

Clinical Trial Agreement Checklist

Principal Investigator's Name:

UPN/PS Number:

Subject: Trial Sponsor:

Protocol Number:

This CTA Checklist is a required document that must be submitted to DSR. The information being collected by this form will help DSR negotiate an acceptable Clinical Trial Agreement (CTA).

I. Clinical Trial Category: Please indicate whether this is an investigator initiated study or a sponsor initiated study by checking the appropriate box below.

- Investigator Initiated: Protocol has been developed by UF Principal Investigator and/or other UF personnel or in collaboration with the Sponsor.
- Sponsor Initiated: Protocol has been developed solely by Sponsor and/or Sponsor's Agent(s) with no involvement of UF Principal Investigator and/or other UF personnel.

II. VA Involvement: Please indicate the following concerning the VA by checking the appropriate box below.

- Yes, this clinical trial will be supported by the VA or conducted at a VA facility or target VA subjects.
- No, this clinical trial will not be supported by the VA or conducted at a VA facility or target VA subjects.

III. Services Payment/Consideration: Please identify which of the following payment scenarios apply to this clinical trial project by checking one appropriate box below from Option #1-5. If there are exceptions, limitations or variations to the Option checked, complete Option 5B also and explain. Choose Option #6A only if none of the choices below apply.

For additional assistance, review the document entitled: [Use the Following in Completing the Clinical Trial Agreement Checklist.](#)

Note: Services Payment/Consideration language is not related to Subject Injury language.

Option 1

Sponsor will pay for all services provided under this protocol, including study-related medical services and routine, standard-of-care medical services, if any, and no claims will be submitted to patients or third party payors for any services associated with the study.

- Check here and provide detail in Option 5B if there are any exceptions, limitations or variations.**

Option 2

Sponsor will pay for all study-related non-billable-to-patient services, which may include study-related medical services provided solely for data collection, but all claims for routine, standard-of-care medical services associated with the study will be submitted to third party payors or the patient and the insurer or the patient will be responsible for these costs.

- Check here and provide detail in Option 5B if there are any exceptions, limitations or variations.**

Option 3

Sponsor will pay for all study-related non-billable-to-patient services, which may include study-related medical services provided solely for data collection, AND some specific routine standard-of-care medical services, but SOME claims for routine/standard-of-care medical services will be submitted to third party payors or the patient and the insurer or the patient will be responsible for these costs.

- Check here and provide detail in Option 5B if there are any exceptions, limitations or variations.**

Note: If checked, Investigator must submit the details of what standard of care services the Sponsor is paying for and what standard of care services are expected to be billed to the patient and their 3rd party payer to DSR. This information will be detailed in one of the following documents and will be included as part of the CTA.

(check box and attach copy of the appropriate document):

- Protocol/SOE
- Billing Grid
- Table
- Other _____

Option 4

Sponsor will only pay for data collection, case report forms, completed assessments, follow-up telephone calls, and other non-billable-to-patient services. No payments by sponsor relate to any medical care provided in conjunction with this study, all of which is understood to be provided as the standard of care and medically necessary for the treatment of the patient. During the course of the study, the investigator may be providing medical services to patients that are understood to be standard-of-care, not associated with the study and otherwise medically necessary to treat the patient's condition.

- Check here and provide detail in Option 5B if there are any exceptions, limitations or variations.**

Option 5

Other: Choose this option if:

- 5A:** None of the choices above apply, then describe in detail below or
- 5B:** I have checked an option above that mostly applies, but the exception, limitation or variation is described in detail here:

IV. Device/Drug Cost: Please select the component(s) provided and a funding source provided below:

Component provided:

- Device Drug Both Other (explain below)

Drug and/or Device will be provided by:

- Sponsor free of charge
- At study site expense (planned to be billed to participant/insurance)
- At study participant/insurance expense
- Other (explain below)

V. Intellectual Property (IP) Ownership: Please review the intellectual property (IP) language in the CTA and indicate, by checking the appropriate box below, if you concur with the language as provided.

- I am willing to accept the (IP) language as provided in the CTA.
- I am not willing to accept the (IP) language as provided in the CTA. My proposed changes are as follows:

VI. Publications: Please review the publication language in the CTA and indicate, by checking the appropriate box below, if you concur with the language as provided. Also, notate whether or not you are willing to accept clinical trials that are not registered for publication purposes.

- I am willing to accept the publication language as provided in the CTA.
- I am not willing to accept the publication language as provided in the CTA. My proposed changes are as follows:

Clinical Trial Registration with ClinicalTrials.GOV

- I am willing to accept this clinical trial whether or not the Sponsor allows the trial to be registered per the requirements of ICMJE (i.e., ClinicalTrials.gov)
- I would like to have this clinical trial registered and am not willing to accept the effort if the Sponsor does not allow the trial to be registered per the requirements of ICMJE (i.e., ClinicalTrials.gov).

VII. Informed Consent Form (ICF): Please indicate you have taken necessary steps to ensure that the approved ICF does not conflict with the executed clinical trial agreement in the area of subject injury compensation and/or payment consideration language.

- The Informed Consent Form has been finalized and is not in conflict with the CTA's subject injury compensation and/or payment consideration language.
- The Informed Consent Form has already been finalized **but it is currently in conflict** with the CTA's subject injury compensation and/or payment consideration language. The appropriate changes are being made and will be submitted to the IRB and I will ensure that the subject injury compensation and/or payment consideration language will not be in conflict with the CTA language.
- The Informed Consent Form has not been finalized and I will ensure that the subject injury compensation and/or payment consideration language will not be in conflict with the CTA language.

VIII. Good Clinical Practices (GCP) and International Committee on Harmonization Guidelines (ICH): This clinical trial may be subject to GCP and/or ICH. As the PI of record, I certify that the following is correct (check all that apply):

- GCP is not applicable to this effort; or
- GCP is applicable to this effort, and
 - I comply with GCP; or
 - I do not currently comply with GCP, but will ensure that all requirements are met before initiating the clinical trial.
- ICH is not applicable to this effort
- ICH is applicable to this effort, and
 - I comply with ICH, or
 - I do not currently comply with ICH, but will ensure that all requirements are met before initiating the clinical trial.

For more information on GCP and ICH see <http://www.fda.gov/oc/gcp/guidance.html>.

Comments/Remarks:

Primary Department Contact:

Name: _____

Phone _____ E-mail: _____

PI Signature Date

Name:

Title:

This box to be completed by the RAC office

This review is for billing compliance purposes only and does not infer legal authority. The following items are noted regarding the CTA draft and ICF language:

CTA language in draft contract

	Yes/Page #	No/Missing	NA	Comment
Drug Provision				
Device Provision				
Payment Language				
Subject Injury				
Reviewer Initials				

The Contract Negotiator will add or correct contract language as necessary.

ICF language as compared to the Grid, CTA terms, PI info, and UF Template language

	Y or N
Normal Clinical Care procedures (provided in absence of study) listed in Question 6?	
Only Study procedures listed in Question 7?	
Costs language is UF Template and does not conflict with CTA or PI info?	
Subject Injury is UF Template and does not conflict with CTA or PI info?	
Reviewer Initials	

Any item designated with "N" will need further review by the RAC Document Coordinator.

RAC Signature Required:

RAC Signature

Date