**Protocol Name: Click or tap here to enter text.**

**Principal Investigator Information**

**Name**: Click or tap here to enter text. **Email**: Click or tap here to enter text. **Phone**: Click or tap here to enter text.

**Mailing Address/Campus Box**: Click or tap here to enter text.

**Is Principal Investigator Washington University full-time faculty member?** Choose an item.

**Department Administrative Contact *(other than PI – department contact, finance, study coordinator, etc.)***

**Name:** Click or tap here to enter text. **Email**: Click or tap here to enter text. **Phone**: Click or tap here to enter text.

**Funding Entity / Sponsor Information**

**Entity Name:** Click or tap here to enter text.

**Please describe the funding flow (example: Company X > WashU; Company X > academic center > WashU):** Click or tap here to enter text.

**Is there a CRO involved in the contracting for this study?** Choose an item.

**Contact Person at funding entity or CRO:** Click or tap here to enter text. **Email (REQUIRED):** Click or tap here to enter text.

**Phone:** Click or tap here to enter text.

**Is the funding entity also the regulatory sponsor of the study?**  Choose an item.

**Are there any other entities providing any support to WashU for this study (drug, device, equipment, funding?)**Choose an item.

*If so, please describe* Click or tap here to enter text.

**Does the study/project require IRB Approval?** Choose an item. **If yes, has the IRB approved as of the date of this form?** Choose an item.

**IRB Number:** Click or tap here to enter text. *Please provide a copy of the informed consent (final or draft) with this form if available.*

**Who developed the protocol?** Choose an item. **Additional Comments / Description:**  *If you chose “both” or “other”, please provide additional details such as which party initiated the protocol, developed the research question(s)/aims.*

**General Study Information**

**Please specify the Study Phase:** Choose an item.

**Additional Info (click all that apply):** [ ]  Inpatient [ ]  Outpatient [ ] Treatment [ ]  Testing [ ]  Data Collection Only

[ ]  Single Site [ ]  Multi-Center [ ]  If Multi-Center, # of sites: Click or tap here to enter text.

**Is Wash U Lead Site** Choose an item.**?** *If this is a WashU PI-initiated multi-center project, please attach a list of sites, contact information at sites for contracting, budget information to include in sub-contracts, etc.*

**How many patients do you anticipate enrolling (at WU)?** Click or tap here to enter text.

**Device Trial:** Choose an item.If yes, specify category of device: Choose an item. If yes, who holds the IDE? Click or tap here to enter text.

**Is the device an implantable medical device?** Choose an item.

If yes, JROC will provide a device form to collect information that must be provided to the hospital and to research billing groups.

 **If no, is the device equipment or a tool that will be provided to WashU to use for testing or analysis?** Choose an item.

**Please describe the device:** Click or tap here to enter text.

**Drug Trial:** Choose an item.

**If Yes**, Who holds the IND application with the FDA? Click or tap here to enter text. If no IND, is there IND exemption letter from FDA or has the IRB determined that no IND application is required? Click or tap here to enter text.

**Where will the study take place/where will subjects been seen?**

[ ]  WashU Facilities Only [ ]  Barnes Jewish Hospital [ ]  Barnes West [ ]  St. Louis Children’s Hospital [ ]  Other Click or tap here to enter text.

**If any procedures will be conducted at any non-WashU facility, please specify type of procedure, location, and department.**

Click or tap here to enter text.

**When will /did enrollment start**? Click or tap here to enter text. **Are any sites currently enrolling**? Choose an item.

**What is Sponsor’s expected enrollment close date**? Click or tap here to enter text.

**STUDY BUDGET** WashU facilities and administrative costs (“F&A”) for industry funded clinical studies is calculated at 26% of direct costs, plus any additional amount assessed by the individual department. All budgets should include appropriate F&A and IRB fees. (*Please note that Department Business Offices require review and approval for your budget prior to submission to the study sponsor and again prior to signature of any agreement. Please involve them early to avoid delays.)* Please forward documentation of department approval of the budget, which is required for JROC files.

**Is the budget provided by the Sponsor acceptable to you?** Choose an item.

**Is the payment schedule provided by the Sponsor acceptable to you?** Choose an item.

**Who will negotiate the budget at the department if different than contact listed above?** Click or tap here to enter text.

**Do you expect the budget to exceed $1,000,000?** Choose an item.

*NOTE: Fund numbers are assigned at the Center for Clinical Studies after receipt of the first payment. Receipt of payment notifications are sent to the individuals on the CCS master list for the corresponding department. CONTACT DIVINE HARTWELL WITH ANY QUESTIONS REGARDING THIS LIST (314-747-0006)*

**STUDY PUBLICATIONS** For company-initiated multi-center studies, we expect there will be a delay required to allow for publication of the multi-center results. Typically this delay on WashU’s independent right to publish ranges from 12-18, but sometimes up to 24 months. Is this time frame acceptable to the PI? Choose an item. If not, what is the PI’s preferred delay period and the circumstances that call for earlier independent publications? Click or tap here to enter text.

**INTELLECTUAL PROPERTY** Do you anticipate that you will make an independent discovery or invention related to the study you are performing, or do you expect to make an improvement to or develop a new use for the company’s drug or product? (A new use is a use beyond the company’s existing patent and/or FDA approved treatment with the study drug) Choose an item.

**If yes, please describe**: Click or tap here to enter text.

**To your knowledge, does this study use a technology developed at Washington University?** Choose an item.

***If yes***, please answer the following:

**Briefly describe the technology**: Click or tap here to enter text.

**Provide the name of the inventor(s) and their department name**: Click or tap here to enter text.

**If yes, is the WashU-developed technology being used in the project currently licensed to a commercial entity?** Choose an item.

**If yes, provide the name of the commercial entity that is party to the license agreement (if known)** Click or tap here to enter text.

**COI DISCLOSURE** **– Do you\* (or any investigator\* participating in the study at WashU) have a financial interest in the sponsor consisting of (**choose all that apply): *\*includes family member(s)*

[ ]  Consulting [ ]  Speaking fees [ ]  Personal Gifts [ ] Honoraria

[ ]  Serving on a Board of Directors or Scientific Advisory Board [ ]  Licensing agreement or royalty income

[ ]  Equity interests, including stock, stock options, warrants, partnership or equitable ownership interests [ ]  Other fees/compensation

**Other Central Services**

**CCS SERVICES**

Are you requesting CCS services for this study (IRB submission/coordinator services/CAM/Recruiting)? Choose an item.

If yes, complete Request for CCS Services Form as found on the CCS web site: <https://ccsforms.wustl.edu/>

For more information about CCS services, budgets, or contract terms, visit the web site: <https://clinicalstudies.wustl.edu/>

**LAB SERVICES\*\***

**Will the study require any of the following from WUSM pathology department, BJH, or SLCH clinical labs?** Choose an item.

If yes, please mark all that apply:

* Patient specimens, tissue (fresh, fixed or frozen) or retained microbial specimens [ ]
* Pathology services, including processing tissue, not performed for routine patient care,
* or digital pathology images  [ ]
* Cellular therapy and apheresis [ ]
* Diagnostic testing not performed for routine patient care or requiring procedure changes [ ]

*\*\* If LAB SERVICES are indicated, please send information about the study to:* *kimberly.zohner@bjc.org* *&* *Christina.Lapka@bjc.org*

**JROC INTAKE CHECKLIST – please send the following items to** **researchcontracts@wusm.wustl.edu** **:**

This intake form (Expeditor) [ ]  Additional Notes regarding intake documents or the study?

ICA Form [ ]  Click or tap here to enter text.

Agreement draft [ ]

Informed Consent Draft [ ]

Protocol or Protocol Synopsis [ ]

**PRINCIPAL INVESTIGATOR’S SIGNATURE**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **DATE:** Click or tap here to enter text.