

## CCR Supplemental Guidance for Use of NIH Box

May 2022

To share source research records (e.g., participant diary) not in CRIS, pharmacy records and/or regulatory files, the secure file sharing platform NIH Box must be used. NIH Box 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.

### NIH Box account

The Office of Education and Compliance has a secure file-sharing application via the NIH Box 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). Please email the CCR OEC mailbox (in Global) to use this system. 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 Box.

Please note: Monitor access to NIH BOX 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.