



**eREG**<sup>TM</sup>

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### ***Yale eREG Notice Regarding IRB & Laboratory Merger***

Dear eReg Users,

The eReg Support Staff in the Yale Center for Clinical Investigation (YCCI) recently reviewed organizations currently maintained within the eReg system. Inaccuracies and inefficiencies were identified in Institutional Review Board (IRB) and laboratory records. YCCI has corrected the records as outlined below. Further action is required by the study team to update your protocol records.

#### **Institutional Review Boards**

The current practice of listing each Yale IRB separately was creating additional system maintenance burdens. As a result, we have inactivated the individual Yale IRB records and replaced them with a single combined entry for all Yale IRB boards.

Inactive Entries:

Name ↑
Yale University Institutional Review Board #0 - Ad Hoc Committee
Yale University Institutional Review Board #2 - Human Investigation Committee 1B
Yale University Institutional Review Board #3 - Human Investigation Committee IV
Yale University Institutional Review Board #4 - Human Investigation Committee II
Yale University Institutional Review Board #5 - Human Investigation Committee III
Yale University Institutional Review Board #6 - Human Investigation Committee IA

New Entry:

Name ↑
Yale University Institutional Review Board

#### **What do I need to do?**

For new studies that utilize any of the Yale IRB boards, please select the Yale University

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Institutional Review Board. The individual board entries will be inactivated by the end of August 2021, so they will no longer appear as an option for you to select.

### **What will happen on my existing studies?**

As part of YCCI's effort to maintain Yale-affiliated organization documents centrally in eReg, we will be phasing out the use of individual Yale boards to eliminate the need to maintain regulatory records across the different board entries.

To do this, the combined Yale IRB entry will be added to the IRB organization list for active protocols using Yale IRB as the IRB of record on your behalf. The original board specific listing will remain and will have a stop date added equal to the effective date of this change.

The start dates of both entries will remain the same to show that there was no transfer of IRB authority.

See the example below where the start date for the new Yale IRB entry is the same start date as the original board specific entry (21 Apr 2015).

Example of current entry:

Organization ↑	IRB?	Laboratory?	Start Date	Stop
Yale University Institutional Review Board #2 - Human Investigation Committee 1B	Yes	No	21 Apr 2015	

Example after adding new Yale IRB organization:

Organization ↑	IRB?	Laboratory?	Start Date	Stop
Yale University Institutional Review Board	Yes	No	21 Apr 2015	
Yale University Institutional Review Board #2 - Human Investigation Committee 1B	Yes	No	21 Apr 2015	11 Au

Maintain this correspondence with your study files to explain the change to external and internal parties who may review your study files.

Regulatory tracking documents for the Yale University Institutional Review Board will be updated by YCCI.

### **Laboratory**

There were laboratories which had duplicate records. As a result, we have inactivated the incorrect records. The correct records remain available for use.

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Incorrect Record	Correct Record
Yale-New Haven Hospital Laboratory	YNHH/Department of Laboratory Medicine
Smilow Cancer Hospital Care Center at Lawrence + Memorial	Smilow Cancer Hospital Care Center – Waterford (CT126)
Smilow Cancer Hospital at Greenwich (CT112)	Greenwich Hospital Laboratory

### **What do I need to do?**

When selecting a laboratory moving forward, Yale-New Haven Hospital Laboratory, Smilow Cancer Hospital Care Center at Lawrence + Memorial, and Smilow Cancer Hospital at Greenwich (CT112) will not be available for selection. For any new studies, utilize YNHH/Department of Laboratory Medicine, Smilow Cancer Hospital Care Center – Waterford (CT126), or Greenwich Hospital Laboratory, when applicable.

### **What will happen on my existing studies?**

As part of YCCI's effort to maintain organization documents centrally in eReg, any protocols using incorrect laboratory records will have the correct record added using the same start date. The incorrect record will then be removed from the protocol. All regulatory documents have been added to the correct record.

Because the original laboratory listing was incorrect, the record is being removed from your protocol entirely.

Maintain this correspondence with your study files to explain the change to external and internal parties who may review your study files.

Regulatory tracking documents for the Yale-affiliated laboratories will be updated by YCCI.

### **Who do I contact with questions?**

Please contact eReg Support ([eReg.Support@yale.edu](mailto:eReg.Support@yale.edu)) with any questions.

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[eReg Production Site](#) | [eReg Support](#) | [YCCI Research Services](#)

Please contact [eReg.support@yale.edu](mailto:eReg.support@yale.edu) with any questions or system related feedback.

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