



Multi-Center Case Report Database For Cases Of COVID-19 In Solid Organ Transplant Recipients

April 3, 2020

Dear Colleagues,

The University of Washington has created a multi-center **case report database for cases of COVID-19 in solid organ transplant** recipients. We welcome case reports (submitted via our electronic case report form) of pediatric and adult patients around the world.

The electronic case report form is available at: <https://redcap.iths.org/surveys/?s=NL3NPKRWYT>

For additional information or to view a PDF version of the case report questions, visit our regularly updated public google drive at: <https://drive.google.com/drive/folders/1JDtVagiFKIy9AHjMypgVjO2CzoQzoa1?usp=sharing>

This study has been approved by the University of Washington Institutional Review Board. The UW IRB has determined that other sites providing **non-HIPAA** clinical data to this project are not engaged in human subjects research and **do NOT need any form of local IRB review**. The IRB application and IRB approval letter are stored in the shared google drive.

For sites that anticipate contributing a large number of cases, we have created the **option of entering a site-specific ID** for each case report. Centers that choose to do this retain the key to these ID codes at their site and do not transmit it to U.W. For centers contributing a large volume of cases, these codes ensure that follow-up reporting is accurate. Centers that choose this option need local IRB approval. This does not affect the IRB requirements of contributors who choose not to use a site-specific ID system.

We encourage you to share this invitation with your colleagues.

Thank you very much for your participation, and best wishes in this busy time. Please contact Olivia Kates at okates@uw.edu with any questions.

Sincerely yours,

Olivia Kates, MD, Senior Fellow
Cindy Fisher, MD, Assistant Professor
Erika Lease, MD, Associate Professor
Ajit P. Limaye, MD, Professor
University of Washington, Seattle

Frequently Asked Questions:

Thank you for your interest in contributing to our prospective multicenter observational study of solid organ transplant recipients with SARS-CoV-2 infection or COVID-19.

Your primary contact for any questions or concerns should be the study principal investigator, Olivia Kates. Olivia is available by email at okates@uw.edu.



Is this study IRB approved?

The study has been approved by the University of Washington IRB. The University of Washington has determined that contributors at other sites do not need local IRB approval to add data to this study UNLESS YOU ARE ADDING A SITE-SPECIFIC ID CODE (optional), however you may wish to communicate directly with your local IRB. Olivia Kates is available to assist with any regulatory concerns.

Requesting a Data Use Agreement (DUA)

The data included in the electronic case report include no HIPAA identifiers. These data do not require a data use agreement (https://privacyruleandresearch.nih.gov/pr_08.asp). If your institution will require a data use agreement despite this, please contact Olivia Kates for contact and signatory information. A sample agreement is stored in this drive.

Who can participate?

Contributors around the world may participate. Case reports may be submitted about any adult or pediatric patient with a history of solid organ transplantation at any time remote or recent in any country. The electronic case report form is in English. Currently, translation services are not available.

Please check with your colleagues to be sure that only one initial case report form is submitted for each patient. Consider using optional site-specific ID codes to track your own patients.

How do I contribute?

Only electronic case reports can be accepted. Please use the PDF version of the case report form to familiarize yourself with the data collection process or to allow multiple contributors to collect data. If you collect data using a paper version of the case report form, please then enter that data using the online electronic case report form located at <https://redcap.iths.org/surveys/?s=NL3NPKRWYT>. If you are unable to use the online case report form for any reason, please contact Olivia Kates as soon as possible.

Uncertain outcomes

For many patients, complete data about their clinical course, treatment, or outcomes will not be available at the time of initial case report entry. Please complete all sections of the form with the most up to date information available at that moment. A follow-up form will allow you to modify, update, or add to your initial report.

Modifications to the case report form

We are able to add or modify form comments that provide additional notes about the questions if you discover an error or inconsistency. In very rare instances, we may be able to add a response choice to an existing question. Unfortunately, we are not able to add any new questions to the current form, but you may suggest questions for the follow-up form via email.

If you have any additional information that you would like to share about a patient, please use the unlimited free text entry box at the end of the form.

If you have any questions about the content of the form, please contact Olivia Kates.

Can I access the data? Can I publish using the data?

Also as a condition of our IRB approval and various data use agreements, currently we are not able to directly share access to the database in production. Contributors “own” all of their own data, and you will receive a copy of your electronic case report form once it is submitted. You are welcome to publish your experience, but we ask that you **please let us know if your patients will be part of another published study**. This is important for academic integrity, and we will acknowledge this when our final dataset is analyzed.



When data collection is complete, we hope to be able to share our complete de-indexed dataset with contributors for your own independent analyses. Discussions regarding how to do this will necessarily include contributors and our IRB.

I want to track my patients with a site-specific ID

Participating sites may develop a site-specific identifier code for each patient and include this in their report. ID codes should not be derived from any patient identifiers such as name or date of birth. Sites should retain the key to their site-specific identifiers and should not share the key with the University of Washington. If you are using a site-specific ID system, this WILL require local IRB review and approval. When data collection is complete, we will be able to return a dataset of records with your site ID codes included, allowing you to identify the data at your site if desired.

- Site-specific IDs should not include or be derived from patient identifiers
- Sites should retain a key to their site-specific ID's, the key should not be transmitted to U.W.
- Although we have advised participants that the study does not require local IRB approval when no identifiers are submitted, if you intend to track site-specific identifiers you will need the approval of your local IRB. If you have already started an IRB, this may require a modification. (I am happy to help with this!)
- Site specific IDs are optional! If you do not think this will be useful to you as a participant in our study, you do not need to go through these additional steps.
- Data will still be entered using the same electronic case report form

Will I be an author on the finished manuscript?

We are very eager to reward contributors for giving their time to our study. We plan to contact those of you who submit completed cases to discuss authorship. Depending on how many different contributors participate, we anticipate that we will be able to invite up to 20 contributors, based on the number of completed submissions by each contributor, to review our manuscript and be recognized as authors. We understand that many of you are working in teams at your institutions, and we will be happy to discuss how best to recognize this when we prepare our manuscript. We are not able to guarantee authorship of secondary manuscripts, particularly if the full dataset is shared with all contributors.