Northwestern | RESEARCH

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APPROVAL OF NEW STUDY

DATE: April 23, 2021

TO: Dr. Michael Ison
FROM: Office of the IRB

DETERMINATION DATE: 4/23/2021
APPROVAL DATE: 4/23/2021

The Northwestern University IRB reviewed and approved the submission described below:

Type of Submission:	Initial Study
Review Level:	Expedited
Expedited Category:	- (5) Data, documents, records, or specimens
Title of Study:	COVID-19 Lung Transplant International Registry
Principal Investigator:	Michael Ison
IRB ID:	STU00214797
Funding Source:	Name: Northwestern University (NU)
Grant ID:	
IND, IDE, or HDE:	None
Documents Reviewed:	• Aslam GCP Training, Category: Training Documents; • Aslam Biomed CITI Training, Category: Training Documents; • Weder CITI Training, Category: Training Documents; • Protocol, Category: IRB Protocol;
Special Determination(s):	Waiver of HIPAA authorization; Waiver/alteration of the consent process;
Unaffiliated External Site(s) that rely on NU IRB:	None
Clinical Trial:	No

In conducting this study, you are required to follow the requirements listed in the Northwestern University (NU) Investigator Manual (HRP-103), which can be found by navigating to the policy section of the IRB website. Additionally, as Principal Investigator (PI) of this research study, you are expected to adhere to the investigator responsibilities outlined in the "What are my obligations as Investigator in order to conduct Human Research" section of the Investigator Manual (HRP-103).

If your study is a clinical trial, there are additional requirements including trial registration and results reporting on ClinicalTrials.gov. Federally-funded clinical trials are also required to post one IRB approved consent form, used during enrollment, on a publicly available federal website such as ClinicalTrials.gov. Please visit the clinical trials page on the IRB website for more information. If you would like an account created or need other assistance with ClinicalTrials.gov, please email clinicaltrials.gov@northwestern.edu.

An annual continuing review is not required for this project. The study team must still submit: modifications for project changes; RNIs (reportable new information); and a Continuing Review to close the project when it ends (for guidance on when a project can be closed, see GUIDANCE on Study Closure – HRP-1901.

All Non-Exempt Human Research, including studies without a continuing review, are subject to routine IRB post-approval monitoring as outlined in the "What are my obligations as Investigator in order to conduct Human Research" section of the Investigator Manual (HRP-103) and the "Reporting Concerns" section of the Human Research Protection Program Compliance (HRPP).

NU IRB approval does not constitute or guarantee institutional approval and/or support. Investigators and study team members must comply with all applicable federal, state, and local laws, as well as NU Policies and Procedures, which may include obtaining approval for your research activities from other individuals or entities.

For IRB-related questions, please consult the NU IRB website at http://irb.northwestern.edu. For general research questions, please consult the NU Office for Research website at www.research.northwestern.edu.

Additionally, please note that the analyst who you worked with during the initial review and approval of your study is not the analyst that is responsible for the review of any subsequent modifications, continuing reviews, or RNIs. As such, please direct any further questions about modifications, continuing reviews, or RNIs to the analyst assigned to the subsequent submission.