

CCR Supplemental Guidance for Use of NIH Microsoft SharePoint

September 2024

To share source research records (e.g., participant diary) not in CRIS, pharmacy records and/or regulatory files, the secure file sharing platform NIH SharePoint must be used. NIH SharePoint will typically be used for industry-sponsored studies, CTEP-sponsored studies and Cancer Network-sponsored studies.

Note: The sponsor may have an existing file-sharing application to upload these documents and that should be used at the sponsor's request.

Access to NIH SharePoint by external collaborators

External collaborators must register their account via the Microsoft Authenticator App to be able to access NIH SharePoint. This allows the use of 2-factor authentication, a requirement for NIH file sharing systems. If this is the first visit for a monitor, the Office of Education and Compliance (OEC) will email [instructions](#) to the monitor the week prior to the visit, as well as a link to the NCI SharePoint Test folder so the app can be set up prior to the visit.

On the morning of the visit, the monitor will get an email invitation to the copy of the electronic regulatory file on SharePoint.

NIH SharePoint account

The Office of Education and Compliance has a secure file-sharing application via the NIH SharePoint system. Each monitor can be given access to a particular file on the system as a "Viewer only." The entire regulatory file can be downloaded there, as well as any research "paper" records that have been scanned and pharmacy documents (e.g., DARFs). At least two weeks prior to the visit, please email the CCR OEC mailbox (in Global) with information (protocol number, date(s) of visit, monitor name, monitor email) about upcoming monitoring visits. The CCR OEC staff will work with your PSO manager to ensure the regulatory file is up-to-date and ready to be downloaded.

At least one week prior to the visit, please send any scanned paper research records to Armine Tumasyan and Deb Grady via encrypted email for uploading into NIH SharePoint.

Please note: Monitor access to NIH SharePoint should be limited to the dates of the visit. However, access can be briefly extended on a case-by-case basis as needed and in consultation with the PSO Manager.