**PEPPERDINE UNIVERSITY**

***(School Affiliation)***

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| **RESEARCH CONSULTANT NON-ENGAGEMENT AGREEMENT** |

This Research Consultant Non-Engagement Agreement (this “Agreement”), by and between the \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Consultant”) and \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (the “Sponsor”), is effective as of the \_\_\_\_ day of \_\_\_\_\_\_\_\_\_\_, 20\_\_\_\_ (the “Effective Date”).

WHEREAS, Consultant provides certain research consulting services for Sponsor, as described below (“Services”);

WHEREAS, Consultant will not be provided with any identifiable private information about research subjects in connection with the Services, but that the information will be coded and identifiable directly or indirectly by other members of the research team;

WHEREAS, federal regulations state that if Consultant is obtaining "coded" data for analysis at the consultant's institution, the consultant's institution is not considered "engaged" in human subjects research, if a written agreement unequivocally prohibits release of identifying codes to the consultant;

NOW, THEREFORE, for and in consideration of the agreements, covenants, representations and warranties herein contained, and intending to be legally bound, the parties agree as follows:

1. Services. Consultant shall provide the following research consulting services to the Sponsor for the following research project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(“Services”).

2. Coded Data. Sponsor shall provide Consultant with coded data in order to perform the Services. The coded data shall include a unique patient identification code for each subject.

3. No Identifiable Information. Sponsor represents and warrants that it will not provide, release or otherwise disclose in any way any identifying codes, indicators or any other information that would permit Consultant to identify human subject participants in the research described above. Identifiable information is defined by the HIPAA privacy regulations, 45 CFR §§ 164.502(d), 164.514(a)-(c). Sponsor shall indemnify and hold Consultant harmless for any liability, losses or damages as a result of Sponsor’s breach of this agreement.

4. No IRB Approval Required. Sponsor understands that Consultant does not require review and approval of the Services by its Institutional Review Board because Consultant is not engaged in human subjects research as defined by the federal regulations and is using de-identified information as defined by the HIPAA privacy regulations.

5. Amendment. This Agreement may be amended only by the written agreement of the parties.

6. Governing Law. This Agreement shall be governed and construed in accordance with the laws of the State of California.

**IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be duly executed as of the day and year first above written.

**CONSULTANT** **SPONSOR**

By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­­­\_\_\_\_ By:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_