**CHECKLIST FOR CLINICAL STUDY AGREEMENTS**

**UF Principal Investigator (PI):**

**PI Department/Division:**

**Study Sponsor and/or CRO:**

**Protocol No. or Short Name:**

**UFIRST PROPOSAL#:       UFIRST AGREEMENT#:**

Through the UFIRST Proposal Module, this Checklist must be submitted to RAC and DSP for agreements that involve human subject clinical research with medical services at the UF Health Sciences Center. The Checklist assists RAC and DSP during contract negotiations and promotes compliance with all UF policies and applicable state and federal regulations.

1. **Clinical Study Category:**  Please mark all applicable boxes below:

[ ]  **UFPI-Initiated:**  The Protocol has been developed by or in collaboration with UF PI/Personnel.

[ ]  **Sponsor-Initiated:** The Protocol has been developed solely by Sponsor, Sponsor’s agents (e.g., CRO), or another institution’s PI without UFPI/Personnel collaboration.

[ ]  **Federally Funded:** The Study is funded in whole or in part by federal funds or flow-through funding.

1. **VA Involvement:** Please mark the appropriate box below:

[ ]  **YES**, the Study will be supported by the VA, or conducted at a VA facility, or targeted to VA subjects/patients.

[ ]  **NO**, the Study will not be supported by the VA, or conducted at a VA facility, or targeted to VA subjects/patients.

1. **Clinical Study Services Payment Options: (Note: These payment options do not refer to subject injury payments.)** Please identify the payment option that ***BEST*** applies to this Study by checking one box:

[ ]  ***OPTION 1****:* *Use when Sponsor has indicated in the Study agreement, protocol or budget that Sponsor will pay for ALL protocol-required services****:* Sponsor will pay for all Protocol-required services. UF will not submit any claims to Study subjects, or third-party payers, or insurance for medical services associated with the Study.**

[ ]  ***OPTION 2a*:** *Use when Sponsor has provided a detailed budget that specifically shows which services are paid by Sponsor and which are to be billed out:* **Sponsor will pay for the Protocol-required services as described in the final detailed budget included in this Agreement. UF will not submit claims to Study subjects, or third-party payers, or insurance for any services for which Sponsor has agreed to pay.**

[ ]  ***OPTION 2b***: *Use when some protocol-required services are paid by Sponsor and some are to be billed out, and the Sponsor budget does NOT detail which services are paid by Sponsor and which are to be billed out; PI has determined what services are routine, standard of care:*  **Sponsor funds will be used only to pay for the Protocol-required services that are not routine, standard of care.** **Routine, standard-of-care services will be billed to Study subjects, or third-party payers, or insurance.**

[ ]  ***OPTION 3****:* *Use when the Protocol requires only non-medical, non-billable activities***: Sponsor funds will be used only to pay for Protocol-required nonmedical activities, such as chart review, data collection, questionnaires, and follow-up phone calls***.*

[ ]  ***OPTION 4:*** **None of the options above** **apply. Please describe below or attach an explanation.**

1. **Drug and Device Provisions:**  Please select **ALL** applicable items below:

[ ]  **No drug is required for the Study.**

**4. A. Drug Provision: *If drug or drugs are required for the Study:***

**Sponsor [ ]  will NOT pay for Protocol-required drugs; and/or [ ]  will NOT provide any Protocol-required drugs.**

[ ]  Sponsor **will pay/reimburse UF** for the following Protocol-required drugs:

[ ]  Sponsor **will provide at no cost to UF** the following Protocol-required drugs:       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **No device is required for the Study.**

**4. B. Device Provision: *If device or devices are required for the Study:***

**Sponsor** [ ]  **will NOT pay for any Protocol-required devices; and/or [ ]  will NOT provide any Protocol-required devices.**

[ ]  Sponsor **will provide or contract with** **Shands** forthe following Protocol-required devices:

[ ]  Sponsor **will pay/reimburse** **UF** forthe following Protocol-required devices:

[ ]  Sponsor **will provide at no cost to** **UF** the following Protocol-required devices:

**5. Intellectual Property (IP):**  Please review the IP language in the Agreement and mark the applicable box below:

[ ]  I accept the IP language as currently stated in the Agreement.

[ ]  I do NOT accept the IP language as currently stated in the Agreement. Below or attached are my objections and suggestions:

**6. Publications:**  *UF’s policy is not to accept restrictions on UF’s or PI’s ability to publish UF results. UF can agree to postpone for a Sponsor’s multi-center publication to be issued; but at some reasonable time point, UF and PI must be able to publish UF’s results without Sponsor’s approval*. Please review the publications language in the AGREEMENT and mark the applicable box below:

[ ]  **I accept** the publication language as currently stated in the Agreement.

[ ]  **I do NOT accept** the publication language as currently stated in the Agreement. Below or attached are my objections and suggestions:

**7. Registration on ClinicalTrials.gov:** Please mark the applicable box below:

[ ]  The Study does not need to be registered on ClinicalTrials.gov. (See http://clinicaltrials.gov/)

[ ]  The Sponsor has registered (insert NCT#       ) OR intends to register the Study on ClinicalTrials.gov.

[ ]  **I will NOT accept** the Study unless Sponsor or UF can register to comply with federal law OR for ICMJE requirements for publishing in most professional journals. (See http://www.icmje.org/)

[ ]  I will register the Study through UF by contacting protocolregistry-L@lists.ufl.edu

**8. Good Clinical Practices (GCP) and International Committee on Harmonization Guidelines (ICH):**  See FDA regulations at http://www.fda.gov/oc/gcp/guidance.html. Please mark the applicable boxes below:

[ ]  IF GCP is applicable, I will meet all GCP requirements before initiating the Study at UF.

[ ]  IF ICH is applicable, I will meet all ICH requirements before initiating the Study here at UF.

**9. PRIMARY DEPARTMENT CONTACT:**

Name:       Phone:       Email:

**10. Informed Consent Form (ICF) and Subject Injury:** PI must mark the acknowledgements below:

[ ]  As PI, I understand that **I must ensure** that the final ICF approved by WIRB or UF IRB does not conflict with the final terms and conditions of the Agreement.

**Please check one of the following options:**

**[ ]** As PI**,** I **accept** that Sponsor **WILL PAY** for subject injury costs related to the Study**.** (Agreement *states Sponsor will pay for subject injury costs*.) **OR**

[ ]  As PI, I **accept** that Sponsor **WILL NOT PAY** for subject injury costs related to the Study. *(Agreement is silent on the issue or states Sponsor will not pay for subject injury costs.)* (Please explain below or attach an explanation. For example: “The Study poses no risk to the Study subjects.”)       **OR**

**[ ]  As PI, I accept the Study with or without Sponsor covering subject injury costs, but prefer UF to negotiate that Sponsor will pay.***(Agreement is silent on the issue or has problematic language in the subject injury provision, but PI will accept the Study without SI coverage if it becomes a deal breaker.)***OR**

**[ ]  As PI, I will not accept this Study unless Sponsor pays for subject injury costs related to the Study.**

*(Agreement is silent on the issue or states Sponsor will not pay for subject injury costs; so UF must negotiate subject injury language into the Agreement or PI will not conduct the study. This is a deal breaker for PI.)*

**UFIRST PROPOSAL#:**

**As Principal Investigator, I have read, understand, and approve the contents of this form:**

*PI Signature*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *Date*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |
| --- |
| **RAC Review of AGREEMENT Draft: To be completed by RAC staff only.** |
| Does AGREEMENT Draft Include | YES (Indicate Page or Section #s below) | NO  | NA | Comments  |
| Payment Terms |  |  |  |  |
| Drug Provision |  |  |  |  |
| Devices Provision |  |  |  |  |
| Subject Injury Terms  |  |  |  |  |
|  |  Initials**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Primary RAC Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Secondary RAC Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **DATE: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Additional Notes:**