UVMClick Website	https://www.uvm.edu/ovpr/uvmclick	Email Support	irb@uvm.edu
UVMClick Login	https://irb.connect.uvm.edu/IRB		

How to Request an Ancillary Review

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

Institutional ancillary reviews are a mechanism in UVMClick to forward a protocol submission to compliance groups or individuals for review and approval. The review may be to determine research feasibility, scientific merit, assurance with a state law or local policy or coordination between UVM and UVMHN.

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 (Protocol Review Committee, Faculty Sponsor review, etc.)
- **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.

Who can submit an Ancillary Review?

PIs/proxies who know the study requires other institutional reviews or Faculty Sponsor signoff can initiate this process at the same time the protocol is being submitted for IRB review in the Click. 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 identify a Faculty Sponsor as a member of the study team as part of the protocol submission.

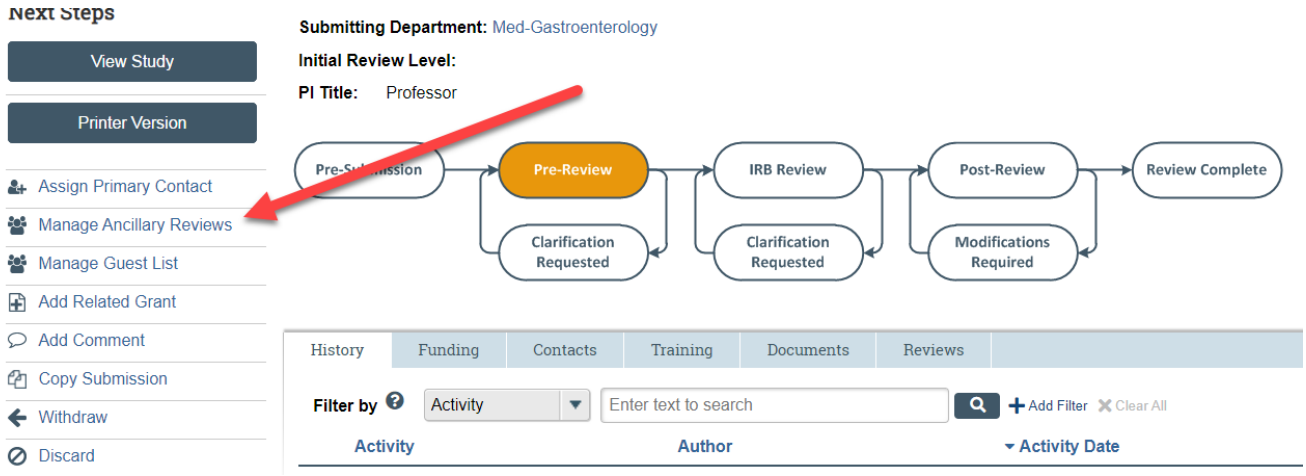
How are Ancillary Reviews Completed?

The system can "push" a notice of ancillary review to the group/individual, but 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 indicate approval of the submission within UVMClick. The IRB then can move forward with their next step, whether that be review of the protocol or final release of the approval.

Steps to Assign an Institutional Ancillary Review

After you have completed data entry, uploaded protocol documents and before you hit the submit button:

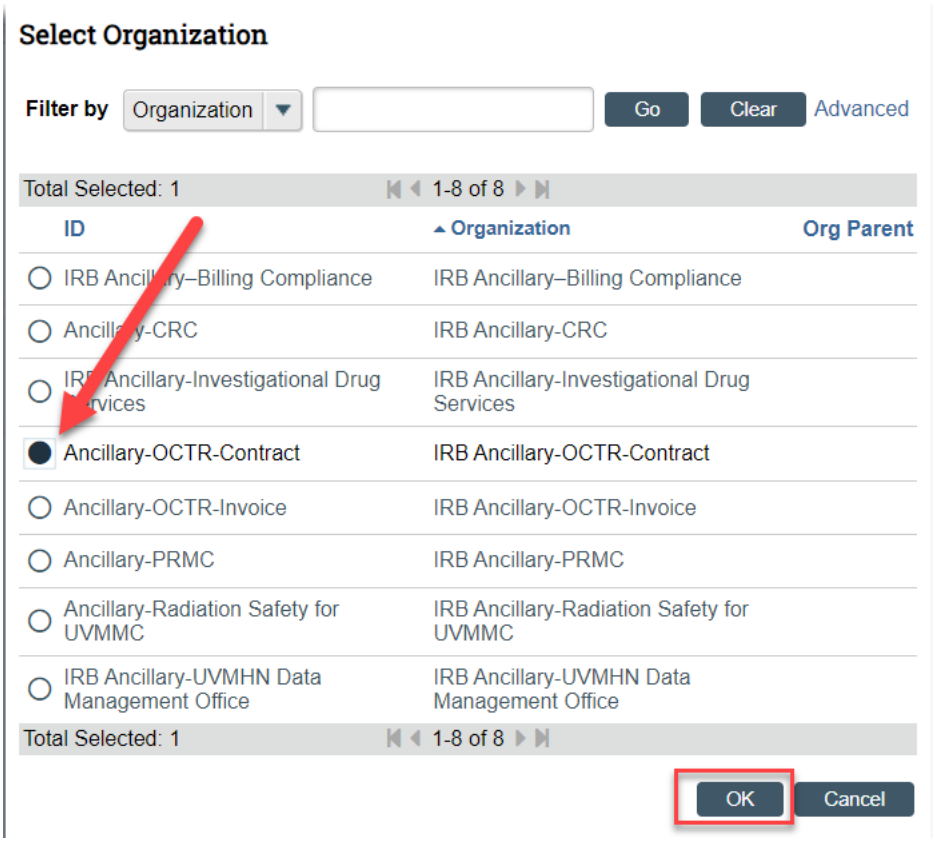
Step 1 - Click on the activity called "Manage Ancillary Reviews" along the left side of the screen.



Step 2 –Click the **+ADD** button

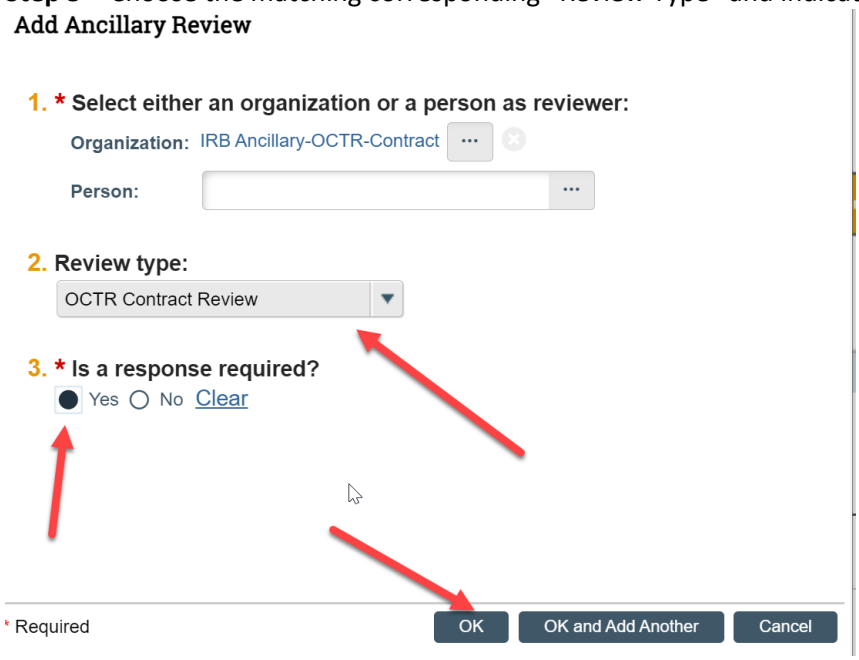
Step 3 - In the "Add Ancillary Review" pop-up window

Select the appropriate reviewing organization such as - **OCTR Contract Ancillary Review**



Step 4 - Click OK

Step 5 – Choose the matching corresponding "Review Type" and indicate a "YES" for a response is required.



Step 6 – Add as many ancillary reviews as applicable. All responses should have a "YES" for Question #3.

Ancillary Review Matrix

Ancillary Review Group	Required prior to IRB review or release of approval?	Generated by either 1) Staff / Pre-Review 2) PI / Pre-Submission	Trigger on Smart form -question #	Submission Types Affected	Contact/Assignee
Data Management Office (DMO)	Prior to IRB Review	PI or Staff	Protocol refers to data coming from the DMO. If all data is coming from the DMO then no ancillary review needed – assign Beth Carter as the analyst.	Initial Application, Amendment	Allison.Holm@uvm.edu Elizabeth.Carter@uvmhealth.org
UVMMC Billing Compliance	Prior to Release of IRB Approval	PI or Staff	Study Scope Q4 or yes for Mods = "Yes" Will this study involve any UVMMC or UVM Health Network patients (including data and/or specimens) or any equipment, facilities, supplies or personnel of UVMMC or UVM Health Network, whether standard of care or protocol-driven, such as laboratory, pharmacy, imaging, EKGs, or other diagnostic or therapeutic items or staff? If the study only involves review of records, please select "No".	Initial Application, Amendment	Christine.Leibold@uvmheath.org Karen.Brautcheck@uvmhealth.org Trenda.jones@uvmhealth.org
Vermont Cancer Center Protocol Review and Monitoring Committee	Refer to separate flow	PI or Staff	Study Scope Q7 = yes/checked on the Modification Information page	Initial Application Amendment	matthew.carter@med.uvm.edu benjamin.briggs@med.uvm.edu prmc@med.uvm.edu
Radiation Safety for UVM	Prior to Release of IRB Approval	Staff	Study Scope Q14 = "UVM' **Where will the procedures involving radiation take place?**	Initial Application	tkellogg@uvm.edu
Radiation Safety for UVMMC	Prior to Release of IRB Approval	Staff	Study Scope Q14 = "UVMMC' **Where will the procedures involving radiation take place?**	Initial Application	matthew.deeley@uvmhealth.org Marc.Chamberland@uvmhealth.org Christin.Young@uvmhealth.org
Clinical Research Center	Refer to separate flow	Staff	Research Locations View – Location selected = 'Clinical Research Center'/checked on the Modification Information page	Initial Application, Amendment	Kimberly.Luebbers@med.uvm.edu Joan.Bertolet@uvm.edu Ashley.Rich@uvm.edu
OCTR Contract Review	Prior to Release of IRB Approval	Staff	Funding Sources View – Q1 "Is it internal, federal/state or industry funded?" must = "Industry"	Initial Application, possibly amendment as applicable	Mark.Tomase@med.uvm.edu
OCTR Invoice Review	Prior to Release of IRB Approval	Staff	Funding Sources View – Q1 "Is it internal, federal/state or industry funded?" must = "Industry"	Initial Application	Gregory.Barrows@med.uvm.edu
Faculty Sponsor Review	Prior to IRB Review	PI or Staff	Study Team Member role = "Faculty Sponsor"	Initial Application	Faculty Sponsor
OCTR DUA	Add ancillary review for new studies and Mods but do not hold unless sharing is imminent. Indicate NO on review.	Staff	Any PHI from UVMMC being sent out of the institution, check DMSP	All submission types	Mark.Tomase@med.uvm.edu Kimberly.Luebbers@med.uvm.edu
SPA DUA	Do not hold	Staff	Identifiable data being sent out of UVM, funding Sources View, check DSMP	All submission types	Brian.Prindle@uvm.edu
IRB Ancillary-Investigational Drug Services	Prior to Release of IRB Approval for all studies	PI or Staff	Study Scope Q1 = "Yes" anything on the drug page needs to be reviewed by pharmacy	Initial Application	Aimee.Merkert@uvmhealth.org callie.fortin@uvmhealth.org

			Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?		