

**UAHS Research Administration Regulatory Startup Questionnaire**

Please email to regulatory@arizona.edu when complete. ALL documents and information on pages 1-3 are required to begin regulatory start-up. Definitions are listed on page 4.

**Date of Request:**

**Study Nickname or Short Title:**

**Study Sponsor:**

**IRB of Record:**

**UA Principal Investigator:**

**UA PI Department:**

**UA Study Team Contact:** (person the regulatory team should contact for questions about the form and study)

**UA Study Site Number:** (if applicable)

**Required Documents:**

[ ]  Protocol

[ ]  Consent template

* If the study is investigator-initiated, internally funded, and overseen by the UA IRB, the regulatory team can help write the protocol and consent. For all other studies, these must be provided by the study team.

As applicable:

[ ]  Editable contract/subaward template

[ ]  Editable budget

[ ]  Budget comments from the study team should be provided as a separate document

[ ]  Investigator’s brochure or device manual for the investigational product(s)

[ ]  CATS approval

[ ]  Central IRB approval letter

**Please assist us by providing the following information about your study:**

1. Sponsor contact name and email for:
	1. Contract negotiations:
	2. Budget negotiations:
	3. Regulatory communication:
2. NCT number, estimated date of availability, or a brief explanation of why one will not be required:
3. For drug/device studies, IND/IDE #, or documentation that IND/IDE# is not required:
4. If the study has multiple cohorts or parts, which cohort(s) or parts would our site participate in?
5. What is the expected enrollment for our site?
6. What recruitment methods will be used for this study?
7. Will study staff be pre-screening the Banner EMR for potential participants?
8. Do you plan to target any of the following populations for recruitment (i.e. make a specific effort to enroll these groups)?

[ ]  Native Americans

[ ]  UA employees or students

[ ]  Banner employees

1. Will you enroll ANY participants in any of the following groups?

[ ]  Pregnant women

[ ]  Prisoners

[ ]  Children

[ ]  Adults who cannot provide consent (i.e. require consent of LAR)?

1. Do you want study documents translated into Spanish or any other language?
2. What is the national/worldwide start date or projected national/worldwide start date?
3. What is the projected national/worldwide enrollment end date?
4. What is the projected national/worldwide study end date?
5. List of study locations and what activities will occur at each (in particular, identify where imaging, lab draws, and other procedures will take place):
6. List of labs being used to run study testing (locations where only processing is occurring do not need to be listed but please include locations where point-of-care testing will be completed):
7. If applicable, who will be administering the study drug or device?
8. Will the trial require any specialty (i.e. ophthalmology, radiation oncology, nuclear medicine, interventional radiology, etc.), specific equipment, or specific certifications?
	1. Please describe if non-standard procedures will be performed on Banner equipment (e.g. specialized MRI scans)
9. Will eConsent or remote consent be used? If yes, describe the method/platform.
10. How frequently will participants be compensated for their participation in the study (e.g. after each visit, monthly, quarterly)?
11. Please provide the location where physical consent forms will be stored and any other locations for storage of physical study records.
12. List all platforms where digital study data will be recorded and indicate whether the data will be identifiable, coded, or de-identified. For data to be de-identified, the study code must be removed.
13. If study data or samples will be stored in a repository or used for other future research, provide the location where they will be stored and describe how they may be used.
14. Will identifiable or coded data be transferred to an outside institution, including the sponsor? If yes, please describe the system for data transfer.
15. Is the sponsor requiring the study team to use a non-UA regulatory platform (e.g. Veeva Vault) or a higher than usual burden of study-specific digital platforms, for which the sponsor should be billed for the additional study team effort?
16. Please provide the current list of study staff. This will only be used internally in the RIA and UA IRB applications and will not be shared with the sponsor until later in the start-up process.
17. Do you want this study posted on studies.medicine.arizona.edu to assist with recruitment? If yes, provide the following information (may be copied from ClinicalTrials.gov or other study listing):
	* 1. Abbreviated study title in non-clinical terms that the general public will understand:
		2. Will this study enroll healthy volunteers?
		3. External Link(s) (if applicable):
		4. Study Contact to be listed on website:
		5. Contact Email:
		6. Contact Phone Number:
		7. Study Phase:
		8. Brief study description for the website:
		9. Eligibility Criteria (summarized for the general public):
		10. Primary research category:
		11. Secondary research category:
		12. Any additional information to be listed on website:
		13. Study Sites:
18. If the study is industry-sponsored, the UA IRB charges a review fee, which is paid by the department and reimbursed by the sponsor. If the contract is withdrawn prior to signature but UA IRB submission has already occurred, the financial team will request sponsor reimbursement, but the sponsor may choose not to pay this fee. Are you comfortable submitting to the UA IRB prior to contract finalization (faster, but you may have to cover the review fee if the study is withdrawn), or do you prefer to wait until final contract before we submit to the UA IRB (safer, but the start-up timeline is extended)?
19. Are there any deadlines or timelines for the study-start up? Please note, we will do our best to meet these deadlines but CANNOT GUARANTEE that start-up will be completed by any given date.
20. Please provide any additional information that you think will be relevant for the regulatory team to know:



**Definitions**

* CATS: Clinical and Translational Sciences Research Center
* CITI: Collaborative Institutional Training Initiative
* CV: Curriculum Vitae
* EMR: Electronic Medical Record
* eReg: Electronic Regulatory Binder
* IATA: International Air Transport Association training for Shipping Hazardous Materials
* IDE: Investigational Device Exemption
* IND: Investigational New Drug
* IRB: Institutional Review Board
* LAR: Legally Authorized Representative
* NCT: National Clinical Trial
* PI: Principal Investigator
* RA: Research Administration
* RIA: Research Intake Application
* Sub-I: Sub-Investigator (synonymous with Co-I/Co-Investigator)
* UA: University of Arizona
* UAHS: University of Arizona Health Sciences

**Additional Documents and Guidance**

Documents and information listed on this page are not required to begin regulatory startup, but will be needed at later points in the startup process. Please contact regulatory@arizona.edu for any questions.

**UA IRB studies**

If the UA IRB will be the IRB of record, the following documents must be completed for UA IRB submission:

* + Data collection documents, including list of data elements to be collected from the EMR and all questionnaires and surveys
	+ All recruitment materials
	+ All other materials that will be seen by subjects

**Study Locations and Approvals**

* CATS approval must be obtained prior to RIA submission
* Approval for Banner locations is secured through the RIA submission and feasibility approval process
* Approval from other UA departments or facilities (outside of the PI’s department) is required for UA IRB submission. This is the responsibility of the study team to obtain.
* Approval from external study sites (outside of Banner and UA) is required for UA IRB submission. This includes any locations where recruitment or any study activities are occurring. These locations may also need to be added as separate sites with the UA IRB. The regulatory team can help determine the regulatory requirements for external sites and assist to draft the external site authorization form, but it is the responsibility of the study team to gain approval from the external sites.
* Approval from the PI’s department is required for the UA IRB submission. The regulatory team will work with the study team to obtain this.
* Applicable biosafety and scientific review approvals are required for UA IRB submission. The regulatory team will be responsible for requesting these approvals as needed, but may request assistance from the study team in this process.



**Study Team Documentation and Regulatory Documents**

**For UA IRB submission** – required for all studies:

1. Principal Investigator CV (and Responsible Physician CV, if applicable)
2. CITI Human Subjects Research (Biomedical Research Investigator) and Native American Research training for all staff: <https://research.arizona.edu/compliance/human-subjects-protection-program/training-requirements>
3. UA Conflict of Interest training for all staff: <https://research.arizona.edu/compliance/office-responsible-outside-interests/individual-conflict-interest-research/conflict-interest-procedures>
4. UA HIPAA training for all staff: <https://research.arizona.edu/compliance/hipaa-privacy-program/hipaa-training-certification>

**At the time of submission to the IRB of record** – required as applicable:

1. 1572 or Investigator agreement
2. Sponsor’s financial disclosure form for Principal Investigator and Sub-Investigators
3. Medical license for PIs and Sub-Is
4. CITI Good Clinical Practice (GCP) for Clinical Trials with Investigational Drugs and Medical Devices training for all staff: <https://arizona.sabacloud.com/Saba/Web_spf/NA7P1PRD161/common/learningeventdetail/crtfy000000000003169>
5. CVs for all other staff – for investigators, must be signed and dated within 2 years
6. IATA training for coordinators if samples will be shipped: <https://risk.arizona.edu/training/shipping-hazardous-materials>
7. UA Box Health training for all staff using UA Box Health to store or access study data: <https://research.arizona.edu/compliance/hipaa-privacy-program/ua-box-health>
8. OnCore training – required for at least one staff member to be able to enter subject data: <https://ctapps.uahs.arizona.edu/oncore/training-and-consultations>
9. eReg training – required for staff who will sign or view documents in the UAHS electronic regulatory binder system