**PI and Study Information**

|  |  |
| --- | --- |
| **Principal Investigator (PI) name** | **Contact person name (if different than the PI)** |
|       |       |
| **PI title and department/division** | **Contact title and department/division** |
|       |       |
| **Study sponsor name** | **Sponsor protocol number** |
|       |       |
| **Study title *(****Must be identical to the title on the official study protocol)* |
|       |

**Investigational New Drug (IND), Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE)**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Does the study involve an IND application?
 | [ ]  Yes | **IND #:**  | [ ]  No |
| 1. Does the study involve an IDE?
 | [ ]  Yes | **IDE #:**  | [ ]  No |
| 1. Does the study involve a HDE?
 | [ ]  Yes | **HDE #:**  | [ ]  No |

**Protected Health Information (PHI)**

|  |  |  |
| --- | --- | --- |
| 1. Will you obtain the subjects’ authorization to access their PHI during the course of the study?
* *If “Yes”, please ensure the consent form submitted to WCG IRB contains the appropriate HIPAA language from the Seattle Children’s WCG IRB consent template. Requests from the sponsor to change the template HIPAA language will result in review delays.*
 | [ ]  Yes | [ ]  No |
| 1. Will you identify potential subjects by “pre” screening health care records without subjects’ consent or authorization? *If yes, then complete the WCG IRB Partial Waiver of Authorization For Recruitment (HIPAA Partial Waiver of Authorization) as part of your WCG IRB submission*
 | [ ]  Yes | [ ]  No |

**Other Compliance Considerations**

|  |
| --- |
| Does the research need any of the following approvals per institutional rules/polices? |
|  |  |  |  |
| Environmental Health and Safety (EHS)  | [ ]  Yes, approval obtained | [ ]  No, not needed | [ ]  Pending |
| Institutional Biosafety Committee (IBC)  | [ ]  Yes, approval obtained | [ ]  No, not needed | [ ]  Pending |
| Recombinant DNA Advisory Committee (RAC)  | [ ]  Yes, approval obtained | [ ]  No, not needed | [ ]  Pending |
| Radiation Safety (RS)  | [ ]  Yes, approval obtained | [ ]  No, not needed | [ ]  Pending |
| Other:  |       |

**To be completed by SCRI IRB Staff**

|  |  |
| --- | --- |
| SCRI study # |  |
| Staff printed name: |  | Staff email: |  |
| Intent to apply to WCG IRB approved by SCRI IRB staff:  |  |
| Signature  | Date signed |