05/26/2021

RE: C.A.R.R.I.E. Submission ID #: **2021-451**
Protocol Title: **Medical Imaging Stewardship and Healthcare Savings: Utilization of Age Adjusted D-dimer to Rule Out Acute Pulmonary Embolism.**

Dear **Brian Helmly, M.D.**

YOU ARE CAUTIONED TO READ THIS LETTER CAREFULLY AND IN ITS ENTIRETY. IT CONTAINS IMPORTANT INFORMATION ABOUT THE SUBMITTED RESEARCH PROPOSAL AND THE RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR. NONCOMPLIANCE WITH THESE REQUIREMENTS MAY RESULT IN DISCIPLINARY ACTION, PREVENTION OF PUBLICATION, AND IN SPECIFIC CIRCUMSTANCES, BEING REPORTED TO THE FEDERAL AUTHORITIES PER REGULATIONS.

What this determination IS NOT:

- This determination IS NOT an approval to do your study. Your local Institution gives the final approval to conduct the study, maintains oversight over the activity and can decline to participate in or support this research for its own reasons at any time**.** *If you have questions about additional Institutional approvals, contact your supervisor.*
- This determination DOES NOT override the decision(s) of a convened IRB that has reviewed this proposal. It also DOES NOT alleviate you from any local policies in making IRB-Exempt determinations. If you have a local policy that requires this decision must be made by an IRB (or other local IRB-Exempt determination process), then you must follow that procedure but you are free to share this information with them.
- This determination IS NOT a clearance to publish your study results or release any data for research purposes. The Institution has other policies to follow concerning the publication of study results and release of data.

What this determination IS:

Based on the information provided and attested as true, the research plan described does not require IRB oversight. This is because you are either a) not engaging in research with human subjects as defined by federal regulations; b) engaging in research with human subjects deemed excluded from IRB oversight per 45CFR46.102(l) OR c) engaging in research with sufficient human subject protections in the design to meet one or more IRB exemption criteria set forth in 45CFR46.104.

While your research activity has been classified as not requiring IRB oversight, you must still adhere to the submitted research plan, all institutional policies and the principles of research ethics as set forth in The Belmont Report to maintain this status. **All other required permissions and reporting obligations of your Institution apply and the Institution reserves the right to contact you in the future to monitor its progress and/or to verify that there have been no changes to this research plan.**

Making Changes To Your Research Plan:

If you wish to change or modify the research activity in a way that alters the answers herein the original submission, this exempt determination is subject to change. Therefore, you are required to resubmit for an updated determination before implementing the proposed modification (unless the change is necessary to eliminate an immediate hazard to subjects, then notification is due within 5 calendar days). This is not limited to modifying the written protocol but all other supporting activity affiliated with the research, such as adding advertisements, identifiable data fields, questionnaires etc.

Reporting Requirements OF IRB Exempt Activities:

Although not under the supervision of an IRB, you still have Institutional obligations to report certain events and circumstances. *With the exception of notification of an audit/inspection/inquiry/notification from a government agency (which is to be reported immediately),* any of the occurrences listed below are expected to be reported to your Institution within five (5) business days of your becoming aware.

- **Unanticipated Problems Involving Risks To Subjects Or Others**
    - **Adverse events** may occur but are also considered reportable unanticipated problems for reporting purposes if they are 1) Serious; 2) Unexpected; and 3) Related (or probably related) to the research. For the avoidance of doubt, an event is automatically deemed "serious" if it results in i) death or a life-threatening condition (i.e. places the subject at immediate risk of death from the event as it occurred); ii) an inpatient hospitalization or prolongation of an existing hospitalization; iii) a persistent or significant disability/incapacity; iv) a congenital anomaly/birth defect; OR v) an event that requires intervention intended to prevent one of the above.
    - **Other unanticipated problems** that are not adverse events (i.e. problems associated with a medical device under investigation, breach of subject confidentiality such as theft or loss of study data etc.) must be reported if they suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.
- **Deviations from the approved research plan or regulations.**
- **Unresolved subject complaints.**

- **Suspensions or termination** of the research activity by the study sponsor or your institution.
- **Notification of audit/inspection or other inquiry/notification by a government agency.**

Note that external research sponsors may also have duplicate and/or additional reporting requirements and timeframes. Failure to timely report on any of the following in a timely manner is a serious violation of research ethics and regulations and such noncompliance may be required by regulation to be reported to federal authorities. *All other Institutional reporting obligations apply.*

Conclusion

If you have any questions or concerns about this determination, believe it was made in error, or have other general questions about research regulations and ethics, please contact the corporate office at irb@HCAhealthcare.com

Thank you and good luck with your research project.

This was a system generated letter by C.A.R.R.I.E. (**C**entralized **A**lgorithms for **R**esearch **R**ules on **I**RB **E**xemption).