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| **Applicant:** | **IRBNet #:** |
| **Phone:** | **Email:** |
| **Project Title:** | |

**Instructions:**

* Complete this form to request written documentation from the IRB on whether this research involves human subjects.
* Submit completed form and supporting documentation via IRBNet.
* For more information, review the [**“WORKSHEET: Human Research Determination.”**](https://www.adventhealthresearchinstitute.com/sites/default/files/2019-05/HRP-421%20WORKSHEET%20-%20Human%20Research.pdf)

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| **Section 1:** | **Yes** | **No** |
| 1. Will any information from this research be submitted to the FDA or held for inspection by the FDA? |  |  |
| 1. Will the research involve intervention or interaction with living persons? |  |  |
| 1. Will the research involve accessing/collecting information about living persons?   **IF YES**, please answer:  Will the information include identifiable, private information from which the identity of the subject is or may readily be ascertained by the investigator or associated with the information? |  |  |
| 1. Will the research involve accessing/collecting data via a Limited Data Set?   ***NOTE:*** *Data/material use agreements may need to be implemented even if the data/specimens are only shared internally.* |  |  |
| 1. Are the data coded in a way where a link exists that could allow the data to be re-identified by the investigator or other research team members? |  |  |
| 1. Does this research involve only the secondary analysis of existing data?   If yes, how was existing data obtained? |  |  |

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| **Section 2:** |
| ***Research Aims***   1. Please indicate why the research is being performed, e.g. test a hypothesis, etc. 2. What are the specific aims/goals of the research? |
| ***Background and Significance***   1. What observations or prior scientific findings serve as the basis for this research? 2. Why is it important to conduct the research? |
| ***Research Design and Methods***   1. How will the research be conducted? 2. How will results be analyzed? |
| ***Include any additional supporting documents for IRB review.*** |