IRB Staff – Data Security Level (DSL) Review Process Guide

This document is intended to assist IRB staff with:
1. When to indicate DSL in the ESTR review process
2. Where to indicate the DSL in ESTR
3. How to manage IRB determinations in ESTR, while HUIT review is pending
4. How to document HUIT review in ESTR

Note: From the IRB process-perspective, Harvard University Information Technology (HUIT) review of the Data Security Plan (DSP) and Sponsored Programs review of the Data Use Agreement (DUA) occur within the same steps. These non-IRB reviews may take place at the same time in the IRB review process but may need to be separately documented. Please consult with the Harvard Research Data Security Policy or ADAMS User Guide for additional information about these non-IRB review processes.

1. When to indicate DSL in the ESTR process

A preliminary DSL determination may be made at any point after a submission has entered pre-review. However, a final DSL determination is made via the Committee or Non-Committee Review activity.

ONLY select DSL on an activity form in ESTR:
1. When there is enough information about the submission **to begin any needed HUIT review process;**

<div align="center">**AND**</div>

2. You will be able to communicate to the study staff if the **suggested DSL is 3, 4, or 5 within the same day**.

FAQ

1. What if the DSL changes based on revisions to the submission (such as via clarifications requested)?
If DSL changes at any point during the review, it should be indicated on the appropriate review activity in ESTR. Updating DSL in one activity will display the change on all other spaces where the DSL is visible. The DSL change should also be communicated to the study team.

2. Does a change to the DSL on a MOD get recorded in the main study workspace?
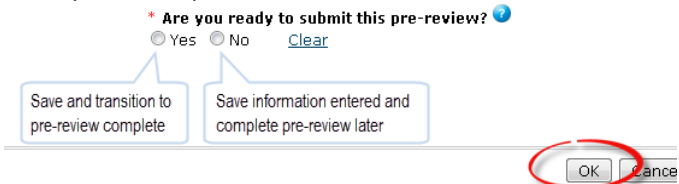No. Every submission should have a DSL determination (relative to the entire study). To check the current DSL please go to the most recently approved submission workspace.

2. Where to indicate the DSL in ESTR

When enough information about the study is available, a DSL can be indicated via certain review activities in ESTR.

> **DSL must be evaluated for _every_ submission:** Initial, Continuing Review, and Modifications. If there is not enough information to make a determination or the IRB is not required to make a determination, DSL should be left blank.

Activities to indicate DSL	Comments
Record preliminary determination: Submit Pre-Review *Record final determination:* Submit Designated Review	Both "submit pre-review" and "submit designated review" activities can be saved without transitioning the state of the submission. Any item on these activities, including DSL, continue to be editable on the pop up until the last question is marked "Yes" before clicking "OK". To save without causing a submission state transition, select the "No" radio button when completing the activity, for example:
Record preliminary determination: Edit Pre-Review	This activity can be edited during the states "pre-review complete" through "post-review". Changes to DSL will be indicated in the system as an official update.
Record final determination: Submit Committee Review	This activity is completed one time after the Committee records a decision in a convened meeting.

FAQ

1. How is the DSL communicated to the study team? Please see "DSL Communications Quick Bite" for details; briefly, as soon as a DSL of 3, 4 or 5 is indicated as above for the first time, the study team must be notified within the same day, by Clarifications Requested, a Modifications Required to Secure 'Approved' letter, or a Deferred letter.

2. What about a Mod which doesn't affect the DSL or has data which meets a lower DSL?
The DSL selected must cover the whole study. Example: If a modification is submitted to add use of de-identified data to a study which otherwise received a DSL of 3, the modification DSL should remain 3.

3. What happens if the preliminary decision is different than the one indicated at final determination?
Any update to the DSL should trigger any subsequent required HUIT review activities. For ADAMS-ESTR integration, an update to the DSL (on any activity) will trigger a system update in ADAMS with the next import.

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3. How to manage IRB determination in ESTR, while HUIT review is pending

Please review the current Research Data Security policy for the most up to date requirements. Additionally, review the following guidance to ensure consistent ESTR use.

Data Use Agreement (DUA) review is indicated in the below table, the IRB often reviews the draft DUAs and is not required to have a copy of the final DUA in ESTR. DUAs are reviewed and final versions are kept by the local Sponsored Programs office.

DSL	Can **INITIAL** IRB Approval be issued before HUIT review is completed?	Can IRB Approval of a **MODIFICATION** be issued before HUIT review is completed?*	Example Determination in ESTR	Comments
0 / Null	Yes	Yes	Whatever is appropriate under regulations (usually NHSR, Not Engaged, Not Research, or Ceded)	HUIT review of the Data Security Plan is not (necessarily) required. Attestation of compliance is required, and recorded with the PI clicks 'submit' in ESTR. DUA review may be required. *Please note that studies which are Ceded may need additional information security review outside of the IRB review process descried in this document.*
1	Yes	Yes	Whatever is appropriate under regulations	HUIT review of the Data Security Plan is not (necessarily) required. Attestation of compliance is required, and recorded with the PI clicks 'submit' in ESTR. DUA review may be required.
2	Yes	Yes	Whatever is appropriate under regulations	HUIT review of the Data Security Plan is not (necessarily) required. Attestation of compliance is required, and recorded with the PI clicks 'submit' in ESTR. DUA review may be required.
3	Yes	Yes	Whatever is appropriate under regulations	HUIT review of the Data Security Plan is required and **documentation of HUIT review must be submitted to the IRB with the next Continuing Review.** DUA review may be required.
4	No	**No** If previous DSL was not 4	If No, clarifications requested, until no other items are needed; then either Deferred or 'Modifications Required to Secure Approved'	HUIT review of the Data Security Plan is required and **documentation of HUIT review is required before IRB approval may be issued** if there is a new determination of level 4. DUA review may be required. Even if the DSL remains unchanged with a modification, some changes to the study (such as change in study staff) may require update to the Data Security Plan with HUIT. Please refer to HRDSP for requirements.
		Yes If previous DSL was 4	If Yes, whatever is appropriate under regulations	
5	No	**No** If previous DSL was not 5	If No, clarifications requested, until no other items are needed; then either Deferred or 'Modifications Required to Secure Approved'	HUIT review of the Data Security Plan is required and **documentation of HUIT review is required before IRB approval may be issued** if there is a new determination of level 5. DUA review may be required. Even if the DSL remains unchanged with a modification, some changes to the study (such as change in study staff) may require update to the Data Security Plan with HUIT. Please refer to HRDSP for requirements.
		Yes If previous DSL was 5	If Yes, whatever is appropriate under regulations	

Note that a Continuing Review approval is never expected to change the DSL.

FAQ
What do I do after I've requested HUIT review from the PI and study team?
1) Based on the table above and the submission, continue with the review through entering the appropriate determinations in ESTR.
2) Wait for the PI or HUIT to send/submit final HUIT decision, as appropriate.
3) Documentation of HUIT review can be received in two ways:
   a. If the submission is in "clarifications requested" or "modifications required to secure 'approved'", documentation of HUIT review may be attached to the SmartForm or activity such as "Submit Changes"; OR
   b. The IRB contact may receive an email (outside of ESTR) from HUIT or the study team documenting HUIT review is completed.
4) Once received, download and re-upload that documentation to the Track Ancillary Approvals activity (see below). Note that this can be done on a study even if the review is completed (for example, for level 3).
5) As appropriate, issue the appropriate determination letter once this and all other clarifications/ modifications have been addressed.

4. How to Document HUIT review in ESTR

HUIT review status should be documented on the Track Ancillary Approvals activity on the main study workspace. At this stage, the draft DUA should be included on the SmartForm during review and the final DUA does not need to be included in the Track Ancillary Approvals activity.

> **HUIT review status should be indicated within the Ancillary Approval activity on the Main Study workspace** each time a DSL determination changes.

STEP	ITEM	COMMENTS
1: CLICK ACTIVITY	☑ Track Ancillary Approvals	Complete this activity: • When a preliminary determination regarding DSL is entered elsewhere in ESTR AND • When additional information about HUIT review is received.
2: UPDATE STATUS	**Track Ancillary Approvals** Use this activity to track required ancillary reviews and record their approval as appropriate. 1. **Please indicate the Ancillary Committee Review(s) required for this study, and if they have been received:** Committee / Required / Approval Pending / Approval Received Update — Committee on Microbiological Safety (COMS) — yes / no / yes Update — Embryonic Stem Cell Research Oversight Committee (ESCRO) — yes / no / yes Update — Harvard University Information Technology (HUIT) — no / no / no Update — HSDM Dean for Research (HSDM) — no / no / no	Use update to indicate if HUIT review is required, pending or received by clicking "update" on the Track Ancillary Approvals activity pop-up.
3: NOTE STATUS	**Edit AncillaryApprovalStatus** **Committee:** Harvard University Information Technology (HUIT) * Is this review required? ◉ Yes ○ No Clear * Is the approval pending: ○ Yes ◉ No Clear * Has the approval been received? ◉ Yes ○ No Clear * Required OK Cancel	The status of HUIT review may be indicated/updated in the *Edit Status Detail* pop up. If the approval refers to a Modification, this should be indicated in the Comments section.
4: ATTACH DOCS	3. **Upload documents:** Add name / description Upload Revision — HUIT Approval of DSL 3, 4 or 5 — Delete	For studies which use data meeting DSL 3, 4, or 5; documentaiion of HUIT approval* should be uploaded to question 3 on the Track Ancillary Approvals activity pop-up. *See FAQ on section 4, above for information on timing of receipt and document source.
5: CLICK OK	OK Cancel	Click "OK" on the Track Ancillary Approvals activity pop-up to save the information.
6: VIEW CHANGES ON HISTORY	**History** / Project Contacts / Documents **Filter by** Activity ▼ Activity ☑ Tracked Ancillary Approvals 📎 HUIT Approval of DSL 3, 4 or 5	After clicking "OK", documents attached to (and comments made on) the Track Ancillary Approvals activity are visible on the study history in the Main Study workspace. The Track Ancillary Approvals popup only retains the most recent status.