Cloud Storage Change Procedures

Background

Due to <u>recent changes</u>, unlimited cloud storage in CyBox will not be available to the Iowa State University (ISU) community after June 30, 2021. Many researchers store human subjects research data and related project files on CyBox, which may be affected by storage limits. This document describes how researchers should handle changes to IRB-approved cloud storage plans resulting from <u>Project: Storage@ISU</u>.

IRB Approval for Use of ISU-Supported Cloud Storage

On January 19, 2021, the convened IRB granted approval for interchangeable use of <u>ISU-supported</u> cloud storage software, including CyBox, Microsoft OneDrive, or Google Drive when:

- o software is accessed using *iastate.edu* credentials (private, non-ISU accounts are not allowable),¹ and
- o appropriate security settings and access controls are employed, and
- o all privacy/confidentiality protections specified in the approved IRB protocol remain in place.

Limitations

This approval applies only to IRB protocols reviewed by the Iowa State IRB. The Iowa State IRB does not have the authority to authorize changes to protocols under the oversight of an external (non-ISU IRB). Nor does the Iowa State IRB have the authority to authorize changes to grants, contracts, or data use/transfer agreements. Researchers must adhere to the data security plans (which may specify use of CyBox) outlined in the contract/agreement unless and until the agreement is revised or it is determined that revision is not necessary. For additional information pertaining to these and other circumstances, see the "Special Situations" section below.

Guidance

Modifying IRB-Approved Protocols and Informed Consent Materials

Federal regulations and IRB policy require IRB review before changes to approved research are initiated. As noted above, the IRB approved interchangeable use of ISU-supported cloud storage options. Therefore, researchers may continue using CyBox or switch to ISU-supported versions of Microsoft OneDrive or Google Drive *without submitting modification applications for IRB review*, unless informed consent materials require revision.

¹ Iowa State IT Security may permit exceptions in some instances. Use of private non-ISU cloud software accounts is NOT included in the IRB's January 19, 2021 approval. To obtain IRB approval to use non-ISU accounts, researchers must submit a modification application describing the change and provide documentation of the exception from IT Security.

Informed consent forms that reference CyBox by name should be revised if CyBox will not be used as described. The IRB recommends using general terminology in lieu of software names in consent forms (e.g., "ISU-supported secure cloud storage").

For non-exempt research, revisions to informed consent forms must receive IRB approval before revised forms are used with participants. Modification applications can be processed quickly if the *only* change is revising reference(s) to CyBox in consent forms.

Informing previously enrolled participants of the cloud storage software change (i.e., "re-consenting") is generally not required.

Special Situations

Data governed by contracts, MOU's, data use/transfer agreements, data management plans, etc.

IRB approval for interchangeable use of ISU-supported cloud storage applies only to IRB protocols. Contracts, data use/transfer agreements, data management plans, etc. that specify CyBox use may require revision before transferring data to another storage software. Researchers should contact the entity who approved the contract/agreement/plan on behalf of Iowa State for guidance.

NIJ Privacy Certificates

Research supported by the National Institutes of Justice (NIJ) is typically covered by a Privacy Certificate, which includes the researcher's description of project-specific confidentiality and privacy protections. Researchers making changes to cloud storage plans should update the content of Privacy Certificates if needed. Revised Privacy Certificates must be submitted to the applicable NIJ Program Officer.

External Reliance Agreements

The IRB's approval for interchangeable use of ISU-supported cloud storage software does not apply to research under oversight by a non-lowa State IRB. Researchers who plan to transition from using CyBox to another storage option should consult with the Principal Investigator at the site of the reviewing IRB for guidance on obtaining approval of this change.

Resources

<u>Project: Storage@ISU website</u> – details, timeline, and tools to support transitioning from CyBox to Microsoft OneDrive or Google Drive.

Knowledge Base: Storage – information about cloud storage options

Document History

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