



Greenlight Tip Sheet



1. What is Greenlight?

Greenlight increases visibility of the required approvals for **new** research studies. Using a single dashboard (**Approval Status** tab in eIRB), study teams will be able to track approvals required to activate a study at the University of Texas Southwestern (UTSW) and its affiliates. Greenlight Approvals can be monitored on the **Approval Status** tab in eIRB, all **“Pending”** approvals will be in red text as shown below:

Approval Component	Component Name	Status
Performance Site	UTSW	Pending
Performance Site	Children's	Approved
Performance Site	PHHS	Not Applicable
UTSW Coverage Analysis	UTSW Coverage Analysis	Approved
UTSW Contract	UTSW Clinical Trial Agreement	Complete/Fully Executed

Note: At least *one* Performance Site Approval must be granted before Greenlight is activated

2. What will happen to my IRB approved studies in eIRB?

Approval status in eIRB for currently approved studies **will change** once Greenlight goes live (12/10/2019) as follows:

Current eIRB Status (pre-Greenlight) is:		Post-Greenlight Status will be:	
	Exempt Acknowledged		Exempt Activated
	Approved		Activated

3. How will Greenlight affect studies in draft/under IRB review/not yet drafted?

Statuses in eIRB prior to IRB Approval will not change. These include statuses such as: IRB Staff Review, Assigned to Meeting, in Expedited Review, etc. The new statuses below apply *after* IRB approval.

- a. **When IRB approves AND at least one Greenlight Approval is pending** - Studies will move through the states below based upon the following activities:

Activity in eIRB:	Study Status changes to:
IRB Approval	Awaiting Correspondence
IRB letter is sent	Approved - Other Approvals Pending
All Greenlight approvals are received	Awaiting Activation
HRPP staff will send an activation letter*	Activated

*Only *one* activation letter will be sent from eIRB; additional notifications will be received from each site after performance site approval is granted.

- b. **When IRB Approves AND all Greenlight Approvals are received (or not applicable)** - Studies will move through the states below based upon the following activities:

Activity in eIRB:	Study Status changes to:
IRB Approval & Greenlight Requirements Met	Awaiting Correspondence
HRPP staff will send an activation letter*	Activated

*Only one activation letter will be sent from eIRB; additional notifications will be received from each site after performance site approval is granted.