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| IRB | Unaffiliated Investigator Agreement |

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| Please provide contact information for a representative who can answer any questions that the IRB might have concerning this submission:   |  |  | | --- | --- | |  |  | | |
| Name: |  |
| Position: |  |
| E-mail: |  |
| Phone #: |  |
| Pager #: |  |
| 2nd Contact: | name + e-mail or phone # |
| Group: |  |

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| Form Instructions:   * ATTACH A COPY OF THE UNAFFILIATED INVESTIGATOR’S CV. * This form is to request UF IRB oversight of an investigator who is not only unaffiliated with UF, Shands, or VA, but also unaffiliated with any other institution or IRB. This form is not appropriate for students or faculty at other universities (they should obtain approval from the IRB at their university). * Research conducted solely at or by personnel at NF/SG VHS may not use this form – VA regulations prohibit unaffiliated investigators. * All submissions must be typed. |

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| Section 1: UF research covered under this agreement | | | | |
| UF Study Title | | |  | |
| UF IRB number | | |  | |
| UF Principal Investigator Name (last, first) | | |  | |
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| Section 2: Unaffiliated Investigator Information | | | | |
| Name (last, first) | |  | | |
| Degree | |  | | |
| Email address | |  | | |
| Phone # | |  | | |
| Place of employment | |  | | |
| Occupation. If a student or if you are currently visiting UF, please explain. | |  | | |
| Is the unaffiliated investigator employed at an institution that has an IRB (e.g. another university) or requires use of a particular IRB?  Yes. STOP. Do not submit this form. Individuals affiliated with another institution or IRB must obtain IRB approval from their own IRB. Contact the IRB office if you want to pursue an IRB Authorization Agreement (IAA) to cover researchers at other universities.  No. Provide the individual’s UF ID#:        If this individual does not already possess a UF ID# you must obtain one by contacting the Office of Research Human Resources at (352) 392-4803. | | | | |
| What research activities will the unaffiliated investigator be engaged in under this agreement? Select all that apply.  No direct contact with subjects. Describe:  Recruit/enroll/obtain informed consent from subjects.  Conduct study interventions. Describe:  If any contact with subjects, select any vulnerable populations who will be involved:  Children  Pregnant Women  Prisoners  Cognitively impaired  Other. Describe: | | | | |
| Will the unaffiliated investigator access, collect, use, or analyze any medical/research records or other data sources? Select all that apply | | | | |
| **No** access to, collection of, or use of **any** data for research purposes. | | | | |
| Access/collect/release (a) PHI or (b) sensitive data (identifiable or not) | | | | |
| Access/collect/release data that is neither PHI nor sensitive. | | | | |
| Data analysis. | Data is:  identifiable  coded  coded with a confidentiality agreement (attach)  anonymous | | | |

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| Section 3: Acknowledgement by **UF PI** | |
| * As the Principal Investigator (PI) of this project, I certify that I will comply with both the regular responsibilities of being the PI on this project at UF (<http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html>) as well as the additional responsibilities of overseeing the conduct of the unaffiliated investigator listed on this form. * As PI I will:   + develop and follow structured plans for insuring the unaffiliated investigator understands and complies with his/her responsibilities   + promptly communicate all necessary information to the unaffiliated investigator to ensure they are only conducting approved research during active IRB approval, including approved revisions to protocol activities.   + If the unaffiliated investigator will obtain informed consent from subjects, I will ensure the unaffiliated investigator:     - has sufficient knowledge of the protocol and has been appropriately trained on how to seek voluntary informed consent,     - will use the most recently UF IRB approved and stamped informed consent form,     - will only obtain informed consent from subjects who meet eligibility criteria,     - will verify that subjects have capacity to consent or that we are appropriately obtaining consent from the appropriate legally authorized representative,     - will obtain written consent prior to initiating any study activities, and     - provide each subject a copy of the informed consent form.   + verify that the unaffiliated investigator is utilizing the most current UF IRB approved protocol and documents (e.g. stamped informed consent form) for the duration of the study.   + be responsible for securing any information UF IRB needs from the unaffiliated investigator including enrollment data and adverse/reportable events.   + promptly communicate any information that impacts (a) subject welfare or safety, or (b) subject willingness to continue in the project (e.g. serious and unexpected adverse events, unanticipated problems, study suspensions, changes to the informed consent, etc) to both the UF IRB and the unaffiliated investigator. | |
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| Signature of the UF PI | Date |

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| Section 4: Acknowledgement by Unaffiliated Investigator |
| * I certify that I am not affiliated with (a) another university or (b) an institution which requires me to obtain IRB approval from a specific IRB. * I will only engage in the study listed in this document while it is actively approved by the UF IRB. I will not conduct activities prior to IRB approval. If study approval subsequently expires or is suspended/terminated, I will cease all study activities until approval is reobtained. * I will ensure the rights and welfare of each research subject. * I will ensure that the rights and welfare of research subjects take precedence over the goals and requirements of the research. * I will complete any training required by UF and the UF IRB prior to initiating research covered under this Agreement. * If I will seek informed consent from potential subjects, I will:   + use the most recently approved UF IRB approved and stamped informed consent form,   + only enroll subjects who meet eligibility criteria,   + ensure that subjects have capacity to consent or that I only obtain consent from the appropriate legally authorized representative,   + obtain written consent from each subject before initiating any study activities,   + provide each subject a copy of the informed consent form. * I will follow the protocol and not implement any changes without prior approval from the UF PI who will obtain approval from the UF IRB. In the event that a subject’s wellbeing is at risk I may take emergency action and deviate from the protocol, however I will immediately report this to the UF PI who will report it to the UF IRB. * I will communicate and collaborate promptly with the UF PI. In particular, I will promptly provide information needed for continuing review, record keeping, or reporting to the IRB or other oversight entities. * I will promptly report any (a) adverse events or unanticipated problems involving risks to subjects or others, (b) protocol deviations, and (c) regulatory noncompliance to the UF PI who will report them to the UF IRB. * I will retain copies of all study related documents (including signed informed consent forms) according to all applicable regulatory requirements. I will not destroy any study related documents unless the UF PI indicates in writing that it is appropriate to do so. * I will comply with all other national, state, or local laws or regulations that may provide additional protection for human subjects. * I will comply with any additional requirements for conducting research at my place of employment. * I will cooperate with any monitoring oversight by UF, the UF IRB, my place of employment, or applicable regulatory agencies. |

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| Signature of the Unaffiliated Investigator | Date |

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| Section 5: Approved by UF IRB Chair | |
| Print IRB Chair Name: | |
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| Signature of IRB Chair | Date |

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| Section 6: UIA Approved by UF Institutional Official | |
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| Signature of Michael Mahoney  Director, Research Operations & Services | Date |