



All repositories at OHSU must track the release of data/specimens for each specific research project that uses data/specimens from the repository. A release includes the use of data/specimens by one of the investigators listed on the repository as well as use by other investigators at OHSU or other institutions. A record of all releases from the repository must be submitted to the IRB at each continuing review.

In addition, repositories that include data/specimens from multiple studies or institutions must track all submissions to the repository. Each individual research activity that contributes data and/or specimens is considered a submission.

The OHSU IRB has created template tables for tracking submissions and releases. Below are some *helpful hints* for using the templates to develop and manage your own repository tracking system:

- There are two versions of the templates – one is an Excel spreadsheet and one is a Word table. You may use either one depending on what works best with your tracking system.
- There are two tables within each template (separate tabs in the Excel version, separate pages in the Word version) – one for releases and one for submissions. Each table contains example entries that demonstrate how different scenarios might appear.
 - Note that the relevant information for each column varies depending on the type of submission or release.
 - Depending on your repository, you might wish to use the columns for flexible “notes,” as shown in the examples, or you might want to narrow and standardize the information in each column a bit more so that you can easily query the data later.
- ***These templates are a guideline only.*** You should consider your own needs in managing your repository when designing your tracking system. Some of the columns may not be applicable to your situation, or you may find extra columns to be helpful.
- In the Submissions table, note that the “Consent and Authorization Methods” column describes any limits on the future use of the data/specimens imposed by the original consent. For instance, Example 1 limits use to research on cancer only. It is important to track these limits to ensure that future uses of your data/specimens are consistent with the subjects’ permissions.
- Be sure to describe your tracking system in your repository protocol.
- The Submissions table can also be helpful for your initial repository submission if you are compiling data/specimens from several studies. Submitting a table or spreadsheet like this helps the IRB determine what consent/authorization mechanisms are required for storage in the repository and what, if any, limits must be placed on future research.
- When you submit your tracking sheets for continuing review (or for a modification), the IRB will want to see what has changed. You can show this in a number of ways – by tracking changes (if you used a Word table), by using strikethrough font for entries that have been removed from your repository, by color coding, etc.
- Remember that submissions and releases beyond the scope of your approved repository protocol require a modification request.

Feel free to contact the IRB at ext. 4-7887, option 1, with any questions about setting up or managing your repository.