



## **IRB: PROTOCOL** ACTIONS TAB

The Protocol Actions Tab is where you will go to finalize and submit the protocol.

## **Data Validation**

- 1) Click the Protocol Actions Tab.
- 2) Click the Data Validation section header to expand the section.
- 3) Click the Turn On Validation button. Turn On Validation
  - a. The system will run a series of validation steps to ensure all required fields have been populated. This is the same validation the system automatically runs when the protocol is submitted.
  - b. If errors are found, the system will display a list of the errors.
- 4) If there are multiple errors click the **Show** button **Show** to address each error one at a time.
- 5) Click the **Fix** button to resolve the issue.
  - a. Clicking the **Fix** button will automatically take you to the tab and section that has an error.
  - b. Correct the error, then click the **Save** button at the bottom of the page. Clicking the Save button automatically takes you back to the Data Validation section.
- 6) Repeat this process for each validation error.

Protocol	* Indi	cates required field
Personnel		
Questionnaire		
Special Review	n 💙 Data Validation	
Permissions	Data Validation 🧿	
Notes & Attachments	You can activate a Validation check to determine any errors or incomplete information. The following Validations types will be determined:	
Protocol Actions	errors that prevent submission into routing	5
Streams	warnings that serve as alerts to possible data issues but will not prevent submission into routing Turn Off Validation	
	Validation Errors	
	Hide Participant Types (1)	
	There must be a minimum of 1 participant type.	Fix
	Show Human Subjects Research Interview (1)	
	Show Personnel (1)	
	Warnings	
	No Warnings present.	
	Unit Business Rules Errors	
	No Unit Business Rules Errors present.	
	Unit Business Rules Warnings	
	No Unit Business Rules Warnings present.	

Continue to the next page for information on the **Request an Action** section.





## **Request an Action**

At this point in the process, the available Actions are limited to submitting or deleting the protocol.

- 1) Click the Protocol Actions Tab.
- 2) Click the Request and Action section header to expand the section.
- 3) To submit the protocol:
  - a. Click the **Show** button **Show** next to the **Submit for Review** subsection.
  - b. Click the drop-down menu next to **Submission Type** and select **Initial Protocol Application for Approval**.
  - c. The **Type Qualifier** field is optional. Select an option from the drop-down menu if applicable.
  - d. Click the drop-down menu next to **Submission Review Type** and select the appropriate level of required IRB review for your protocol.

NOTE: For details regarding different levels of required IRB review UADA & UAF faculty and staff can go to the <u>Research Compliance-Human Subjects webpage</u>, or contact the IRB Coordinator at <u>irb@uark.edu</u> for assistance.

- e. If you select a **Submission Review Type** of **Expedited** or **Exempt**, the system will present a checklist to qualify the submission type. Make your selection by clicking the appropriate checkbox(es) that correspond to your protocol.
- f. Click the **Submit** button **Submit** to submit your IRB Protocol.

Protocol		4
Personnel		1
Questionnaire	✓ Request an Action	
Special Review	Available Actions 🞯	
Permissions	Hide Submit for Review	
Notes & Attachments	* Submission Type : Initial Protocol Application for Approval 🔹	Se
Protocol Actions	*Chacklist	He
Streams	(Expedited) Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly inc	
	Continuing review of research previously approved by the convened IRB as follows (c) where the remaining research activities are limited to data analysis.	
	Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting th	
	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and c	
	Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for e	
	Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/a	
	Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from t	
	Collection of data from voice, video, digital, or image recordings made for research purposes.	
	Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing s	
	Continuing review of research previously approved by the convened IRB as follows (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the r	
	Continuing review of research previously approved by the convened IRB as follows (b) where no subjects have been enrolled and no additional risks have been identified.	
	Submit	
	Show Delete Protocol, Amendment, or Renewal	
	Show Manage Notes (0)	
	Show Unavailable Actions	





Continue to the next page for information on how to delete a protocol if you no longer want to submit it.

If you not longer want or need to submit this protocol, you can delete it.

- 4) To delete the protocol:
  - a. Click the **Show** button **Show** next to the **Delete Protocol, Amendment or Renewal** subsection.
  - b. Enter a reason for deleting this protocol, amendment or renewal.
  - c. Click the **Submit** button **Submit** to submit the deletion of the protocol.

✓ Request an Action	
Available Actions 2	
Show Submit for Review   Hide Delete Protocol, Amendment, or Renewal	
Delete Reason : This is the reason I am deleting this protocol.	~
Submit	
Show Manage Notes (0)	
Show Unavailable Actions	