

---

## How to Request an Institutional Ancillary Review

### What is an Institutional Ancillary Review and Why Would I Request it?

Institutional ancillary reviews are a mechanism in UVMClick to forward to other institutional (UVM and UVMCC) compliance groups or individuals. Submitting an ancillary review forwards to the specific group or individual a notice through the system that you have submitted a research project to the IRB that requires review. There are three different possible actions the IRB can take when an ancillary review is submitted:

- **IRB reviews and approves but holds final release of approval to the PI** - Some groups/individuals with the institution require that the IRB hold releasing approval until the ancillary approval is complete (for instance Billing Compliance, Contract negotiation);
- **IRB does not begin its review** - In some instances it does not make sense for the IRB to begin its review until the ancillary review is complete as often times there are many changes to the protocol as a result of that other review
- **IRB does nothing as FYI only** - Other groups/individuals want the notice as an FYI only

### To which submissions do Ancillary Reviews apply?

Ancillary reviews are used for initial and in some instances amendment review. Ancillary reviews are not used for key personnel changes as the groups/individuals have access to review a list of key personnel on a given protocol at any time. See matrixes at end of document.

### Who can submit an Ancillary Review?

PIs/proxys who know that the study requires other institutional reviews or Faculty Sponsor signoff can initiate this process at the same time that the protocol is being submitted. If the study is submitted without a required ancillary review, and one applies, the IRB Office will initiate the process on behalf of the PI.

**NOTE:** Student projects require a faculty sponsor sign off prior to IRB review. Therefore, student PIs will need to submit a Faculty Sponsor Ancillary Review to obtain this sign off.

### How are Ancillary Reviews Completed?

The system can “push” a notice of ancillary review to the group/individual, but the IRB staff are not involved with the review. That review is completed outside of the UVMClick ancillary review mechanism. The review and any clarifications are managed by these ancillary groups/individuals following their procedures. Once the group/individuals are satisfied, they sign off with the IRB. The IRB then can move forward with their next step, whether that be review of the protocol or final release of the approval.

**NOTE:** The UVMClick system does not maintain any ancillary review materials or documentation other than the date the review was “pushed” and the approval date if a response was required. Therefore, it is important that the researcher maintain all the ancillary review documentation.

## Steps to Assign an Institutional Ancillary Review

When you have completed data entry and uploaded applicable materials and before you hit submit:

**Step 1** - Click on the activity called “Manage Ancillary Reviews” along the left side of the screen.



**Step 2** – Click the +ADD button

**Step 3** - In the “Add Ancillary Review” pop-up window

–Questions #1 - 3

Here are two examples and there are two **Ancillary Review Matrixes** in this section to assist you.

### Examples

#### Billing Compliance Ancillary Review

A screenshot of the 'Add Ancillary Review' form. The title bar says 'Add Ancillary Review'. The form has three sections: 1. '\* Select either an organization or a person as reviewer:' with 'Organization:' and 'Person:' fields. 'Denise Quint' is entered in the 'Person' field. 2. 'Review type:' with a dropdown menu set to 'Billing Compliance'. 3. '\* Is a response required?' with radio buttons for 'Yes' (selected) and 'No', and a 'Clear' link. At the bottom are buttons for 'OK', 'OK and Add Another', and 'Cancel'. A red arrow points to the 'OK' button.

#### Jeffords Institute for Quality Ancillary Review

A screenshot of the 'Add Ancillary Review' form. The title bar says 'Add Ancillary Review'. The form has three sections: 1. '\* Select either an organization or a person as reviewer:' with 'Organization:' and 'Person:' fields. 'Ancillary-JIQ' is entered in the 'Organization' field. 2. 'Review type:' with a dropdown menu set to 'Jeffords Institute for Quality'. 3. '\* Is a response required?' with radio buttons for 'Yes' (selected) and 'No', and a 'Clear' link. At the bottom are buttons for 'OK', 'OK and Add Another', and 'Cancel'. A red arrow points to the 'OK' button.

**Step 4** - Click OK

**Ancillary Review Matrix –  
“Add Ancillary Review” pop-up window  
Initial Protocol Review**

<b>Institutional Ancillary Review Type</b>	<b>Question #1 - Organization or Person</b>	<b>Question #2 – Review Type</b>	<b>Question #3 – Is a response required?</b>	<b>IRB Response</b>
Jeffords Institute for Quality	Organization	Ancillary-JIQ	yes	IRB Review is held until complete
Billing Compliance	Person	Denise Quint	yes	Review begins, approval is held until complete
Vermont Cancer Center Protocol Review and Monitoring Committee	Organization	Ancillary-PRMC Full Review Designated Review	yes	See VCC specific flow on their website
Radiation Safety for UVM	Person	Tom Kellogg	yes	IRB Review is held until complete
Radiation Safety for UVMCMC	Person	Brian Oyadomari	yes	IRB Review is held until complete
Clinical Research Center	Organization	Ancillary-CRC	yes	See CRC specific flow on their website
OCTR Contract Review	Organization	Ancillary-OCTR-Contract	yes	Review begins, approval is held until complete
OCTR Invoice Review	Organization	Ancillary OCTR-Invoice	yes	Review begins, approval is held until complete
Faculty Sponsor Review	Person	Faculty Sponsor name	yes	IRB Review is held until complete
Department Chair	Person	Department Chair name	no	IRB Review is held until complete
Data Use Agreement	Person	Kim Luebbers (OCTR) OR Brian Prindle (SPA)	yes	Review begins, approval is held until complete

**Ancillary Review Matrix –  
“Add Ancillary Review” pop-up window  
Amendments**

<b>Institutional Ancillary Review Type</b>	<b>Question #1 - Organization or Person</b>	<b>Question #2 – Review Type</b>	<b>Question #3 – Is a response required?</b>	<b>IRB Response</b>
Vermont Cancer Center Protocol Review and Monitoring Committee	Organization	Ancillary-PRMC	yes	IRB Review is held until complete
Clinical Research Center	Organization	Ancillary-CRC	yes	IRB Review is held until complete