**PI and Study Information**

|  |  |
| --- | --- |
| Project/Study Title: | |
| The COG Institution PI designates individual study implementation and oversight responsibilities to the Delegated Local Study PI. | |
| COG Institution Principal Investigator (PI): | Phone: |
| Delegated Local Study PI: | Phone: |
| IRB Contact Person: | Phone: |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Does the study involve prisoners? | | | No | | Yes | |
|  | | | | | | | |
| **Protected Health Information (PHI)**   |  |  |  | | --- | --- | --- | | 1. Will you obtain the subjects’ authorization to access their PHI during the course of the study?  * *If “Yes”, attach the* [*Seattle Children’s HIPAA Authorization Form*](https://www.seattlechildrens.org/research/resources/institutional-review-board/forms/) *that you will use with subjects.* * *The HIPAA Authorization Form may only be changed in the gray shaded areas of the template. Requests from the sponsor to change other sections of the form will result in submission delays.* | Yes | No | | 1. Will you identify potential subjects by “pre” screening health care records without subjects’ authorization? *If yes, then completely respond to the following criteria for your study; the IRB will use this information to determine if your study meets the minimum criteria for this waiver.* | Yes | No | | | | | | | | |
|  | | | | | | | |
| **Explain why the use or disclosure of PHI for recruitment involves no more than minimal risk to privacy of individuals, based on, at least the presence of the following elements:** | | | | | | | |
| An adequate plan to protect the identifiers from improper use and disclosure. | | | | | | | |
|  | | | | | | | |
| An adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research**.** | | | | | | | |
|  | | | | | | | |
| Assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research. | | | | | | | |
|  | | | | | | | |
| Explain why the recruitment could not practicably be conducted without the waiver of authorization. | | | | | | | |
|  | | | | | | | |
| Explain why the recruitment could not practicably be conducted without access to and use of the PHI. | | | | | | | |
|  | | | | | | | |
| Does the research need any of the following approvals? | | | | | | | |
| Environmental Health and Safety (EHS) | | | Yes | | No | | Pending |
| Institutional Biosafety Committee (IBC) | | | Yes | | No | | Pending |
| Recombinant DNA Advisory Committee (RAC) | | | Yes | | No | | Pending |
| Radiation Safety (RS) | | | Yes | | No | | Pending |
| Other: |  | | | | | | |

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COG Institution Principal Investigator Date

The COG Institution PI designates individual study implementation

and oversight responsibilities to the Delegated Local Study PI

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Delegated Local Study Principal Investigator Date

**To be completed by SCRI IRB Staff**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date received: |  | SCRI study #: |  | |
| Staff printed name: |  | Staff email: |  | |
| Staff title: |  | Staff phone: |  | |
| Intent to open new PedCIRB study approved by SCRI IRB staff: |  | | | |
| Signature | | | Date signed |

HIPAA Determinations:

N/A

Waived per 45 CFR 164.512(i) for recruitment

Authorization Required