**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 Advarra/Schulman/Chesapeake IRB contains the appropriate HIPAA language from the Seattle Children’s Advarra/Schulman/Chesapeake 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 Advarra/Schulman/Chesapeake IRB Partial Waiver of Authorization For Recruitment (HIPAA Partial Waiver of Authorization) as part of your Advarra/Schulman/Chesapeake IRB submission* | Yes | No |

**Other Compliance Considerations**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Does the research need any of the following approvals per institutional rules/policies? | | | | |
|  | |  |  |  |
| 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 SCH IRB Staff**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SCH study # |  | | | |
| Staff printed name: |  | Staff email: |  | |
| Intent to apply to Advarra/Schulman/  Chesapeake IRB approved by SCH IRB staff: |  | | | |
| Signature | | | Date signed |