**GUIDANCE: Study Monitoring and auditing at Washington State University during the Covid-19 pandemic:**

WSU Guidance on study monitoring and auditing is consistent with the [University of Washington HSD guidance](https://www.hsd.washington.edu) from April 30, 2020. These activities are subject to the mandatory temporary halt to in-person research activities as well as any additional restrictions placed by the facility where the activities will occur. Monitoring/audit visits should be postponed or rescheduled where possible. Alternatively, the activities may be conducted remotely with the following conditions:

- Access to research data must comply with the data security requirements and data storage locations outlined in the IRB-approved application. Consult your IRB application, if existing data security requirements prevent remote access, follow WSU IT policy and consult with your Departmental IT or Area Technology Officer (ATO) and then submit an amendment to the IRB.
- WSU currently recognizes several HIPAA compliant platforms including Zoom and Epic, please consult with your departmental IT and/or the IRB/HRPP to ensure that your preferred method is acceptable for this use.
- Consider reviewing the following publication to develop a restricted access workflow for monitoring: [Clin Res (Alex). Author manuscript; available in PMC 2019 January 03](https://www.clinicalresearchjournal.com/article/S1054-3813(18)30238-9/abstract).
- Access to research data must comply with any commitments made to subjects in the consent form.
- Direct access to PHI by a site monitor or auditor (i.e. monitor has direct access to the electronic medical record) must be approved in compliance with WSU data security policies. For PHI maintained by non-WSU entities, contact that institution for guidance on how to obtain remote access.
- Verify the identity of the monitor/auditor before providing access. This is no different than asking a monitor to present his/her ID when they show up for an in-person visit.
- Limit access to read-only and for the minimum time necessary to complete the visit.
- Ensure data cannot be copied or downloaded without authorization or, enable any audit features to ensure you are aware if an unauthorized download occurs.

**Additional guidance on remote monitoring and auditing, HIPAA compliance and telehealth during the Covid-19 pandemic. (Source: Advarra.com)**

The FDA recognizes that monitors may not be able to access the trial sites for on-site visits in a timely manner during the COVID-19 pandemic. Sponsors should work to find alternative approaches to maintain trial participant safety and trial data quality and
integrity, such as enhanced central monitoring, telephone contact with the sites to review study procedures, trial participant status, and study progress, or remote monitoring of individual enrolled trial participants, where appropriate and feasible. FDA recognizes that delays in on-site monitoring may result in delayed identification of GCP non-compliance (including major protocol deviations) at the clinical trial site(s) (including protocol deviations not due to the impact of COVID-19). Sponsors should carefully document situations where monitors were unable to access, or had to delay, monitoring of a clinical site.

Sponsors/monitors should also include in their documentation of protocol deviations or other GCP non-compliance issues identified at clinical sites whether delayed identification was due to postponed monitoring. FDA recognizes that unique situations at clinical sites will occur due to COVID-19 control measures and will consider these circumstances when evaluating inspectional observations.

FDA also recognizes that sponsors may not have remote access to electronic health records maintained by hospitals, universities, and other institutions because of data privacy and security concerns as well as technological challenges. Sponsors should consider risk-based approaches to monitoring using the study information format (i.e., electronic, paper, or combination of electronic and paper), tools, and other resources available to them.

Consider the following approach for conducting remote monitoring visits:

- At the site, establish the use of a HIPAA compliant tool (e.g. Dropbox Business, EPIC restricted access account, etc.) to provide access to source materials.
- Add the source materials and provide the monitor specific access to only the source materials needed.
- Notify the monitor when the materials are ready for review.
- Establish a limited time frame for when the materials will be available.
- Promptly remove the monitor’s access at the end of that time frame, and delete source materials if appropriate.

For the purpose of HIPAA, the HHS Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency waives penalties for noncompliance with HIPAA. OCR will exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered healthcare providers in
connection with the **good faith provision of telehealth** during the COVID-19 nationwide public health emergency. This notification is effective immediately. The OCR guidance Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency identifies the following popular video chat applications that may be used to help provide telehealth visits during the COVID-19 public health emergency:

- Apple FaceTime
- Facebook Messenger video chat
- Google Hangouts video
- Skype

Providers are encouraged to notify patients that these third-party applications potentially introduce privacy risks. Providers should enable all available encryption and privacy modes when using such applications.

The following applications should not be used in the provision of telehealth by covered healthcare providers:

- Facebook Live
- Twitch
- TikTok
- Similar video communication applications that are public facing

Vendors that represent that they provide HIPAA compliant video communication products and that they will enter into a HIPAA business associate agreement (BAA) include:

- Skype for Business
- Updox
- VSee
- Zoom for Healthcare
- Doxy.me
- Google G Suite Hangouts Meet
For more guidance related to the conduct of human subjects research during the Covid-19 pandemic, please visit: https://www.advarra.com/coronavirus-guidance/#remote-monitoring-visits

https://wsu.edu/covid-19/2020/03/18/immediate-modification-of-research-practices-to-address-covid-19/

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