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| --- | --- |
| IRB#: | PI: |
| Submitter: | Date Submitted: |

Note: Numbers in parentheses indicate eIRB section and research summary section. [i.e. (06 & 10) referes to eIRB 06. Research Summary & Abstract and 10. Subject Population Groups and Enrollment.]

|  | **Division Submitter** |  | cru reviewer |
| --- | --- | --- | --- |
| Item Needed | **Y,N,N/A** | comments | Y,n,n/a |
| **Required elements prior to submission for IRB review** |  |  |  |
| Is the funding source cited? (04) |  |  |  |
| Is SPS# entered? (if applicable) (04) |  |  |  |
| If funding is Federal, AHA or March of Dimes, are the entire grant & budget attached? (04) |  |  |  |
| If funding is from private industry, is the sponsor’s protocol attached? (07) |  |  |  |
| If funding is from private industry and involves an investigational drug/device, is the investigational brochure included? (08) |  |  |  |
| Number of subjects in the study population (10) |  |  |  |
| Age of study population (06) |  |  |  |
| Are there exclusions in study population? (06 & 10) |  |  |  |
| Are exclusions justified? If not, why? (06 & 10) |  |  |  |
| **Data Use/Transfer Agreement?** Duke researchers wishing to transfer or use human subject data must contact ORC to initiate a discussion on the proposed data transfer or use. **Material Transfer Agreement (MTA)?** An agreement entered into by the parties to govern the provision or receipt of research material. The specific form of agreement depends upon the nature of the material, the intended use, whether the recipient is an academic or commercial organization, and the consideration of any intellectual property interests associated with the material. |  |  |  |
| Potential subject identification & recruitment: --Will a review preparatory to research occur? If not, (13.1) --Is a waiver of HIPAA authorization for records review requested? (13.2) --How subjects will be identified? (06,5) --How subjects will be recruited? (06,6) --Is PHI to be collected justified? (13.1) |  |  |  |
| Plan for protection of subject privacy? (12,06) |  |  |  |
| Plan for protecting confidentiality of PHI &/or specimens? (12, 14) |  |  |  |
| **Is a consent form attached?** (14)--If not, is a waiver of consent request attached? (13.2)--If a waiver is requested, is it justified? (13.1) |  |       |  |
| If a consent form is attached, are the specific requirements for valid authorization listed below included in the document:--The information--Who may use or disclose the information--Who may receive the information--Purpose of the use or disclosure--Expiration date or event--Re-disclosures not protected--Right to refuse to sign authorization--Right to revoke authorization--Individual's signature and date |  |  |  |
| Are the following additional consent form requirements included:--Is sponsor paying DUHS to perform this research?--If treatment is involved, must the unused drug be returned?--If treatment is involved and the subject is withdrawn, will the  subject be asked to return for a trial checkup?--If no treatment is involved, will the subject be asked to complete closeout tests?--Does the research include providing medical care?--If tissue/blood/RNA/DNA stored, are sample withdrawal options described?--If subjects are not Duke patients, will study data relevant to  healthcare be sent to the subject's physician? |  |  |  |
| --Is there 24-hour contact information to contact PI for questions/problems, complaints, concerns or suggestions? |  |  |  |
| --Is there a contact number to contact IRB for questions about research rights, to discuss problems, concerns, or suggestions, or to offer input?  |  |  |  |
| Are copies of any questionnaires used in this study attached? (07) |  |  |  |
| Is investigational drug/device number included? If Yes, supply number/status. If No, why?  |  |  |  |
| Are minors included in study population? (10) |  |  |  |
| Are the advertisments attached? (11) |  |  |  |

**Please email checklist to monica.harris@duke.edu.**

#### CRU Admin Reviewer: Date:

#### Amount of time required to conduct review: : (HH:MM)