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December 9, 2020

ACR cIRB Review of ACR COVID-19 Imaging Research Registry (CIRR) Project

**PROJECT:** American College of Radiology – ACR COVID-19 Imaging Research Registry (CIRR) (Pro00043960)

**CURRENT PROTOCOL VERSION:** Protocol Version 3.3 (Dated 5Nov2020)

**DECISION DATE:** 27May2020

**DECISION:** Exempt Determination Granted

Dear Potential Data Contributing Site,

Using the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(4), American College of Radiology received an exemption determination from the Advarra Institutional Review Board for the *COVID-19 Imaging Research Registry (CIRR)*. This project will be exempt from IRB oversight. This project is not subject to requirements for continuing review.

The IRB granted this exemption with an understanding of the following:

1. The research project will only be conducted as submitted and presented to the IRB, without additional change in design or scope.
2. Should the nature of the research project change, or any aspect of the study change such that the nature of the study no longer meets the criteria found in 45 CFR 46.104(d)(4), ACR will resubmit revised materials for IRB review.
3. It is the responsibility of each investigator to ensure that the project meets the ethical standards of the institution. Specifically, the research involves no more than minimal risk to participants, the selection of subject is equitable, and there are adequate provisions to maintain the confidentiality of any identifiable data collected.

Protocol Version 3.3 includes the following updates. Because Advarra’s initial determination was made based on correspondence with ACR asserting that there would be collection of PHI in the form of a limited dataset, the changes, outlined below, do not change the design, scope, or nature of the project and, therefore, the original exempt determination by the IRB is still applicable.

**Changes to Protocol Version 3.3**

Section	Change
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Risk\Benefit Assessment	Clarified language in paragraph 1 of this section by removing “in lieu of real medical record numbers” and corrected a typo where the word “date” should have appeared in place of “data.”
Risk\Benefit Assessment	Clarified in paragraph 3 of this section that only a HIPAA-defined limited dataset will be collected by ACR.
Study Design and Procedures: Privacy and confidentiality	Clarified that only a HIPAA-defined limited dataset will be collected by ACR and that no identifiable data will be shared outside ACR.
Study Design and Procedures: Informed consent	Clarified in paragraph 2 of this section that the registry comprises a limited dataset.

If you have any questions or concerns, please contact the ACR COVID-19 Imaging Research Registry team at [CIRR@acr.org](mailto:CIRR@acr.org).

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