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| **IRB Reviewer Checklist**  **Initial Application** | **UNC logo-blue** | | |
| **IRB #:** 00-0000 | | **PI Name:** Click or tap here to enter text. | | |
| **Date completed:** Click or tap to enter a date. | | **Reviewer Name:** Click or tap here to enter text. | | |
| **General Study Details** | | | | |
| **Conflict of Interest**—Disclosure completed by members of research team (as required) and if applicable details of the management deemed appropriate and implemented as described. | | | Yes | \*No |
| The study team has the resources necessary to protect participants. | | | Yes | \*No |
| **Notes:** | | | | |
| **Required Documents** | | | | |
| All required documents (e.g., consent forms, questionnaires, surveys, scripts, advertisements) have been attached to or otherwise addressed in the IRBIS application (e.g., translated consents may be provided later). | | | Yes | \*No |
| **Notes:** | | | | |
| **ADDITIONAL CONSIDERATIONS**  **If any of the following are checked, the Additional Considerations Checklist must also be completed.** | | | | |
| Research involving Prisoners  Department of Defense  EPA Regulated Research  Department of Justice  Department of Energy  Department of Education  Research involving Non-Viable Neonates or Neonates of Uncertain Viability  Research involving waiver or alteration of consent process for research involving public benefit or service programs conducted by or subject to the approval of state or local officials iv | | | | |
| **Notes:** | | | | |
| **REGULATORY FINDINGS** | | | | |
| **Consent Waivers** | | | | |
| **Waiver of Written Documentation of Consent[[1]](#endnote-2) (Refer to Section D.2 of IRBIS application)**  N/A (no waiver of documentation requested) | | | | |
| One of the following is true:  The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of research context;  The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; **(NOTE: This is only applicable to research that is not FDA-regulated)**  If the subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained. **(NOTE: This is only applicable to research that is not FDA-regulated)**  Choose one of the following:  Written information describing the research ***shall be provided*** to the subject or the LAR; OR  Written information describing the research ***does not need to be provided*** to the subject or the LAR. | | | | |
| **Waiver or Alteration of Consent Process (Refer to Section D.3 of IRBIS application)**  N/A (no waiver or alteration of consent process requested)  **Choose one of the following 2 situations:** | | | | |
| **1 General waiver or alteration of consent process for research which is not FDA-regulated[[2]](#endnote-3)**  The research is not FDA-regulated.  The research involves no more than minimal risk to subjects.  The research could not be practicably carried out without the requested waiver or alteration.  If the research involves using identifiable private information or identifiable biospecimens, the research could not be  practicably carried out without using such information or biospecimens in an identifiable format.  The waiver or alteration will not adversely affect the rights and welfare of the subjects.  Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.  For alterations only:  The alteration of consent process only omits or alters the basic and/or additional elements of consent. | | | | |
| **2 Waiver or alteration of consent process for FDA-regulated research[[3]](#endnote-4)**  The research is FDA-regulated.  The clinical investigation involves no more than minimal risk to subjects.  The waiver or alteration will not adversely affect the rights and welfare of the subjects.  The clinical investigation could not be practicably carried out without the waiver or alteration.  Whenever appropriate, the subjects will be provided with additional pertinent information after participation. | | | | |
| **HIPAA Waivers and Alterations (Refer to Sections B.2 and D.3 of IRBIS application)** | | | | |
| N/A (no waiver or alteration of HIPAA requested) | | | | |
| Yes No The use or disclosure of protected health information involves no more than minimal risk to the privacy of   individuals, based on, at least, the presence of the following elements:  Yes No There is an adequate plan to protect the identifiers from improper use and disclosure  Yes No There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law  Yes No There are adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted  Yes No The research could not practicably be conducted without the waiver or alteration; and  Yes No The research could not practicably be conducted without access to and use of the protected health information  Notes: Click or tap here to enter text. | | | | |
| **Outcomes:**  Choose one:  Full waiver of authorization granted.  Limited waiver of authorization granted (i.e., for screening/recruitment purposes only).  Waiver of documentation of authorization (waiving signature and date requirement).  Alteration of authorization is granted. Description of alteration: Click or tap here to enter text. | | | | |
| **Vulnerable Populations** | | | | |
| **Research involving Decisionally Impaired Individuals (Section A.2.5 in IRBIS)**  N/A, or  **46.102(c)/50.3(l)**] LAR may consent on behalf of prospective subject.  Yes  No The proposed plan for the assessment of the capacity to consent is adequate  Yes  No Assent of the participants is a requirement  **If yes:**  Yes  No The plan for assent is adequate  **Notes:** Click here to enter text. | | | | |
| **Research involving Children (Section A.2.4 in IRBIS)**  N/A, or  **46.404/50.51**, Research not involving greater than minimal risk. (1 parent’s signature) OR  **46.405/50.52**, Research involving greater than minimal risk but presenting the prospect of direct benefit to the  individual subjects. (1 parent’s signature) OR  **46.406/50.53**, Research involving greater than minimal risk and no prospect of direct benefit to individual  subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition. (2 parents’  signatures)  **46.407/50.54**, Research not otherwise approvable which presents an opportunity to understand, prevent, or  alleviate a serious problem affecting the health or welfare of children.  AND, if applicable↓  **46.409/50.56,** Children who are wards of the state or any other agency, institution, or entity can be included if research  is related to status as Ward OR Conducted in Schools, Hospitals, or similar settings in which a majority of the children  are NOT Wards.   * + An advocate will be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The advocate has the background and experience to act in the best interests of the child and is not associated in any way with the research, the investigator(s), or the guardian organization.   **Adequate provisions to solicit the assent of children:**  Assent will be obtained from (check one):  All children\*  Some children\*  Which children are not required to assent: Click or tap here to enter text.  **One or more of the following must be true for the children not required to assent (mark all that apply):**  The children are not capable of providing assent based on the age, maturity, or psychological state  The capability of the children is so limited that they cannot be reasonably consulted  The intervention of procedure involved in the research holds out a prospect of direct benefit that is important to the  health or well-being of the child and is available only in the context of research  Assent can be waived using the criteria for waiver of the consent process  None of the children  **One or more of the following must be true (mark all that apply):**  The children are not capable of providing assent based on the age, maturity, or psychological state  The capability of the children is so limited that they cannot be reasonably consulted  The intervention of procedure involved in the research holds out a prospect of direct benefit that is important to the   health or well-being of the child and is available only in the context of research  Assent can be waived using the criteria for waiver of the consent process  **\*If assent is a requirement:**  Yes No Assent will be documented  If yes:  Yes No The plan to document assent is adequate  Notes: Click or tap here to enter text.  **Waiver of parental permission[[4]](#endnote-5)** N/A, or all the following must be true:  The research is not FDA-regulated  The research protocol is designed for conditions or for a subject population for which parental or guardian permission is  not a reasonable requirement to protect the subjects (e.g., neglected or abused children).  An appropriate mechanism for protecting the children who will participate as subjects is substituted.  The waiver is not inconsistent with Federal, state, or local law. | | | | |
| **Research involving Pregnant Women or Fetuses (Section A.2.B in IRBIS)**  N/A, or  **46.204(d)** The research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit  both to the pregnant woman and the fetus, **or** no prospect of benefit for the woman nor the fetus when risk to the fetus  is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that  cannot be obtained by any other means. Requires consent of pregnant woman only.  **46.204(e)** The research holds out the prospect of direct benefit solely to the fetus. Requires consent of the pregnant  woman and the father except if the father is unable to consent because of unavailability, incompetence, or temporary  incapacity or the pregnancy resulted from rape or incest.  **Study-specific justification:** Click here to enter text. | | | | |
| **FDA Regulated Research – Drug and Device Determinations** | | | | |
| N/A, or  Study exempt from IDE (investigational device) requirements, and reviewer concurs with IDE exempt checklist as  completed by investigator.  **Study-specific justification:** Click here to enter text.  Investigational device; study meets criteria for Non-significant Risk (NSR) — (Abbreviated IDE)  **Study-specific justification:** Click here to enter text.  Study exempt from IND (investigational drug) requirements, and reviewer concurs with IND exempt checklist as completed by investigator.  **Study-specific justification:** Click here to enter text.  Investigational device; study conducted under IDE  Investigational drug; study conducted under IND | | | | |
| **Notes:** Click here to enter text. | | | | |
| **CRITERIA FOR APPROVAL (45 CFR 46.111/21 CFR 56.111)** (All must be checked)  N/A – This is an expedited study and criteria for approval are documented by the reviewer in IRBIS | | | | |
| Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not  unnecessarily expose subjects to risk. | | | | |
| Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment  purposes.  N/A if none. | | | | |
| Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the important of the knowledge  that may reasonably be expected to result. | | | | |
| Selection of subjects is equitable, considering the purposes of the research and the setting in which the research will be  Conducted | | | | |
| Informed consent will be sought from each prospective subject or the subject’s LAR, in accordance with, and to the  extent required by applicable regulations (45 CFR 46.116/21 CFR 50.20). | | | | |
| Informed consent will be appropriately documented or appropriately waived in accordance with applicable regulations  (45 CFR 46.117/21 CFR 56.109(c)). | | | | |
| The research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects. N/A if  minimal risk. | | | | |
| There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. | | | | |
| When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have  been included in the study to protect the rights and welfare of these subjects.  N/A if the research does not include  vulnerable populations. | | | | |
| **EXPEDITED REVIEWER DETERMINATIONS**  **[Note additional expedited reviewer determinations are housed in IRBIS]** | | | | |
| Identification of the participants or their responses will *not* reasonably place them at risk of criminal or civil liability or be   damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and   appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are   no greater than minimal. | | | | |
| **FULL BOARD REVIEWER RECOMMENDATIONS** | | | | |
| Approval **without stipulations**  Minor stipulations  Deferral  Disapproval  **Category 9** Research not conducted under IND/IDE; the IRB determines that this study   involves no greater than minimal risk and no additional risks identified—Future reviews may be reviewed by   expedited review.  **Review Period**  12 months  6 months  3 months  Other: Click or tap here to enter text.  If less than 12 months, provide justification: Click here to enter text. | | | | |

**\*** Response requires the addition of stipulations in IRBIS.   
Once you have completed your review:

1. Save the completed checklist using the following naming convention: IRB#\_Submission type\_Reviewer last name. *Example: “16-6666\_Initial\_Jones”*
2. Upload into IRBIS.

1. 45 CFR 46.117(c) or 21 CFR 56.109(c) [↑](#endnote-ref-2)
2. 45 CFR 46.116(f) [↑](#endnote-ref-3)
3. [IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects (fda.gov)](https://www.fda.gov/files/about%20fda/published/IRB-Waiver-or-Alteration-of-Informed-Consent-for-Clinical-Investigations-Involving-No-More-Than-Minimal-Risk-to-Human-Subjects---Printer-Friendly.pdf#:~:text=Title%20III%2C%20section%203024%20of%20the%20Cures%20Act,rights%2C%20safety%2C%20and%20welfare%20of%20the%20human%20subject.) [↑](#endnote-ref-4)
4. 45 CFR 46.408(c)

   **Approval and Revisions:**

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   | 8/15/2022 | Checklist created and approved | DY |
   | 11/7/2022 | Updated to remove requirement for Reference ID in naming convention. | CDC |
   | 12/6/2022 | Add N/A option for HIPPA Waivers; Updated reference sections | DY |

   [↑](#endnote-ref-5)