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| **1. UAB IRB Protocol Number:\*** | | **IRB-** | | |
| **2. UAB Principal Investigator (PI)** | | | | |
| **Name (with degree)** |  | | **Blazer ID** |  |
| **Department/Division** |  | | **Email** |  |
| **Phone** |  | | | |
| **PI Contact (Optional)** | | | | |
| **Name** |  | | **Email** |  |
| **Phone** |  | | | |
| **UAB Billing Contact (if applicable)** | | | | |
| **Name** |  | | **Email** |  |
| **Phone** |  | | | |

\*The UAB IRB Protocol Number is available as soon as you create your IRB submission in IRAP.

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| **3. UAB IRB Protocol Identification** | |
| **Protocol Title** |  |
| **Study Sponsor(s)** |  |
| **Study Sponsor Protocol Number (if applicable)** |  |
| **OSP Assigned Number (9 digits)** |  |

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| **4. Reliance Information** | |
| **Reviewing IRB (who will you rely on)** |  |
| **Plan for reliance** | WIRB SMART IRB IAA\*\*  IREx/TIN |
| **Lead Site (if applicable)** |  |

\*\*IRB Authorization Agreement (IAA), if available, include the document from the lead site or lead IRB in your submission.

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| **5. Performance Facilities**  Check all that will apply | |
| The Kirklin Clinic  UAB Hospital  UAB Highlands  Children’s of Alabama  UAB Callahan Eye Hospital | Jefferson Tower  Jefferson County Department of Health  Birmingham Veterans Affairs Medical Center  Other (i.e., any performance site not listed above)  **Describe:** |

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| **6. Drugs**  Add more lines as needed | | | |
| **Drug Name** | **IND Number** | **IND Exempt/IND Waived** | **Used in accordance with its approved labeling** |
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| **7. Devices**  Add more lines as needed | | | | | |
| **Device Name** | **Class I** | **510(K)** | **PMA** | **IDE #** | **Used in accordance with its approved labeling** |
|  |  |  |  |  |
| **HUD** | **HDE #** | **NSR** | **Exempt** |
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| **8. Required (unless noted) for all submissions** |
| [Protocol Oversight Review Form](http://www.uab.edu/research/administration/offices/IRB/Documents/205%20-%20porf.doc) **or**  Protocol Review Committee Approval |
| Study Protocol |
| Sponsor’s/Lead Site’s Approved Consent Template |
| UAB Site Consent (with Boilerplate language included; use tracked changes) |
| Lead site IRB approval (non-WIRB studies only) |
| Billing information Form (for WIRB and other Commercial IRB studies only; completed by the financial representative of the department) |
| IBC Approval (if applicable) |

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| **9. Protocol Personnel**  **Complete** the **IRB PERSONNEL FORM to list all key personnel (each individual involved in the design and conduct of this protocol).** |

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| **10. Include if applicable:** | |
| Infection Control Approval  Fiscal Approval Process (FAP) email  Radiation Safety Approval | Release of Drugs for Human Research Use  Release of Pathologic Materials  Form FDA 1572 |

**INVESTIGATOR ASSURANCE STATEMENT**

As Principal Investigator, I acknowledge my responsibilities for this protocol, including:

* Certifying that I and any Co-Investigators or Other Investigators comply with reporting requirements of the UAB Conflict of Interest Review Board and any management plan;
* Certifying that the information, data, and/or specimens collected for the research will be used, disclosed and maintained in accordance with this protocol and UAB policies;
* Following this protocol without modification unless (a) the IRB has approved changes prior to implementation or (b) it is necessary to eliminate an apparent, immediate hazard to a participant(s);
* Verifying that all key personnel listed in the protocol and persons obtaining informed consent have completed initial IRB training and will complete continuing IRB training every 3 years;
* Verifying that all personnel are licensed/credentialed for the procedures they will be performing, if applicable;
* Certifying that I and all key personnel have read the *UAB Policy/Procedure to Ensure Prompt Reporting of Unanticipated Problems Involving Risks to Subjects or Others to the IRB, Institutional Officials*, *and Regulatory Agencies* and understand the procedures for reporting;
* Submitting documentation of each continuing review by the reviewing IRB (at least annually or more frequently as required by the reviewing IRB);
* Conducting the protocol as represented to the reviewing IRB and in compliance with reviewing IRB determinations and all applicable local, state, and federal law and regulations; refraining from protocol activities until receipt of initial and continuing RB approval.

***NOTE – If you do not have existing IRB Authorization Agreement/Reliance Agreement for protocols being reviewed by an external IRB, the following process applies:***

***After the IRB Authorization Agreement is executed, you will be asked to submit a copy of the reviewing IRB’s approval. The UAB IRB protocol will have the same approval period, meaning the expiration date will remain the same as the reviewing IRB’s expiration date.***

***When you receive a notification from the UAB IRB that it is time to renew your protocol, submit a copy of the reviewing IRB’s approval for renewal in IRAP as a Continuing Review.***