UF UNIVERSITY of FLORIDA

Health Science Center – *Jacksonville*
Office of Research Affairs
(904) 244-9478

580 West Eighth Street
Tower II, 9th Floor, Suite 9015
Jacksonville, FL 32209

Informed Consent (IC) Financial Language Assessment (FLA)
CRO-JAX FLA Form

UF Principal Investigator (PI):	
Research Coordinator/Manager:	
PI Department:	
Study Sponsor:	
Study Title:	
Protocol Number:	
UFIRST/AGR # (to be used as the Institutional # for JAX/WIRB submissions):	
Institutional # (for IRB-01 submissions):	

CRO-JAX Review:
Email this completed FLA form and the red-lined IC (including the UF required FLA language based on your selections herein) to the applicable CRO-JAX reviewer listed below BEFORE obtaining Sponsor review/approval.

IRB:
IRB-01
(including Ceded, EAP, Investigator-Authored, and Registry reviews)

CRO-JAX FLA Reviewer:
Anne Shumway at anne.shumway@jax.ufl.edu

WIRB:

Regina Leonard at regina.leonard@jax.ufl.edu
Shannon Kennedy at Shannon.kennedy@jax.ufl.edu

If uncertain if your study is required and/or eligible for WIRB review, please click on the following UF IRB links:

https://irb.ufl.edu/irb-04-home-western-irb.html
https://irb.ufl.edu/irb-04-home-western-irb/what-studies-are-eligible-for-wirbr-submission.html

Main IC Cost Language

(Please select all applicable options.)

DRUG or DEVICE:

☐ The study < *drug or device*> will be provided at no cost to you while you are participating in this study.

☐ 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 research studies. Please contact your insurance company for additional information.

MEDICAL SERVICES:

☐ **OPTION 1** *(sponsor paying for ALL protocol-required medical services)*

The Sponsor will pay for all medical services required as part of your participation in this study. There will be no cost to you. If you receive a bill related to this research study, please contact <*insert Principal Investigator's name and phone number*> or the study coordinator at <*insert Study Coordinator's name and phone number*>.

☐ **OPTION 2a** *(sponsor paying for all protocol-required medical services listed in the budget and IC)*

The Sponsor will pay for the medical services required as part of your participation in this study as described above as what will be done only because you are in this research study. This may include 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, co-payments, for those services, and for any non-covered or out-of-network services. Some insurance companies may not cover costs associated with research studies. Please contact your insurance company for additional information.

☐ **OPTION 2b** *(sponsor paying for all protocol-required medical services that are not considered standard-of-care)*

The Sponsor will pay for all Protocol-required medical services that you receive as part of your participation in this study that are not routine, standard-of-care services. All other medical services 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 research studies. Please contact your insurance company for additional information.

☐ **OPTION 3** *(all medical services are considered standard-of-care or this is a data collection or observational study)*

Any medical services you receive 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. Some insurance companies may not cover

costs associated with research studies. Please contact your insurance company for additional information.

☐ **OPTION 4** *(If none of the above apply, please insert IC language that is consistent with the Payment terms in the Agreement/Award. This language must be written at an 8th grade level. Please have CRO-JAX review this language BEFORE submitting to the WIRB or IRB-01.)*

Main IC Subject Injury Language

(Please select the appliable option.)

☐ **SPONSOR WILL PAY:**

[This minimal risk text will be included by the site if appropriate: Since this is a <data collection> <registry> <observational> study, there is a very low risk of study-related injury. However,] If you are injured or become ill as a result of your participation in this study, the Sponsor will pay for all reasonable and necessary expenses required to diagnose and treat your injury, including hospitalization, as long as:

The following four caveats are approved per General Counsel. **All red caveat clauses should only be added if verified with matching contract clauses.**

1. The injury occurs as a result of your participation in the study.
2. The injury results from the study <drug> <device> <product> <and/or> <study-required procedures> Add next phrase only if in contract <that you would not have received as part of your routine medical care>.
3. The injury is not the result of the natural course of your disease or some other underlying condition unless made worse by your participation in the study.
4. The study doctor and/or study staff have followed the study procedures.

The following caveat should be used sparingly and ONLY in place of caveat 4 "followed study procedures" for sponsors who insist on using stronger language for UF negligence. DSP-Jax will get UF Legal Counsel's permission before you offer it to a sponsor in the ICF.

5. The study doctor and/or study staff have met all their obligations to the sponsor.

The following caveats should be used ONLY if we were unable to negotiate out a "3rd party negligence or product caveats in the contract (deal breaker). DSP-Jax will get UF Legal Counsel's permission before you offer them to a sponsor in the ICF.

6. The injury is not a result of the negligence or misconduct of any third party.
7. The injury is not the result of the <name of the third-party product> <another company's product>.

The Sponsor and the Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact <insert Principal Investigator's name and 24-hour phone number> if you experience an injury or have questions about any discomforts that you experience while participating in this study.

The following paragraph can replace the previous paragraph for IRB-01 studies

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

Add the following only at sponsor request and then only if this statement does not show up in any other part of the ICF

By signing this consent form, you are not giving up any legal rights.

☐ **SPONSOR WILL <u>NOT</u> PAY** *(UF department responsible for any professional fees)*

Since this is a <data collection> <registry> <observational> study, there is a very low risk of study-related injury. However, If you are injured as a result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands/UFHJ hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered.

The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact [insert Principal Investigator's name and 24-hour phone number] if you experience an injury or have questions about any discomforts that you experience while participating in this study.

PREGNANT PARTNER IC

(no medical services required and no risk of injury)

☐ **COST**

There will be no cost to you for allowing us to collect this information about your pregnancy. The regular medical care costs related to your pregnancy and the birth and care of your baby will be billed to you and/or your health insurance in the usual way.

☐ **SUBJECT INJURY**

We do not anticipate that the collection of information about your pregnancy will result in any injuries. If you believe that you have been injured as a result of taking part in this study, contact <insert Principal Investigator's name and 24-hour phone number>.

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If you have any questions related to FLA provided, please contact the appropriate CRO-JAX Reviewer (listed above).

Financial Language Assessment (FLA):

Based on information provided by the Principal Investigator in the documents submitted to our office for this study, the Billing Compliance Risk and Financial Language Assessment for the Informed Consent Form has been completed.

Signature: _____ **Date:** _____

CRO-JAX FLA Reviewer: [Print Name]

Disclaimer: This assessment is based on the information provided to our office at this time. If at a later date, the Study information changes due to protocol amendments, changes in award/agreement terms, budget amendments, or error corrections, the study should be reassessed to ensure that the protocol, informed consent, budget and agreement terms do not conflict.

It is the Principal Investigator's responsibility to verify that the ICF COSTS and SUBJECT INJURY language is consistent with the Contract, Award, or Agreement language and to resubmit compliance paperwork to our office as needed.