DATE: January 30, 2024

FROM: Michael Mahoney
Director of Research Operations & Services

RE: New required subject injury language for IRB approved research consent forms: Subject injury language for greater than minimal risk research

Effective March 1st, 2024 all new human research informed consent forms must include the following language if subject injury is a possibility or if deemed appropriate by the IRB:

**What if you are injured because of the research study?**

It is important that you promptly tell any member of the research team if you experience an injury or have questions about any discomforts that you experience while participating in this study.

If you are injured as a result of being in this study, the costs of the diagnosis and/or treatment may be covered by the University of Florida or the study sponsor or billed to you or your insurer just like other medical costs, depending on a number of factors. The University of Florida and the study sponsor do not normally provide any other form of compensation for injury. 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.

This language was developed after benchmarking how peer universities approach this issue and with input from the Institutional Review Board, Division of Sponsored Programs, General Counsel, and the UF Health Self-Insurance Program. This new language should streamline sponsor negotiations, simplify writing the informed consent form, and improve compliance while continuing to properly inform subjects.

Dr. David Norton, Vice President for Research, determined this language will be required on January 26th, 2024. This applies to all new human subjects research where subject injury is a possibility (e.g. greater than minimal risk research) or if deemed appropriate regardless of the IRB that is reviewing the research: not only UF IRB-01 and UF IRB-02, but also any IRBs that research is ceded to (e.g. WCG,
Advarra, or other universities). This requirement does not apply to any research approved prior to March 1st, 2024.

If you have any questions please contact me at (352) 392-1587 or mmahoney@ufl.edu.

Sincerely,

Michael Mahoney
Director, Research Operations & Services