Clear All

CLINICAL TRIAL AGREEMENT CHECKLIST

UF Principal Investigator (PI):
PI Department/Division:
Trial Sponsor and/or CRO:
Protocol No. or Short Name:
DSR UPN#: **PeopleSoft Proposal#:**

This CTA Checklist must be submitted to RAC and DSR for any human subject clinical trial research that requires a Clinical Trial Agreement (CTA) or a "paid-per-patient" contract. The Checklist assists RAC and DSR during CTA negotiations and promotes compliance with all UF policies and applicable state and federal guidelines.

1. Clinical Trial Category: Please mark the applicable box or boxes below:

☐ **UF PI-Initiated:** Protocol has been developed by UF PI/Personnel, or has been developed in collaboration with UF PI/Personnel.

☐ **Sponsor Initiated:** Protocol has been developed solely by Sponsor and/or Sponsor's agents (e.g., CRO) without UF PI/Personnel collaboration.

☐ **Federally Funded Clinical Trial or a Trial with federal flow-through funding.**

2. VA Involvement: Please mark the appropriate box below:

☐ **YES**, this Trial will be supported by the VA, or conducted at a VA facility, or targeted to VA subjects/patients.

☐ **NO**, this Trial will not be supported by the VA, or conducted at a VA facility, or targeted to VA subjects/patients.

3. Clinical Trial Services Payment Options: (Note: These payment options do not refer to subject injury payments.) Please identify the payment option that ***BEST*** applies to this Trial by checking <u>one</u> box below:

☐ ***OPTION 1:*** **Sponsor will pay for all Protocol-required services. UF will not submit any claims to study subjects or third-party payors/insurance for medical services associated with the Trial.**

☐ ***OPTION 2:*** **Sponsor will pay for the Protocol-required services as described in the final detailed CTA budget. According to UF's normal billing practices, study subjects or their insurers will be responsible for payment for all routine, standard-of-care services that ordinarily would be provided to the subjects in the absence of the Trial *<u>and</u>* are not paid by Sponsor.**

☐ ***OPTION 3***: **Sponsor will pay for all Protocol-required services that are not routine, standard-of-care services. According to UF's normal billing practices, study subjects or their insurers will be responsible for payment for all routine, standard-of-care services provided in conjunction with this Trial that ordinarily would be provided to the subjects in the absence of the Trial.**

☐ ***OPTION 4:*** **Sponsor will pay only for non-billable patient services and activities--such as data collection, case-report forms, completed assessments, and follow-up telephone calls. Sponsor will not pay for any medical care or services provided in conjunction with this Trial, all of which are routine, standard-of-care and medically necessary for treatment of the study subjects.**

☐ ***OPTION 5:*** **None of the options above apply. Please describe below or attach an explanation.**

4. Drug/Device Provision: Please select **ALL** applicable items below:

☐ **No drug is required for this Trial.**

4. A. Drug Provision:

Sponsor ☐ <u>will NOT pay for Protocol-required drugs</u>; and/or ☐ <u>will NOT provide any Protocol-required drugs</u>.

☐ 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 this Trial.**

4. B. Device Provision:

Sponsor ☐ <u>will NOT pay for any Protocol-required devices</u>; and/or ☐ <u>will NOT provide any Protocol-required devices</u>.

☐ Sponsor **will provide or contract with Shands** for the following Protocol-required devices:

☐ Sponsor **will pay/reimburse UF** for the following Protocol-required devices:

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

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

☐ I accept the IP language as currently stated in the CTA.

☐ I do NOT accept the IP language as currently stated in the CTA. Below are my objections/suggestions (or see attached explanation):

6. Publications: *UF's policy is not to accept restrictions on publications although UF can wait for a multi-center publication to be issued but must be able to publish at some point without sponsor approval*. Please review the publications language in the CTA and mark the applicable box below:

☐ **I accept** the publication language as currently stated in the CTA.

☐ **I do NOT accept** the publication language as currently stated in the CTA. Below are my objections/suggestions (or see attached explanation):

7. Registration on Clinical.Trials.gov: Please mark the applicable box below:

☐ The Trial does not need to be registered on Clinical.Trials.gov.

☐ The Sponsor has registered the Trial on Clinical.Trials.gov.

☐ **I will NOT accept** the Trial unless Sponsor or UF can register to comply with ICMJE requirements for publishing in most professional journals.

☐ I will register the Trial through UF by contacting DSR at ufproposals@ufl.edu.

8. Good Clinical Practices (GCP) and International Committee on Harmonization Guidelines (ICH): (For information see 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 Trial at UF.

☐ IF ICH is applicable, I will meet all ICH requirements before initiating the Trial 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 IRB does not conflict with the final terms and conditions of the CTA.

Please check one of the following options:

☐ As PI**,** I accept that the sponsor **WILL PAY/REIMBURSE** for subject injury costs related to the study**. OR**

☐ As PI, I accept that the sponsor **WILL NOT PAY/REIMBURSE** for subject injury costs related to the study. (Please attach explanation—e.g., study poses no risk to the study subjects, etc.) **OR**

☐ **As PI, I will not accept this study unless the sponsor pays/reimburses for subject injury costs related to the study.**

I have read and I approve the contents of this form:

PI Signature: _____ *Date*: _____

RAC Review of CTA Draft: To be completed by RAC staff only.				
Does CTA 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: _____