NON-AFFILIATED INVESTIGATOR AGREEMENT

Name of Non-Affiliated Investigator (hereafter known as "Investigator"):_____

Name of CCC Principal Investigator (hereafter known as "PI"):_____

Name of Institution Providing IRB Oversight: _____

Applicable FederalWide Assurance Number: _____

CCC IRB Study #:_____

Section 1: Research covered under this agreement	
Study Title	
IRB number	
Principal Investigator Name (last, first)	

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 CCC, please explain.	

Section 3: Activities to be performed

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 or procedure. 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

Unaffiliated Investigator Checklist

For each Unaffiliated Investigator:

Note: The request includes a section requiring a statement from the Principal Investigator, describing the proposed Unaffiliated Investigator's role in the research protocol, the Principal Investigator's supervision of the Unaffiliated Investigator, and the reason the Unaffiliated Investigator is needed for the research

Requested Documents:

- ☐ Copy of Unaffiliated Investigator curriculum vitae
- ☐ Copy of Unaffiliated Investigator current license and 1572 Form if applicable
- ☐ Copy of verification of human subjects' protection training
- ☐ Copy of verification of HIPAA training
- ☐ Copy of verification of GCP training
- ☐ Letter of Institutional Support (for Unaffiliated Institutional Investigators)

Section 4: Acknowledgement by **CCC 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 CCC 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 CCC 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 CCC IRB approved protocol and documents (e.g. stamped informed consent form) for the duration of the study.
    - be responsible for securing any information CCC 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 CCC IRB and the unaffiliated investigator.

Signature of the CCC PI	Date

Section 5: 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 CCC 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 CCC and the CCC 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 CCC 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 CCC PI who will obtain approval from the CCC 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 CCC PI who will report it to the CCC IRB.
- I will communicate and collaborate promptly with the CCC 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 CCC PI who will report them to the CCC 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 CCC 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 CCC, the CCC IRB, my place of employment, or applicable regulatory agencies.

Signature of the Unaffiliated Investigator	Date

Protocol-Specific Procedures to be Performed by the Non-Affiliated Investigator:

(1) The above-named Investigator has reviewed *the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research,* the U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46, the Food and Drug Administration (FDA) regulations for the protection of human subjects at 21 CFR 50 (if applicable), the Assurance referenced above, and the relevant institutional policies and procedures for the protection of human subjects.

(2) The Investigator understands and hereby accepts the responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this Agreement.

(3) The Investigator will comply with all other Federal, State, or local laws or regulations that may provide additional protection for human subjects.

(4) The Investigator will abide by all determinations of the CCC IRB designated under the above Assurance and will accept the final authority and decisions of the CCC IRB, including but not limited to directives to terminate participation in designated research activities.

(5) The Investigator will complete any training required by the CCC IRB prior to initiating research covered under this Agreement.

(6) The Investigator will report promptly to the PI who will then report to the CCC IRB proposed changes in the research conducted under this Agreement. The investigator will not initiate changes in the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.

(7) The Investigator will report immediately to the PI who will immediately report to the CCC IRB any unanticipated problems in research covered under this Agreement that involve risks to subjects or others.

(8) The Investigator will seek, document, and maintain records of informed consent from the subject or the subject's legally authorized representative as required under HHS regulations (or other international or national equivalent) and stipulated by the CCC IRB (if applicable).

(9) The Investigator will report any significant new findings to subjects.

(10) The Investigator acknowledges and agrees to cooperate with the PI in CCC's responsibility for initial and continuing review, record keeping, reporting, and certification. The Investigator will provide all information requested by the PI and CCC IRB in a timely fashion.

(11) In conducting research involving FDA-regulated products, the investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 and 812 (if applicable).

(12) The investigator will not enroll subjects in research under this Agreement or perform any protocol specific procedures prior to its review and approval by the CCC IRB.

(13) Emergency medical care may be delivered without IRB review and approval to the extent permitted under applicable Federal regulations and State law. However, such medical care may not be included as part of Federally-supported research.

(14) This Agreement does not preclude the investigator from taking part in research not covered under the Agreement.

(15) The investigator acknowledges that her/his primary responsibility is to safeguard the rights and welfare of research subjects, and that the subjects' rights and welfare must take precedence over the goals and requirements of the research.

Signatures:

Non-Affiliated Investigator:_____ Date:_____

CCC Principal Investigator (PI):_____ Date:_____

CCC Institutional Official:_____ Date:_____

Marcia Cruz-Correa, MD, PhD, AGAF, FASGE
Executive Director
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