The following language is required by UF to be provided in the WIRB Informed Consent Form template in the **Costs** section titled: “If you choose to take part in this study, will it cost you anything?”

### PART 1 OF 2 - DRUGS AND DEVICES SECTION

For studies that involve a drug or device, you need to add appropriate language based on the funding source for the investigational agent. Copy and paste the appropriate language into the Costs section of all appropriate Informed Consent Forms.

☐ If the Sponsor is providing the drug or device free of charge, add the following consent language:

<Insert name of drug or device> will be provided at no cost to you while you are participating in this study.

☐ OR if the drug or device will be provided at third party payor’s or study subject’s expense, add the following consent language:

The cost of <insert name of drug or device> will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or co-payments for those services, and any non-covered or out-of-network services. Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.

### PART 2 OF 2 - MEDICAL SERVICES SECTION

The appropriate consent language for this section will be based on the Option box you selected on the CTA Checklist [http://rgp.ufl.edu/research/pdf/clinical_trial_checklist.pdf](http://rgp.ufl.edu/research/pdf/clinical_trial_checklist.pdf). Copy and paste the appropriate language into the Costs section of all appropriate Informed Consent Forms.

Please Note: If your study will not have a Contract with the sponsor, select the language that best describes the payment plan.

☐ For Option 1, use the following consent language:

If you completed a CTA Checklist, choose the appropriate language based on the box you checked on the CTA Checklist. The corresponding italicized language goes in the consent form.
Option 1. Sponsor will pay for all medical services provided under this protocol, including study-related medical services and routine, standard-of-care services, if any, and no claims will be submitted to third party payors for any services associated with this study. Use the following consent language:

The Sponsor will pay for all medical services provided as part of your participation in this study, including those medical services you would have even if you were not in this study. There will be no cost to you. If you receive a bill related to this study, please contact the Principal Investigator in question 3, <insert Principal Investigator’s name and phone number> of this consent form or the study coordinator at <insert Study Coordinator’s name and phone number>.

Option 2. Sponsor will pay for all study-related, non-billable-to-patient services, which may include study-related services provided solely for data collection, but all 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 paying these costs. Use the following consent language:

The Sponsor will only pay for medical services that you receive as part of your participation in this study as described in the question “What Will Be Done Only Because You Are In This Research Study” question 7 above. All other medical services that you would have received if you were not in this study will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, co-payments, for those services, and for any non-covered or out-of-network services. Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.

OR for Option 3, use the following consent language:

Option 3. Sponsor will pay for all study-related, non-billable-to-patient services, which may include study-related 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 paying these costs. Use the following consent language:

The Sponsor will pay for medical services that you receive as part of your participation in this study as described in the question “What Will Be Done Only Because You Are In This Research Study” question 7 above. This includes some medical services that you would have received if you were not in this study. All other medical services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or
co-payments for those services, and for any non-covered or out-of-network services. Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.

**OR for Option 4, use the following consent language:**

**Option 4.** Sponsor will pay for all study-related, non-billable-to-patient services, which may include study-related medical services provided solely for data collection. Sponsor will also pay for routine, standard-of-care medical services if denied by third party payors. Use the following consent language:

*The Sponsor will pay for medical services that you receive as part of your participation in this study as described in question 7. All other medical services not listed in question 6 will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or co-payments for these services. However, if your insurance company denies payment for these medical services, or you do not have insurance, the Sponsor will cover the costs of the medical services listed in question 6.*

*[PI, please include details of any exceptions provided in the clinical trial agreement]*

**Option 5.** Sponsor will only pay for data collection, case report forms, completed assessments, follow-up telephone calls, and other non-billable-to-patient services. The study does not require any study-related or routine, standard-of-care medical services. Therefore, the Sponsor will not pay for any medical care provided in conjunction with this study. During the course of the study, investigator may only be providing services to patients that are understood to be standard of care and otherwise medically necessary to treat the patient’s condition. Use the following consent language:

*Any medical services provided to you during your participation in this study would have been provided to you if you were not in this study. These medical services will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or co-payments for these services, and any non-covered or out-of-network services. Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.*

**Option 6.** If there are exceptions, limitations, or variations to the Option checked, you should have chosen Option 6B also and explained in detail. You should have chosen Option 6A only if none of the options above applied.

**Note:** If you select Options 6A or 6B, ICF language must be drafted consistent with the description of the Payment Consideration.
OR for Option 5, the ICF language must be drafted consistent with the description of the Payment Consideration in the CTA. The language must be written at an 8th grade level. Please have the Research Administration and Compliance office review this language BEFORE submitting to the WIRB or IRB-01. Email drafts to <ezettler@ufl.edu> or call Edy Zettler at 273-6244 for more information.

If the study involves a drug or device, insert appropriate language from Section III. of the CTA Checklist. The corresponding italicized language goes in the consent form.

☐ Sponsor is providing the drug or device free of charge.

<insert name of drug or device> will be provided at no cost to you while you are participating in this study.

☐ The drug or device will be provided at third party payor’s or study subject’s expense.

The cost of <insert name of drug or device> will be billed to you or your insurance company. You will be responsible for paying any deductible, co-insurance, or co-payments for those services, and any non-covered or out-of-network services. Some insurance companies may not cover costs associated with studies. Please contact your insurance company for additional information.