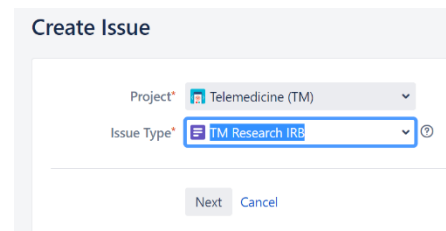


Guidance for Telemedicine Related Research

Last Updated 6.30.21

Since March of 2020, we have seen a rapid increase in the number of research studies involving delivery of healthcare services through telemedicine or other digital modalities. The Johns Hopkins Office of Telemedicine manages the coordination and strategic deployment of all Johns Hopkins Medicine programs that deliver clinical services using electronic communications and technology and works closely with a number of groups to ensure high quality care and legal and regulatory compliance.

These guidelines take effect as of March 1st 2021. If your new research project or change in research fit the criteria below, please submit a [Telemedicine Research Project Request Form](#) to the Office of Telemedicine to receive guidance regarding technical and regulatory/compliance issues that may impact your research project. If you have an existing research project prior to March 2021 and have questions, please contact [JHM telemedicine@jhu.edu](mailto:JHM_telemedicine@jhu.edu).



The screenshot shows a 'Create Issue' form with two dropdown menus. The first dropdown, labeled 'Project*', is set to 'Telemedicine (TM)'. The second dropdown, labeled 'Issue Type*', is set to 'TM Research IRB'. Below the dropdowns are 'Next' and 'Cancel' buttons.

Research projects in the following categories should be [submitted](#) to the Office of Telemedicine:

- Uses telemedicine beyond ambulatory video visits, in a way that not yet part of routine practice at Hopkins (e.g. eVisits, eConsults, teleconsults, interprofessional consultation, remote patient monitoring).
- Uses an outside clinical telemedicine tool/vendor that is new to the institution or a new telemedicine-related Epic integration/build.
- Involves providing clinical care for a patient who is located at another healthcare facility (e.g. hospital, skilled nursing facility, long term care facility).
- Involves providing clinical care for a patient across state lines.
- Plans to bill any telemedicine codes beyond standard ambulatory billing codes.

Projects including video or audio recording of clinical care provided by telemedicine should follow the processes of the IROC (Imaging and Recording Oversight Committee).

NOTE: Clinical care is defined as the provision of healthcare by a healthcare professional operating under the scope of their professional license. Per JHM leadership announcement May 2020, all international projects are currently on hold excluding projects currently in progress.

Guidance for Using Telemedicine to Conduct Clinical Research Visits

In general, if telemedicine is being used to conduct clinical research visits and your project does not fit into the categories listed above, your project can proceed with usual IRB approval and does not need to be additionally reviewed by the Office of Telemedicine.

The guidance below provides information for research teams seeking to use telemedicine to conduct clinical research visits as part of IRB approved research projects. Study teams seeking to incorporate the use of telemedicine into their research as part of the resumption of in-person activities/new enrollment must obtain IRB approval of the plan to use telemedicine. Study teams wishing to utilize telemedicine visits as an alternative to in-person visits should include flexibilities in their protocol to allow for study visits to occur in-person or via telemedicine, where appropriate. Additionally the informed consent form for research participants must specify when visits/study procedures may occur via telemedicine.

This guidance has been developed for studies where PRA review is required that utilize Epic for scheduling and documentation. It is anticipated that providers seeking to use telemedicine for clinical research visits will already have the roles/permissions needed to perform intake, scheduling, registration, and care via Epic.

Education Materials – For Study Teams:

- [Telemedicine Educational Slides](#)
- [Telemedicine Tip Sheets](#)
- [Telemedicine Intranet Site](#)
- [Cisco WebEx Tip Sheet](#)

Education Materials – For Patients:

- [Johns Hopkins Telemedicine Internet](#) (Telemedicine general information)
- [Video and Telephone Visit Instructions](#) (Tip sheets for preparing for visit)

Telemedicine Requirements:

- All clinical research participants must complete the [Telemedicine Acknowledgement](#) form in accordance with standard clinical practice before beginning a clinical research visit.
 - The form may be completed in person or via mail or using the remote process detailed below.
 - Study team members may access the form from Epic Forms on Demand, print, obtain signature and upload it to the media tab, storing it under Telemedicine Consent
 - For mailed forms, please review with the research participant via video. The participant should sign the form on video and may email/text image of the signed form or send a hardcopy of the form through the mail. The video should not be recorded unless it is part of the approved process.
 - In cases where a signature cannot be obtained, the following remote process is permitted:
 - Review the telemedicine acknowledgement with patient via video or phone
 - A second Johns Hopkins employee [the witness] must join the video or phone call and confirm that the participant has agreed to the use of telemedicine.

- The study team member then notes on the form that consent was obtained and the method used [e.g. phone or video], and documents in the note the name of the witness who was present to affirm the participant's agreement.
 - For research participants who utilize MyChart, the acknowledgement may be transmitted to the participant through MyChart eCheckIn. Research participants will be prompted to eSign the form and it will be auto filed.
- Research Teams must ensure providers have licensure in states where research participants are consented
 - If additional licensure (permanent or temporary) is obtained, send a confirmation email to bstroh1@jhmi.edu in order for the license to file in MSOW and Epic
 - During the COVID crisis there are flexibilities for licensing by state, see these [Legal FAQs](#)
- Research Teams must ensure providers are credentialed in facilities where participating subjects are located (if applicable)
 - If patient is within a facility (hospital, nursing home), the provider must be credentialed at that facility
 - During the COVID crisis, there are flexibilities within the JHHS system for credentialing, see these [Legal FAQs](#)

Billing:

- If billable encounters are covered by a grant, pre-consultation with Liza Rodriguez from the Office of Clinical Research Billing Compliance (CRBC) is required.
- Time tracking is needed for all telemedicine visits.
- The charges related to research participants encounters will be reviewed by CRBC staff and routed as appropriate to the research account or to the participant/insurance account.
- Charges billable to insurance or as self-pay will follow all other workflows and charge router rules in place for telemedicine visits.

Tips for Successful use of Telemedicine for Clinical Research Visits:

- Ensure that staff/providers have Epic access with applicable roles/permissions
 - Contact Louise Welch at lwelch5@jhu.edu if additional roles/permissions are needed
- Ensure participants/subjects have Epic MRN and MyChart (optional)
 - [MyChart Instant Activation tip sheet](#)
- Ensure that participants have all applicable software available and downloaded
- Ensure that participants have signed the telemedicine acknowledgement form
- Upload signed Telemedicine Acknowledgement form into Epic > Media> Telemedicine Consent
- Schedule remote visits or phone calls using the Video/Telephone-General visit type in Epic
- Join the visit
 - [Scheduled Visit](#) (for patients using MyChart links)
 - [On-the-Fly Visit](#) (for patients using MyChart links)
 - [Scheduled or non-scheduled](#) visits (for patients using Zoom)
- In your documentation, use appropriate Epic phrases

- .TMVISIT for video visits
- .TMPHONE for telephone visits
- Enter in billing codes as per usual, utilize dummy codes if approved by Liza Rodriguez

Tips for Reporting:

- Utilize the [Telemedicine Dashboard](#) to track volume
- Utilize the JHM Telemedicine Encounter Volume Adhoc report within Epic to audit volume capture
- Utilize the Telemedicine Audit report within Epic to track/correct compliance

Helpful Contacts:

Office of Telemedicine general questions can be sent to:

Legal questions should be sent to: TelemedicineLegal@jhmi.edu

Billing questions should be sent to: CLINIRESBILLING@exchange.johnshopkins.edu

IRB questions should be sent to: jhmeirb@jhmi.edu