



Institutional Review Board
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Standard Operating Procedures for Research Involving Human Subjects Data Storage in BOX and eRegulatory Storage in BOX

Recommendation to use BOX for electronic storage of study materials (rather than stored on a specific piece of hardware). Allows for flexibility and secure sharing of data with research team and will the IRB and IRB Audit Committees, as needed.

Responsibilities for Electronic Research Data and eRegulatory Binder

A Pacific University faculty member is responsible for studies conducted at Pacific University under the IRB's oversight, even student projects. As the responsible party for the research and for all interactions with the IRB, a faculty member must be the Principal Investigator. The PI/faculty member is responsible for ensuring the research is conducting according to all federal, state, and local regulations, adheres to Pacific University policies, and is conducting according to the approved protocol.

A Pacific University faculty member, the PI, is responsible for ensuring appropriate electronic storage of study materials and the eRegulatory Binder. For study data that is not already housed in a particular system (clinic data, patient data, etc.), the IRB recommends using secure folders in BOX to house these documents. The IRB has provided recommendations for structuring your electronic files that follows the structure of the Regulatory Binder checklist and has provided step-by-step instructions for establishing these folders in BOX in such a way to ensure that all privacy protections are met.

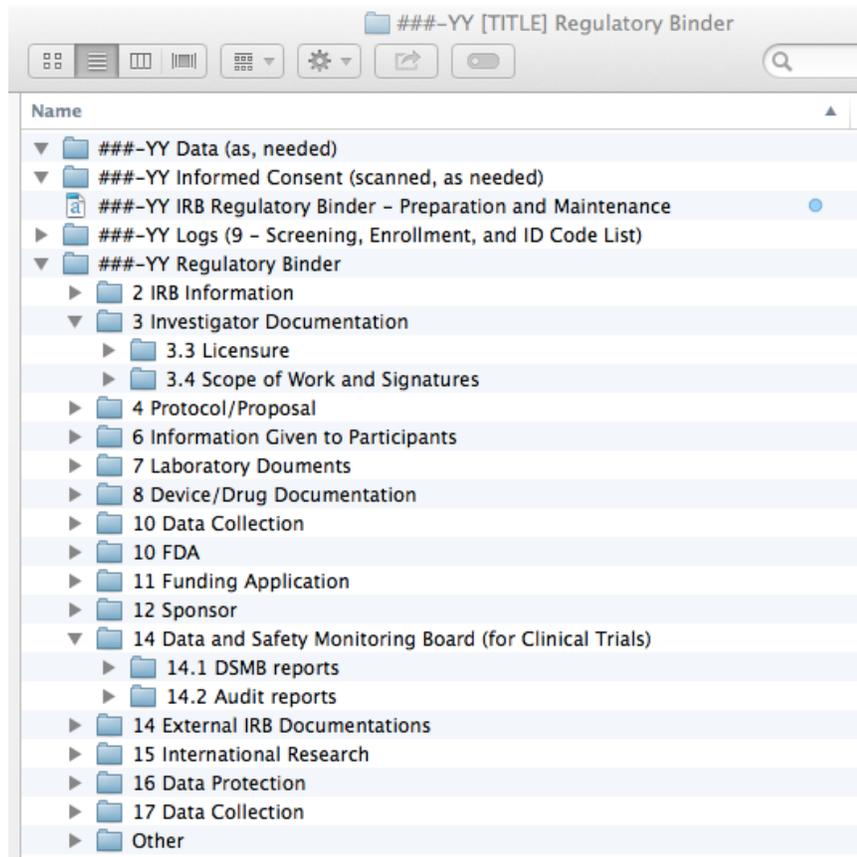
For general use questions about BOX, please refer to the Technology Helpdesk Portal for articles on how to use features in BOX.

The Regulatory Binder is established immediately following approval by the IRB.

Creating Human Subjects Research Folders and an eRegulatory Binder in BOX

1. The Pacific University Faculty member (PI) creates a folder in BOX. Include the IRB number ###-YR as part of the folder title for IRB and IRB Audit Purposes.
 - 1.1. When creating the folder, choose to keep the folder private for now. The icon will be tan instead of blue.
 - 1.2. Ensure that the folder you created is not housed under a folder shared with others. When you log into BOX, the All Files page is the first page that appears. You should see the IRB folder you have created listed here with no collaborators.

- 1.3. For faculty with multiple projects, it might be useful for you to have a parent IRB folder on your All Files page, then add study-specific folders in your IRB parent folder.
2. Create subfolders under the main Project Folder according to the recommendations below. It is important that you create separate folders for the Data, the Informed Consent documentation, the Logs, and the general Regulatory Binder information, as not all members of the research team will or should have access to all components of the study.



3. The main project folder (###-YY [TITLE] Regulatory Binder) should currently be accessible only to you. You will now share folders with other members of the Research Team, as appropriate.
4. Sharing Folders: It is essential that you only grant access to the appropriate individuals in order to adhere to regulations and ensure participant privacy. For instance, some members of the research team may be involved in collecting informed consent and have access to the personally identifiable data, but there are others on the team that will only be handling the de-identified data and should not have access to the Logs or the Informed Consents.
 - 4.1. Add collaborators to folders as needed. Do not grant more access than is necessary for each research team member's scope of work.
 - 4.2. The Faculty PI may assign maintenance of the Regulatory Binder to another member of the research team. The Faculty PI, however, remains responsibility for remaining compliant with all requirements.

5. The numbered subfolders refer to section headings in the *Regulatory Binder – Preparation and Maintenance* document. Depending on the nature of your study, you may not need all of these folders. The folders have been provided here for ease of the research community.
6. For the Informed Consent and the Logs documents, be sure that you maintain these records as detailed in your study protocol. The Informed Consents, the Enrollment Log, and the Screening Log must be maintained for a minimum of three years from the date the study is officially closed with the IRB. The ID Code list/Master Key should be destroyed as stipulated in your IRB protocol.

Audits and BOX

1. If you are selected for an audit by the IRB Audit Committee, you will receive a letter announcing the date of the audit and providing basic information for the next steps. If you maintain files in BOX (or another system) or have an eRegulatory Binder in BOX, you will be required to grant the IRB Audit Committee Access to the main Project Folder (####-YY [TITLE]) by adding irb@pacificu.edu as a collaborator with co-owner access.
2. Once you have self-audited in preparation for submitting your materials to the IRB Audit Committee, you will follow these steps:
3. Add the IRB as a collaborator on the main Project Folder. The IRB Audit Committee will then have access to all subfolders.
4. The IRB will remove itself as a co-owner upon conclusion of the audit.

Changing Access Permissions in BOX

1. Under certain circumstances, ownership and access to these folders may need to change.
2. If the Faculty PI is no longer the faculty member responsible for the study, you are required to (1) Submit a Modification Request changing the Faculty PI on record and updating any documentation necessary and (2) transfer responsibility of all documentation to the new Faculty PI. If a study has been closed, the IRB can take ownership of the files.
3. Once the modification request has been approved by the IRB to change the faculty member on record as the PI, the new faculty PI will be added as a co-owner on the BOX folder tree, then the former faculty PI's access will be removed. In the event that the IRB is assuming responsibility for the study documentation, you will need to grant the IRB will ownership (irb@pacificu.edu).
4. Instances in which the Faculty PI may change:
 - 4.1. Faculty Member Leaves Pacific University: In the event that a Faculty PI is serving as an advisor for a student project, responsibility must shift to another faculty member (following a modification request)
 - 4.2. Faculty PI changes, but the original faculty member remains at Pacific University.
 - 4.3. Faculty leaves Pacific and must transfer oversight of study to someone else.
 - 4.4. Faculty leaves Pacific and will be continuing study at new institution. The Pacific University IRB will need documentation that shows how you will transfer your current study materials to the new institution and you must provide approval documentation from the new institution that lists their IRB as the IRB of record. Additionally, you will need to check with funding and sponsors for their internal requirements that may limit your ability to take funding and studies with you to a new institution.
 - 4.5. Unexpected Departure from Pacific – IRB closes study and maintains files.

- 4.6. Faculty retires. The faculty member must close all studies or transfer to other faculty member. Informed consent and data must still be maintained per regulations. Please discuss your options with the IRB well in advance of retirement.