HRP-502COI – TEMPLATE - Conflicts of interest (cOI) consent LANGUAGE template

(January 3, 2022)

Instructions:

Use the template language below when informing or updating prospective and current study participants/human subjects about conflicts of interest related to your research.

Information about such conflicts of interest may be included as the first paragraph in the “What else do I need to know” section of the HRP-502 consent form; after the first paragraph in the “What is this study about” section of the HRP-502a or HRP-502c consent forms; or at the end of the first paragraph in the HRP-502i Information Sheet form.

Edit or remove any highlighted text or parentheticals before submitting your consent form to the IRB.

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|  | Financial Interest | Template Consent Language |
|  | Funding or sponsorship of the study | The [insert name of the funding agency, foundation or other sponsor, e.g., National Institutes of Health, National Science Foundation, Bill & Melinda Gates Foundation, Novo Nordisk Foundation, Johnson & Johnson, NatureMade] pays (or helps to pay or support) this study, including part of [insert Dr. LastName or other researchers]’s salary (if the latter applies). You have the right to ask about this funding or payment. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study. |
|  | Product (drug, device, assay, supplement or biologic) being used in the study is being provided by a supplier or other study funder or sponsor | The [insert the name(s) of the drug, device, assay, supplement or biologic product] being used in this study is provided at cost (or no cost or donated) to the study team (or study participants). This disclosure is made so that you can decide if this information will affect your willingness to participate in this study.  *As applicable, add other products being used in the study.* |
|  | Researcher is being paid by the research sponsor | Dr. LastName (and/or other researchers involved in conducting this study) is (or are) being paid to conduct this study. You have the right to ask about how they are being paid. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study. |
|  | Researcher has stock or other financial investments in the company | Dr. LastName has [select stock or describe other financial interests] in a company that is funding this study. You have the right to ask about these interests. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study.  *As applicable, add the following:*  Dr. LastName has [select stock or describe other financial interests] in a company that is providing [insert the name(s) of the drug, device, assay, supplement or biologic product]. You have the right to ask about these interests. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study. |
|  | Researcher has stock or other financial investments in another company | Dr. LastName has [select stock or describe other financial interests] in a company that is performing research in the same area as this study. You have the right to ask about these interests. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study.  *As applicable, add the following:*  Dr. LastName has [select stock or describe other financial interests] in a company that is performing research in the same area as this study [insert the name(s) of the drug, device, assay, supplement or biologic product]. You have the right to ask about these interests. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study. |
|  | Researcher is a Scientific Advisory Board member of the research sponsor | Dr. LastName (as applicable, list other researchers involved in conducting this study) is a [select paid or unpaid] member of a scientific advisory board of the company (or foundation) that is sponsoring this study. You have the right to ask about this membership. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study. |
|  | Researcher is a Scientific Advisory Board member of another research company or foundation | Dr. LastName (as applicable, list other researchers involved in this study) is a [select paid or unpaid] member of a scientific advisory board of a related company (or foundation) (or other unrelated company or foundation) that is performing research in the same area as this study. You have the right to ask about this membership. This disclosure is made so that you can decide if this relationship will affect your willingness to participate in this study. |
|  | Researcher is the treating physician or other clinician | Dr. LastName (as applicable, list other researchers involved in this study who are treating physicians or other clinicians), who is also the person (or who are persons) responsible for or involved in conducting this study, is interested in both your clinical care and the conduct of this study. You have the right to talk to another person who is not part of the research team before deciding whether or not to be in this study. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study. |
|  | Researcher and/or FSU owns or is listed on a patent for a product (drug, device, assay, supplement or biologic) being used in the study | Dr. LastName (as applicable, list other researchers involved in this study, FSU or other institution(s) involved in the study) has a patent interest in the [insert the name(s) of the drug, device, assay, supplement or biologic product] that is being used in this study. That means that he/she/they has/have a personal financial interest in owning or using the [insert the name(s) of the drug, device, assay, supplement or biologic product] and may benefit financially if the (drug, device, assay, supplement or biologic) does what they hope it will do. You have the right to ask about this patient interest. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study. |
|  | Researcher receives or received honoraria or travel reimbursement | Dr. LastName (as applicable, list other researchers involved in this study) receives (or has received) an honorarium (or payment for travel) from [insert name of the study’s funding agency, foundation or other sponsor, e.g., National Institutes of Health, National Science Foundation, Bill & Melinda Gates Foundation, Novo Nordisk Foundation, Johnson & Johnson, NatureMade] during the past 12 months. You have the right to ask about this Honoria or travel reimbursement. This disclosure is made so that you can decide if this information will affect your willingness to participate in this study. |
|  | A researcher’s family member has any of the above interests | Edit the above template language as follows:  Dr. LastName’s (as applicable, list other researchers involved in this study) [insert spouse or dependent children] has (or is) [then insert any and all applicable interests from 1-10 above]. |
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| **IMPORTANT NOTICE:**  The COI consent text template language above should be adapted to your specific circumstances involving your and your family’s interests. The template language is not exhaustive; other circumstances involving possible conflicts of interest may apply. The FSU Institutional Review Board (IRB) may pursuant to its review and approval of human research require additional language.  Federal law provides the IRB with authority to, for example, review human research; require modifications to secure approval; and ensure that legally effective informed consent will be and is obtained, including disclosure of the above interests. FSU institutional officials may not approve of research involving human subjects that has not been approved by the IRB, including IRB approval of or required modifications for COI consent language (see 45 CFR §§46.109, 46.111(a)(4), 46.116; 42 CFR §50.605(a)(1)(ii); and 45 CFR §94.5(a)(1)(ii)).  Visit this FSU Office of Research [Conflicts of Interest](https://www.research.fsu.edu/research-compliance/conflict-of-interest/) page to obtain authoritative conflicts of interest-related information. | | |