IRB Presenter Checklist

IRB# _____ PI _____ Reviewer Signature _____ Date _____

| Section | Questions and relevant section IRB Application | 111 Criteria | Criteria met? Y = Yes N = No N/A | Comments *If No, enter stip in IRBIS* |
|---|---|---|---|---|
| General 3.1 | Recipient Federal Funding | | Yes | **If UNC is the direct recipient of Federal funding by DoD, DoJ, DoN, DoE, DE or EPA; complete related section of the "Additional Considerations Worksheet"** |
| A.1 | Are the rationale (background) and study purpose (hypothesis) adequately described? | **111.1** | N/A | |
| A.1 | Are the objectives and outcome measures consistent with the rationale? | **111.1** | N/A | |
| A.1<br>Also see A.5 | Will the study result in generalizable knowledge that benefits society? | **111.2** | N/A | |
| A.2 | Are the study groups clearly described? | **111.1** | N/A | |
| A.2 | Is the selection of subjects equitable? | **111.3** | N/A | |
| A.2 | If vulnerable populations are involved, are adequate protections in place? (Complete "Vulnerable Populations" section below) | **111.3** | N/A | |
| A.3 | Are inclusion /exclusion criteria appropriate and do they minimize risk to subjects? | **111.2** | N/A | |
| A.4 | Is the study design adequately justified? *(e.g., randomization, placebo, phase, deception)* | **111.1** | N/A | |
| A.4 | Will procedures be performed at proper facilities by qualified personnel? | **111.1** | N/A | |
| A.4.A | Is there a valid IND or IDE from the FDA (when applicable)? | **111.1** | N/A | |
| A.4.A | Are experimental procedures distinguished from standard of care or treatment? | **111.1** | N/A | |
| A.5 | Are the potential benefits to subjects and/or society adequately described? | **111.2** | N/A | |
| A.6 | Are foreseeable risks clearly defined? | **111.2** | N/A | |
| A.6 | Are risks to subjects reasonable when compared to anticipated benefits? | **111.2** | N/A | |

| Section | Questions and relevant section IRB Application | 111 Criteria | Criteria Met? *If No, enter stip in IRBIS* | Comments |
|---|---|---|---|---|
| A.6 | If a medical device, what is the risk? | **111.1 & 111.2** | N/A | ☐ **Non-significant Risk** ☐ **Significant Risk** |
| A.7 | Are data monitoring provisions adequate for subject safety? | **111.6** | N/A | |
| A.10 | Are provisions to maintain confidentiality of collected data/specimens adequate? | **111.7** | N/A | |
| A.12 | Are plans for post-study disposition of identifiable data/specimens adequate? | **111.7** | N/A | |
| B.1 | Are recruitment practices fair and equitable? | **111.3** | N/A | |
| B.2 | Is a limited waiver of HIPAA authorization to identify potential subjects justified? | **111.7** | N/A | |
| B.3 | Is the study duration (and visit frequency) appropriate to achieve stated objectives? | **111.2** | N/A | |
| B.3 | Are provisions to protect subject privacy adequate? | **111.7** | N/A | |
| B.3 Also see A.4 | Are the time demands, number of visits, procedures, and interventions clearly outlined? | **111.4** | N/A | |
| B.4 | Are inducements for participation reasonable and adequately described? | **111.4** | N/A | |
| B.4 | Will incentives exceed $200 per year so that SSN collection required? | | N/A | |
| B.5 | Are costs to be borne by subjects adequately described? | **111.4** | N/A | |
| D.1 | Will consent/assent be obtained from all potential subjects or LARs? (check CF lines) | **111.5** | N/A | |
| D.2 | Are criteria for waiving written documentation of consent satisfied? | **111.5** | N/A | |
| IRB Coordinator to Assess | Are there Conflicts of Interest with this study, disclosed by PI or perceived by reviewer? | | N/A | |
| Consent Forms | Is information in the consent form consistent with the application/protocol? | | N/A | |
| Attachments | Is IRB application concordant with the NIH grant submission? | | N/A | |

| Vulnerable Populations | 111.b. | |
|---|---|---|

**Research involving individuals with diminished capacity (i.e., decisionally impaired)**

**Research involving children (45 CFR 46, Subpart D):**

☐ 46.**404**, Research not involving greater than minimal risk. (1 parent's signature)

☐ 46.**405**, Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (1 parent's signature)

☐ 46.**406**, 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 parent's signatures)

☐ 46.**407**, Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (2 parent's signatures)

☐ 46**.409,** Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407

☐ Waive of minor assent (child unable to provide assent or prospect of benefit not available outside of research)

**Justificatio**n **(describe risk, benefit and how risk will be minimized):**

**Research involving prisoners (45 CFR 46, Subpart C):**

1. (Select the most appropriate category)

☐ **(i)** -- study of possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

☐ **(ii)** -- study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

☐ **(iii)** -- research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the stud may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.

☐ **(iv**) -- research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.

AND confirm that each of the following requirements have also been satisfied:

☐ 2. Any advantages accruing to the prisoners are not of such a magnitude as to impair the subject's ability to weigh risks against benefits.

☐ 3. The risks involved are commensurate with risks that would be accepted by non-prisoner volunteers.

☐ 4. Procedures for selection of subjects are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

☐ 5. The information is understandable to the subject population.

☐ 6. Assurance exists that this research will not affect decisions regarding parole and that the subjects will be made aware of this.

☐ 7. Follow-up care will be provided to the extent and for the length of time necessary.

**Research involving pregnant women, fetuses, neonates (45 CFR 46, Subpart B):**

☐ **46.204** Research involving pregnant women or fetuses.

☐ **46.205** Research involving neonates.

☐ **46.206** Research involving, after delivery, the placenta, the dead fetus or fetal material.
☐ **46.207** Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.
**Justification (describe risk, benefit and how risk will be minimized):**

**Research involving economically, educationally disadvantaged individuals**
**Describe additional protections in place:**

## §46.116- Informed Consent Checklist

**Required Elements**

- ☐ A statement that the **study involves research**
- ☐ An explanation of the **purposes** of the research
- ☐ The **expected duration** of the subject's participation
- ☐ A description of the **procedures** to be followed
- ☐ Identification of any **procedures which are experimental**
- ☐ A description of any **reasonably foreseeable risks or discomforts** to the subject
- ☐ A description of any **benefits to the subject or to others** which may reasonably be expected from the research
- ☐ A disclosure of appropriate **alternative procedures or courses of treatment**, if any, that might be advantageous to the subject
- ☐ A statement describing the extent, if any, to which **confidentiality of records** identifying the subject will be maintained
- ☐ For research involving more than minimal risk, an explanation as to whether **any compensation**, and an explanation as to whether **any medical treatments are available, if injury occurs** and, if so, what they consist of, or where further information may be obtained
- ☐ An explanation of **whom to contact** for answers to pertinent questions about research subjects' rights, about the research and in the event of research-related injury.
- ☐ A **statement that participation is voluntary**, refusal to participate will involve **no penalty or loss of benefits** to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
- ☐ Include **clinicaltrials.gov** language

**Additional elements**

- ☐ A statement that the particular treatment or procedure **may involve risks to the subject** (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
- ☐ Anticipated **circumstances under which the subject's participation may be terminated** by the investigator without regard to the subject's consent
- ☐ Any **additional costs to the subject** that may result from participation in the research
- ☐ The consequences of a subject's decision to withdraw from the research and **procedures for orderly termination of participation by the subject**

- ☐ Statement that **significant new findings** developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
- ☐ The **approximate number of subjects** involved in the study
- ☐ **FDA-regulated clinical investigations:** Subjects must be informed that the FDA may inspect the records of the study.

**The OHRP recommends that the following be included in informed consent documents for bio-specimen collection:**

- ☐ A clear description of the operation of the bio-specimen resource. This description could include details that may be of interest to human research participants, such as whether identifiable information will be maintained by the bio-specimen resource and/or whether research results will be linked to the bio-specimen.
- ☐ The conditions under which samples and data will be released to recipient investigators. Procedures for protecting the privacy of human research participants and confidentiality of data.
- ☐ Specific descriptions of the nature and purpose of the research.
- ☐ Information about the consequences of DNA typing if human genetic research is anticipated.

**Core Elements of HIPAA Authorization**

- ☐ Specific and meaningful description of what will be used or disclosed.
- ☐ The name or other specific identification of the person, or class of persons, authorized to make the use or disclosure.
- ☐ The name or other specific identification of the person, or class of persons, to whom the covered entity may make the requested use or disclosure.
- ☐ A description of each purpose of the requested use or disclosure.
- ☐ An expiration date/expiration event that relates to the individual or the purpose of the use or disclosure.
- ☐ Statement regarding the right of the individual to revoke the authorization in writing, and the limits of that right.
- ☐ Statement regarding the right of the individual to refuse to sign authorization
- ☐ Statement regarding ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization
- ☐ Re-disclosure Statement - Information disclosed to others not subject to the Privacy Rule may be re-disclosed by them without the Privacy Rule protections (cannot promise that information will definitely be protected)

**Reviewer Recommendation (select one):**

☐ **Approval** ☐ **Contingent approval** ☐ **Deferral** ☐ **Disapproval**

**Frequency of Continuing Review:** ☐ **12 months (max)** ☐ **6 months** ☐ **3 months** ☐ **Other (explain):**

**Comments:**