THE UNIVERSITY OF ALABAMA AT BIRMINGHAM.

For Internal Use
Date Received: _____
SRC Protocol Number: _____

UAB Department of Medicine

Institutional Review Board- Protocol Oversight Review Form

Date:_____

Title of Project:_____

Name of Principal Investigator (print or type):_____

Signature of Principal Investigator:_____

School: Medicine Department: Medicine

Division:_____

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1) Which IRB will oversee this study?

   *If Other, specify*_____

2) What is the source of funding for the study?

3) Is this protocol/scientific project a clinical trial?

   (A clinical trial is a study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. NIH Definition, Oct 23, 2014.)

4) Has the protocol / scientific project received prior, external scientific review?

   (Examples of prior scientific review include NIH review, NSF review or Industry Sponsorship)

5) Was a recruitment feasibility of the project sample size performed?

   If Yes, please indicate the source of the feasibility

   ☐ I2B2 *(http://www.uab.edu/ccts/researchcommons/research-data-requests)*

   ☐ Internal database ☐ Internal feasibility form

   ☐ Other (please specify)_____

   If Not Applicable, please briefly explain. _____

6) What type of IRB review is being requested?

7) Is this protocol/scientific project related to COVID research?

If Yes, please complete all COVID related questions

a) Which setting does the study take place?

b) What type of COVID population is involved in the study?

c) Will the study require a research team member to be at the bedside of COVID + patients?

d) Indicate the team member.

e) Which of the following does the study work with?

f) Is the team member properly trained in COVID + precautions?

g) Do you have PPE for the study?

If Not, how much is needed?

The DOM Scientific Review Committee has reviewed the proposed research and concluded that the following apply:

- The research is scientifically valid and is likely to answer the scientific question;
- The researcher and the study team are qualified and/or credentialed to conduct the procedures proposed;
- The researcher has identified sufficient resources in terms of experienced research personnel, facilities, and availability of medical or psychological services that may be necessary as a consequence of participation in the research to protect the research participants;
- The researcher and research team has designed a statistical rigorous study that addresses, when appropriate, sample size and power, recruitment feasibility, data management, and analytic strategy.

Department of Medicine Scientific Review Committee approval of this project is indicated through IRAP with an approval in the IRAP submission routing and attachment of the DOM PORF. This document will not be signed by the DOM SRC.