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The Cycle of a Clinical Trial

Our office provides clinical trial support to investigators, research nurses, and study staff at the Colleges of Medicine (Tucson & Phoenix), Pharmacy, Nursing, Public Health, and the Cancer Center. Our team of experienced and knowledgeable research administrators and coordinators can assist you with all aspects of clinical trials from feasibility through closure.

RESEARCH INTAKE APPLICATION (RIA) & BANNER FEASIBILITY REVIEW

STEP 1

All submissions involving patients, facilities, services, health records, or resources of a clinical provider must be submitted via the online Research Intake Application (RIA) prior to submission to the University of Arizona Institutional Review Board (IRB).

Applications are on our website: <http://research.uahs.arizona.edu/clinical-trials/research-intake-form>

Completed application packets should be submitted to: ResearchApp@email.arizona.edu

For questions contact us at: CRC@email.arizona.edu

REGULATORY & IRB

STEP 2

We provide regulatory support to investigators within UAHS as well as navigation guidance for the UAHS research processes. We have dedicated staff, with years of experience, available to assist with the IRB and regulatory processes including: protocol/informed consent development, study start-up & maintenance throughout the research project, and assistance with ClinicalTrial.gov submissions. For questions contact us at: regulatory@email.arizona.edu

COVERAGE ANALYSIS (CA)

STEP 3 & 4

UAHS and our medical partners require CA source documentation. The CA details all required study procedures and documents Medicare billing determinations of who is responsible for payment of each each research activity before the clinical trial begins. The CA is required for all clinical trials and the documentation and designation of research procedures is used to ensure that the informed consent form (ICF), external budget, billing grid of clinical care expenses, and contract are congruent. For questions contact us at: CRC@email.arizona.edu

BUDGET DEVELOPMENT

Our team of experienced budget negotiators utilize the CA, extensively review the research protocol, and work with the research team to develop a comprehensive budget. This ensures that all associated research costs are accounted for and incorporated into the budget. Current research pricing is received from our medical partners and is based on Fair Market Value (FMV) pricing. Our team negotiates the budget and payment terms directly with sponsors. For questions contact us at: CRC@email.arizona.edu

CONTRACT SUPPORT

STEP 5

UAHS Research Administration works directly with our medical partners and the research sponsor to facilitate execution of these time-sensitive documents including Confidential Disclosure Agreements (CDA), Material Transfer Agreements (MTA), Research Collaborations, Clinical Trial Agreements (CTA), student/resident rotation contract requests, and many more.

For questions contact us at: UAHSContracts@email.arizona.edu

POST-AWARD ACCOUNT SET-UP

STEP 6

Our office assists departments with clinical trial account reconciliation (including account financial reports on a bimonthly basis and meeting with departments/programs on a regular basis to discuss financial health). We work directly with study sponsors to issue requests for payment, follow-up on outstanding invoices, budget forecasting, and account payable functions.

For questions contact us at: CTFinance@email.arizona.edu



Pre-Award Services

Please contact our office at preaward@email.arizona.edu as early as possible to discuss upcoming submission plans, so we can assist with timelines, document preparation, and facilitate the grant process for you!

Proposal Development

- Identification of award opportunities
- Maintain core facilities descriptions
- Maintain T32 tracking database

Pre-Award Grant Submission

- Assistance with eligibility determination
- Budget & justification development
- Document assistance: biosketch, facilities, current & pending support, letters of support
- Subaward proposal organization
- Internal routing & compliance
- Application assembly
- Submission through SPCS and/or sponsor portal*
- Just-in-Time and Post-submission Assistance

Post Award Activities

- Supplemental application development & submission
- Re-budget, no-cost extension request, & other prior approval requests to Sponsor
- RPPR/Progress report assistance & submission
- Internal routing for administrative & budgetary changes
- Grants transfers (incoming & outgoing)
- Assistance with Public Access Compliance

*Sponsored Projects & Contracting Services must receive the proposals in final form (completely approved in UAccess Research and ready for submission to the sponsoring agency) three full business days prior to your sponsor's due date. SPCS will continue to review proposals in the order they are prioritized (first-in, first-out) but there is no guarantee of submission by the sponsor deadline if they have not met the three-day deadline.



Contact Information

Website <http://research.uahs.arizona.edu/>

For Contracting Support:

UAHSContracts@email.arizona.edu

UAHS Contracting questions and assistance including: clinical trials, material transfer agreements, confidentiality agreements, data use agreements, research collaborations, new student/resident service rotation contract requests, and more.

For Research Intake Applications:

ResearchApp@email.arizona.edu

Research application submission for new projects, amended projects, and retrospective chart reviews.

For Clinical Trials:

CRC@email.arizona.edu

Coverage analysis, budget development and negotiation support. Research Intake Application (RIA) questions.

For Clinical Trial Post-Award:

CTFinance@email.arizona.edu

Clinical Trial account reconciliation, sponsor payments, budget forecasting, and accounts payable functions.

OnCore Support:

OnCoreSupport@email.arizona.edu

CTMS questions, training, inquiries, updates and general questions.

For New Grants: Pre-Award

Preaward@email.arizona.edu

Grant pre-award questions including new submissions, searching for grant funding, advice on submission strategy, and letters of support

For Existing Grants: Post-Award

Postaward@email.arizona.edu

Grant post-award questions including post-award management services (progress reporting and closeout), guidance on expenditure allowability, interpreting sponsor and institutional policies, and regulations.

For Clinical Research Operations Support:

VPHS-CRO@email.arizona.edu

Clinical research questions, open clinical trial listings, study coordinator services, study preparation, and management questions.

For Regulatory Support:

Regulatory@email.arizona.edu

Regulatory submission assistance, Research Intake Application (RIA) navigation and questions, ClinicalTrials.gov, and general questions.





Research Administration Services



Proposal Development

- Find grant opportunities
- Coordinate internal grant competitions
- Maintain description of core facilities services
- Develop and maintain trainee tracking database (T32s)



Grants

- Budget development
- Prepare grant administrative sections
- Provide institutional support letters
- Secure institutional endorsements
- Route for internal approvals
- Submit grant to external sponsor
- Progress reports
- Consulting agreements, subawards
- Grant close-outs & no-cost extensions
- Data reports and metrics
- Departing PI transitions
- Sponsor prior approval & carryforward requests
- Public Access Compliance



Contracts

- Receipt of award
- Interpret terms and conditions as well as sponsor requirements
- Offer consultations with faculty seeking external funding and explain university requirements relative to funding
- Negotiate terms and conditions with sponsors
- Sign the negotiated agreement



Regulatory

- IRB application preparation and submission
- Sponsor start-up documents
- Protocol & informed consent development and review
- Regulatory file maintenance
- Clinicaltrials.gov
- Research intake application (RIA) system navigation & guidance



Clinical Trials

- Research intake application (RIA) management
- Coverage Analysis development
- Budget development, negotiation
- Secure institutional endorsement for CTAs, CDAs, MTAs, amendments
- Monthly Newsletter for Research Community
- Visit earning reconciliation, invoicing
- Cash collection, deposits



OnCore Support

- Management of clinical research studies in OnCore
- Assistance with system use, protocol updates, financial management
- Training and support for research study staff