Template Options for Cost to Study Subjects

Select the appropriate template to be utilized in the study informed consent, sign and submit this to CRH as part of the intake package of documents or to Jacksonville Office of Research

☐ **OPTION 1** *(The sponsor is paying for ALL protocol-required clinical services both study only interventions and those considered to be the current standard-of-care)*

Template Language to be placed in the informed consent:

> The Sponsor listed on this informed consent form will pay for all clinical services (both study related and standard of care) that are required to participate in this study. There will be no cost to you or your insurance provider. If you receive any bill related to your participation in this research study, please contact *the Principal Investigator or study coordinator listed in this informed consent form.*
>
> *If you receive any healthcare at UF Health that is not related to this study, this care will be billed as usual.*

☐ **OPTION 2** *(The sponsor is paying for all **Protocol-Required** clinical services provided as part of this research study that are listed in the informed consent)*

Template Language to be placed in the informed consent:

> The Sponsor will pay for all study related clinical services and certain routine clinical services that are required as part of your participation in this study. This may include some clinical services that you could have received if you were not in this study. All other non-study related clinical services will be billed to you or your insurance company as usual. For those services, you will be responsible for paying any deductible, co-insurance, co-payments, and for any non- covered or out-of-network services. Some insurance companies may not cover the cost of routine clinical services if they are associated with research studies. *The study coordinator can help you work with UF Health to answer any financial questions you have about your participation in this study.*

☐ **OPTION 3** *(The sponsor is paying for all **Protocol-Only** clinical services provided as part of this research study that are **NOT** considered standard-of-care)*

Template Language to be placed in the informed consent:

The Sponsor will pay for all study related clinical services that you receive as part of your participation in this study that are not considered routine clinical services, also called standard-of-care services. All standard of care clinical services will be billed to you or your insurance company as usual. You will be responsible for paying any deductible, co-insurance, co-payments, for those standard of care clinical services, and for any non-covered or out-of-network services. Some insurance companies may not cover the cost of routine clinical services if they are associated with research studies.
The study coordinator can help you work with UF Health to answer any financial questions you have about your participation in this study.

☐ **OPTION 4** *(When all clinical services provided as part of this research study are considered standard-of-care or if this is a data collection or an observational study only)*

Template Language to be placed in the informed consent:

Any clinical services you receive as part of your participation in this study would have been provided to you even if you were not in this study. These services will be billed to you or your insurance company in the usual manner. 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.

The study coordinator can help you work with UF Health to answer any financial questions you have about your participation in this study.

Your signature acknowledges your understanding of the cost implications for a participant in your study and you are selecting a template option that will be utilized in your submitted consent to outline the costs that may be incurred by study participants. This template use will be verified by CRH or Jax ORA during the final review of the approved informed consent form. This form needs to be signed by the principal investigator or appropriate designee for the study team

Full Study Title: _____

Principal Investigator: _____

Signature: _____ Date: _____

IRB01 Institutional Number: _____