Policy: Regulatory Management Responsibilities

1. **Purpose:** Define responsibilities for UAHS Research Administration Regulatory Coordinator and UAHS clinical research coordinator regarding regulatory management of studies that use UAHS Research Administration regulatory services

2. **Scope:** UAHS Research Administration Regulatory staff and UAHS clinical research staff

3. **Definitions**
   - BUMC: Banner University Medical Center
   - CATS: Clinical and Translational Sciences Research Center
   - CDA: Confidential Disclosure Agreement
   - COI: Conflict of Interest
   - CRC: clinical research coordinator (synonymous with study coordinator)
   - CTA: Clinical Trial Agreement
   - eReg: Electronic Regulatory Binder
   - HSPP: Human Subjects Protection Program
   - IB: Investigator Brochure
   - ICF: Informed consent form
   - IDE: Investigational Device Exemption
   - IND: Investigational New Drug
   - IRB: Institutional Review Board
   - NCT: National Clinical Trial
   - PA: Protocol amendment
   - PI: Principal Investigator
   - PSP: Protocol Signature Page
   - PSSV: Pre-study Site Visit
   - RA: Research Administration
   - RIA: Research Intake Application
   - SIV: Site initiation visit
   - Sub-I: Sub-Investigator (synonymous with Co-I/Co-Investigator)
   - UA: University of Arizona
   - UAHS: University of Arizona Health Sciences

4. **Procedure Outline**

   1. UAHS Research Administration Regulatory Contact
      a. Email: regulatory@arizona.edu
      b. Set up a meeting through Microsoft Bookings
      c. UAHS RA Regulatory website: https://research.uahs.arizona.edu/regulatory/home
      d. Contact individual regulatory staff through direct email or Microsoft Teams

   2. Introduction: UAHS RA regulatory support services are available to all faculty members of UAHS. If PI chooses to utilize the UAHS RA Regulatory team to provide regulatory coordination services, most regulatory concerns for the study will handled by the UAHS RA regulatory coordinators.
      a. Even if a study uses a departmental regulatory coordinator, the study team can reach out to the RA regulatory staff for advice on general regulatory questions.

3. Site Selection: The study team has the primary responsibility for activities during the site selection stage (if applicable), but the UAHS RA regulatory team is able to assist with some parts of this process.
    a. CDA submission: The UAHS RA regulatory team can submit CDA templates to the UAHS Contracts team upon request. Study teams should provide the CDA template and sponsor contact information.
    b. Regulatory information: The UAHS RA regulatory team can provide regulatory information for the completion of site selection or feasibility questionnaires.

TASKS AND RESPONSIBILITIES – Site Selection		
	UAHS RA Regulatory	**Study Team**
Communication	Submit CDA to UAHS contracts department upon request.	Communicate with sponsor regarding site selection processes.
	Provide requested information regarding site regulatory processes and requirements.	Complete and submit any site selection or feasibility questionnaires.
		Coordinate and conduct any pre-study site visits

4. Study Start-up: The regulatory team will work closely with the study team and sponsor (if applicable) to establish key information about the study and initiate start-up submissions.
    a. The RA regulatory staff will complete most aspects of start-up submissions. The primary exception is approvals from UA departments outside the PI's (e.g. CATS approval), which should be submitted by study staff.
    b. The study team will need to complete the first three pages of the UAHS RA Regulatory Startup Questionnaire in order to begin the startup process.
    c. Study staff should work with RA regulatory staff to provide study information and facilitate communication with the PI throughout start-up.

TASKS AND RESPONSIBILITIES – Start-up		
	UAHS RA Regulatory	**Study Team**
Communication	Communicate with sponsor regarding timelines, consent forms, regulatory documents, and other regulatory questions.	Provide requested information about study plans to regulatory staff.
	Facilitate communication regarding contract/budget negotiations between study team, sponsor, and negotiations team	Forward emails, documents, and regulatory inquiries received from sponsor to regulatory staff.
Document Management	Determine if shared digital regulatory folder will be used. If yes, create folder if one does not already exist and upload start-up documents.	Assist in obtaining PI and Sub-I signatures/approvals as requested by regulatory staff.
	Create eReg digital regulatory binder.	Provide CVs and training documentation as requested by regulatory staff.
	Advise study staff on physical regulatory binder and filing requirements.	Prepare physical regulatory binder and file regulatory documents as they become available.
Approvals	Prepare and submit RIA, IRB, and other	Submit for applicable UA departmental

	required reviews.	approvals (e.g. CATS) and forward to regulatory staff when complete.
	Keep PI, study team, and sponsor updated on progress of reviews.	Complete COI certification and help remind PI and Sub-Is to complete certification, as request by regulatory staff or the COI office.
OnCore	Add basic study information to OnCore.	

5. Study Activation: In order to activate a study and start enrolling, the following must occur:
    a. Approval must be received from all of the following groups/individuals:
        i. IRB of record
        ii. UAHS RA Clinical Trials and Contracts department
            1. Coverage Analysis (CA), Budget, and Contract finalization (as applicable)
        iii. PI
        iv. Sponsor
        v. Banner and UA departments where study activities will occur
    b. The RA regulatory coordinator will notify the study team when IRB approval and UAHS RA Clinical Trials approval are received. The study team will work with the PI, sponsor, and Banner/UA departments to ensure that all parties are ready to start enrollment.
    c. Study staff should notify the RA regulatory coordinator as soon as they know when enrollment will open. This will ensure that OnCore and other study records are updated appropriately.
    d. In this phase, primary responsibility for communication with the sponsor will shift from the RA regulatory coordinator to the study team. The regulatory staff will remain available as a point of contact for regulatory topics.

TASKS AND RESPONSIBILITIES – Activation		
	UAHS RA Regulatory	**Study Team**
Document Management	Provide initial IRB approval documents to study coordinator and upload to OnCore, eReg, and any shared digital regulatory folder.	Print and file initial IRB approval documents, sponsor communications, and regulatory documents in physical regulatory binder.
	If there is a shared digital regulatory folder, upload approved ICF(s) to ICF/Consents folder and confirm that approved Protocol and IB are uploaded to Protocol and IB folders.	If there is a shared digital regulatory folder, upload approved subject and recruitment documents to subject material and recruitment folders. Subject and recruitment documents are the responsibility of CRCs to update, as they will have the best understanding of the purpose of each document and where it is most appropriately filed.
	Send approved ICF(s) to RA Clinical Trials team for project finalization.	If there is not a shared digital regulatory folder, study team will be responsible for maintaining their own electronic regulatory files in addition to the physical regulatory binder.
Communication	Notify study team when UAHS RA clinical trials/contracting has signed off	Work with sponsor to set up SIV and coordinate shipping of study supplies.

	on study activation.	
	Ensure that current study coordinators are listed as staff/contacts with the IRB of record, as applicable	Notify RA regulatory staff when the study opens to enrollment.
OnCore	Mark study as Open to Accrual in OnCore once notified that the study has opened to enrollment.	If possible, notify OnCore staff two weeks prior to the first expected subject visit to ensure that the calendar can be built prior to subject enrollment.
	Ensure that study staff, study sites, and disease/diagnosis information is correctly entered in OnCore	Validate OnCore calendar when alerted by OnCore staff.

6. On-going Regulatory Maintenance: The RA regulatory staff and study team will work together to maintain regulatory compliance after the trial has been opened.
    a. There are a number of study documents that must be processed and/or approved when they are added to a study or updated.
        i. Documents that require IRB approval prior to use
            1. Protocol documents – protocol amendments, addendums, and administrative changes
            2. Informed consents and informed consent addendums
            3. Recruitment documents and other documents that subjects will see
            4. Investigator brochure
            5. Other documents sponsor has provided to the IRB for review
        ii. Documents that require RA Clinical Trials processing. (IMPORTANT – implementation of protocol amendments and consent forms should NOT be delayed for RA Clinical Trials processing. Protocol amendments should be implemented as soon as IRB and sponsor approval is provided; consent updates should be implemented as soon as they are received from the IRB.)
            1. CTA amendments
            2. Budget amendments
            3. Protocol amendments and addendums
            4. Coverage Analysis amendments/updates
            5. Informed consents and informed consent addendums
            6. PI changes
    b. Study staff will remain the primary contact with sponsors and/or central sites. However, regulatory documents and study modifications will still be processed by the RA regulatory coordinator. If the study staff do not see regulatory@arizona.edu or the individual RA regulatory staff as recipients on emails regarding regulatory issues, they should forward these emails to the RA regulatory team.
        i. The RA regulatory coordinator will receive documents and communications from the UA IRB, Advarra, WCG IRB, Alpha IRB, and Sterling IRB automatically so these do not need to be forwarded

TASKS AND RESPONSIBILITIES – On-going Maintenance		
	UAHS RA Regulatory	**Study Team**
Approvals	Submit modifications and renewals to RIA and/or IRB, as needed.	Forward all documents received from IRBs not mentioned in 5.b.i above to RA regulatory coordinator.

Communication	Communicate with study team, sponsor, and RA Clinical Trials department regarding progress of modifications.	Respond to RA regulatory staff questions regarding information for renewals and RIA submissions.
	Update sponsor regarding changes to study personnel and ensure current study coordinators are contacts with IRB of record.	Notify RA regulatory coordinator when personnel are added to or removed from the study team.
	Respond to sponsor requests for regulatory information or documents.	Communicate with PI and sponsor regarding conduct of the study, monitoring visits, etc.
		Notify RA regulatory coordinator when the study has closed to enrollment.
Document Management	Provide IRB approvals and approved documents to study coordinator and upload to OnCore, eReg, and any shared regulatory folder.	Forward protocol documents, informed consent updates, and contract/budget amendments received from PI or study sponsor to RA regulatory coordinator.
	If there is a shared regulatory folder, upload approved protocol documents and informed consent documents to Protocol and ICF/Consents folders.	Assist in obtaining PI and Sub-I signatures/approvals as requested by regulatory staff
	If documents (e.g. protocols and IBs) are not posted by the IRB and are not already in a shared regulatory folder, communicate with study staff and the sponsor to locate the documents	Provide CVs and training documentation as requested by RA regulatory staff
	Send approved ICFs to RA Clinical Trials team for amendment finalization.	If there is a shared regulatory folder, upload approved subject and recruitment documents to appropriate folders upon receipt from RA regulatory coordinator.
	Maintain eReg digital regulatory binder.	If there is not a shared digital regulatory folder, study team will be responsible for maintaining their own electronic regulatory files in addition to the physical regulatory binder.
		Print and file approvals, approved documents, updated regulatory documents, and sponsor communications. Properly dispose of unused/blank documents that have been superseded. (Documents that have already had information entered should NOT be disposed of and should be retained in the appropriate study binder.)
Protocol Deviations	Submit protocol deviation reports to IRB of record (and UA IRB, if applicable) and forward approvals to study team when complete.	Notify RA regulatory staff when protocol deviations are identified and provide relevant information as requested. File documents to the subject and regulatory

		binders, as applicable.
Reconsent	Review IRB approval letters for new consent forms and alert study staff to reconsent requirements. Update OnCore with reconsent requirement.	Review RA regulatory staff communications and ICF approval letters to identify reconsent requirements and prepare study binder accordingly.
OnCore	Updating key protocol information: • General protocol details • Accrual goals • Study sites (e.g. CATS, BUMC-T) • Diagnoses associated with the study • Study staff • IRB review dates and documents • Study status • Study expiration date	Entering and updating subject information: • Enrollment (either individual subjects or summary accrual, as applicable) • Consent and re-consent • Study visits • Study completion
	Respond to OnCore audits or queries related to topics listed above.	Respond to OnCore audits or queries related to topics listed above.

7. Study Closure: When the study is complete, the RA regulatory staff and study team will work together to ensure it is closed out appropriately.

TASKS AND RESPONSIBILITIES – Closure		
	UAHS RA Regulatory	**Study Team**
Communication	Provide any missing regulatory documents to sponsor.	Work with sponsor to set up closure visit and manage data finalization.
		Notify RA regulatory staff when sponsor has provided approval for IRB closure.
		Respond to RA regulatory staff questions regarding information for closure report.
Approvals	Submit closure report to IRB of record.	Print and file the closure approval.
Document Management	Provide IRB closure report and approval to study coordinator and sponsor, and upload to OnCore, eReg, and any shared regulatory folder.	Send physical binders to Archives per department standard procedures.
OnCore	Enter IRB closure review and update study status to IRB Closure.	Ensure all participants have been marked as Off Study.

Version 1.0 (DATE month/day/year) Revision History Log:

Version Number	Revision Date	Author	Changes
1.0	01/06/2023	Kirsten Anderson	Drafted