --- |
| SUMMARY:* Study purpose:
* Funding source (funded/unfunded/sponsor name):
* Study intervention and duration of study:
* Planned enrollment number:
* Special populations (if any):
* Informed consent process
* Monitoring process
* Incentives

 [describe any additional findings]COMMENTS:[Reviewer describes any necessary modifications or concerns]**EXAMPLE:**SUMMARY:The purpose of this unfunded study is to create a repository of speech and language samples from individuals in Appalachian communities. Subjects will be interviewed and recordings made for future investigation. Data collected will be used only by Ohio State investigators and will not be shared externally. Future data requests from the repository will be reviewed and considered with appropriate IRB approval, as necessary. The investigators seek 100 adult participants for the repository. Recruitment flyers will be used. A waiver of consent documentation is requested as some participants will be contacting the investigators over the phone. A small incentive will be provided to subjects, such as a pencil or lotion and a thank you card. COMMENTS:Buck-IRB:* The data repository section does not include a clear answer to what happens to the data collected if the PI leaves the university.

Informed consent:* Page 2 does not fully describe that data and recordings are stored indefinitely for future, unspecified research.
* Page 2: The survey is not included as a requirement of study completion.
* Page 3 includes a statement that payments are considered taxable income, however, there are no subject payments in this research.
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|  | Jane Doe |  | 7/1/2016 |  |
|   | IRB Reviewer |  | Date |  |