# Key Study Personnel Information

## Investigators

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| --- | --- |
| **Faculty/Administrative/Regulatory Offices**Enter appropriate address **Outpatient Clinic/Lab/Pharmacy**Enter appropriate address **NP Investigator Address**Enter appropriate address  | **PI Name:****Phone:** **Email:** **Sub-I Name:****Phone:** **Email:**  |

## Pharmacy – Outpatient – IP/Drug Shipment

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| --- | --- |
| **IP/DRUG SHIPMENT ADDRESS:**Enter appropriate address ***PLEASE use this email address for ALL CORRESPONDENCE:*** | **Pharmacist Name:** **Email:****Phone:****Fax:** **Pharmacy Tech name:****Phone:** **Fax:** **Email:**  |

## Pharmacy – Inpatient

|  |  |
| --- | --- |
| **N/A** | **N/A** |

## Lab– Central Lab Kit Supplies Shipping Address

|  |  |
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| **Central Lab Kit Supplies Shipping Address:**Enter appropriate address **Overflow Storage Location:**Enter appropriate address  | **Coordinator name:** **Phone:** **Fax:** **Email:**  |

## Research Nurse (RN) Coordinator(s)

|  |  |
| --- | --- |
| Enter appropriate address  | **RN Name:** **Phone:****Email:**  |

## Clinical Research Coordinators (CRCs)

|  |  |
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| **Subject Materials Shipping Address:**Enter appropriate address  | **Coordinator name:** **Phone:** **Fax:** **Email:**  |

## Regulatory Coordinator / Project Manager

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| Enter appropriate address ***\* Study Start-Up POC; also contact for safety reports*** | **Name:** **Fax:** **Email:**  |

## Monitoring Information

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| **Source Documentation Review at:** Enter appropriate address  ***REMOTE*** **Remote EMR (Cerner) Access:**to be granted by CRC during scheduled IMV  | **Source Review Monitor Room** **Update with room info. e.g. Wi-Fi, phone, printer, etc.** |

# Financial & Contract Information

## Legal Institution – Master Address

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| --- |
| Arizona Board of Regents on behalf of the University of Arizona888 N. Euclid Avenue, Room 510Tucson, AZ 85719Phone: 520-626-6000Fax: 520-626-4137Email: sponsor@email.arizona.edu For pre-award communications, please email CRS-ORD@email.arizona.edu  |

## Contract & Budget

|  |  |
| --- | --- |
| Health Sciences Innovation BuildingUniversity of Arizona Health SciencesResearch Administration1670 E Drachman StTucson, AZ 85719 | All contract and budget information should be communicated through the IRB/Regulatory Coordinator(s) during initial submission and study start-up processes. **When a negotiator is assigned to the project, he/she will reach out to the sponsor/CRO directly.**PLEASE DO NOT send protocol amendments, CTAs, or budgets directly to Contract/Budget team or to the clinic staff (CRCs, RDCs or RNs) – **DO send to Regulatory Coordinator and PI.** |

## Accounts Receivable & Invoicing

|  |  |
| --- | --- |
| Enter appropriate address  | **Name:****Phone:** **Email:**  |

## Payment / Notice Address

|  |  |
| --- | --- |
| The University of Arizona Sponsored Project ServicesPO Box 210158, Room 510Tucson, AZ 85721-0158Phone: 520-626-6000Fax: 520-626-4137Email: sponsor@email.arizona.edu  | **If sent by USPS:**The University of Arizona (KFS # )Sponsored Projects Services/Bursar Office1303 E. University Blvd., Box 3Tucson, AZ 85719-3520**If sent by overnight delivery service:**The University of Arizona (KFS # )Sponsored Projects Services/Bursar Office888. N. Euclid, Room 104Tucson, AZ 85719P: 520-621-1998 |

## Payee Tax ID #

|  |
| --- |
|  |

## Individual to Sign Contract

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| --- |
| **Elisha Johnson, JD**Assistant Director, Research AdministrationPhone: 520-626-7822Email: elishajohnson@email.arizona.edu  |

##  Other Individual to Sign Contract

|  |
| --- |
| **Principal Investigator** |

## Institution Contact for Administrative Matters

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| **Name:****Address:****Phone:****Fax:****Email:** |

# Start-Up Committees & Process

## Overview

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| All start-up activities are coordinated by the Regulatory Coordinator.Total time for start-up activities is *estimated* at **16-20 weeks**, *highly* dependent on CTA/budget negotiation timelines.1. Clinical Research Team Review
2. Simultaneous prep and submission:
	* University of Arizona Health Sciences (UAHS) / Banner Health (Hospital Partner) Feasibility Review – Research Intake Application (RIA) Submission \*
	* Radiation Laboratory Safety Services (RLSS – UAHS) / Radiation Safety Committee (RSC – Banner) for Radiation Safety Review
	* Institutional Biosafety Committee (rarely needed)
	* ICF Review and finalization
3. Simultaneous prep and submission:
* UA IRB (Human Subjects Protection Program) Initial Submission for Deferral Review
1. Central IRB (WCG or Advarra)
2. SIV

\* *Completion of Banner Health Feasibility Review triggers assignment of CTA/budget negotiators to trial.**NOTE: all ‘Turnaround Times’ are estimated / approximate* |

## Clinical Research Team (CRT) Review

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| --- | --- | --- | --- |
| **Meeting Frequency** | **Turnaround Time** | **Required Documents** | **Notes** |
| Updated as appropriate  | Updated as appropriate  | Protocol, site selection letter/status | Study team reviews for study resources, PK schedule, special requirements (e.g. dermatology, ophthalmology, interventional radiology, etc.) |

## Simultaneous Prep & Submissions

### UAHS / Banner – RIA Submission

|  |  |  |  |
| --- | --- | --- | --- |
| **Meeting Frequency** | **Turnaround Time** | **Required Documents** | **Notes** |
| N/A – RIA submission triggers multiple reviews (i.e., Banner Feasibility, Coverage Analysis, Budget, and Contract) | Banner Feasibility:2 – 6 weeksCoverage Analysis: 4 – 6 weeksContract and Budget:90 – 120 days | Protocol, IB, ICF, subject materials, draft UA (local) IRB application, draft budget/contract | **Internal portal submission for UA and Banner feasibility and official submission of contract and budget.*****Budget-specific timeline process:***The first step in our budgeting process is to create a Payor Coverage Analysis (PCA). The PCA consist of reviewing the protocol and schedule of events to determine the study activities that are research related vs. conventional care. Once the PCA has been completed and approved by our medical partner, then budget negotiations will begin.***Contract/budget submission:***The University of Arizona Medical Center works in affiliation with Banner Health. Send all initial documents to the regulatory/start-up coordinator. All protocols must go through internal resource review before the budget/contract can be submitted for negotiations. Once these documents are submitted to our budget and contracts teams, they undergo internal review with Banner for feasibility. Once feasibility review is completed, a UA contract negotiator will be assigned to your study. This is considered “Day 0.” The University’s contract office completes its initial review of the contract terms, and the document is then sent to Banner’s legal department for review. Once all initial changes from both parties are consolidated, the UA contract negotiator will reach out to you directly with any redlined edits. Our institution has a goal of having the contract and budget executed within 90 days of Day 0. However, because Banner’s review is an independent process, we are not able to provide a timeline for their response. *Note: FE CTA/budget* ***NOT*** *required for IRB submission.* |

### RLSS/RSC (Radiation Safety) Review

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| **Meeting Frequency** | **Turnaround Time** | **Required Documents** | **Notes** |
| As needed | 2 weeks | Protocol, IB, tracked ICF radiation risk language, RLSS/RSC cover sheet | Email submission to RLSS (UAHS):rlss-help@email.arizona.edu; harris23@arizona.edu Email submission to RSC (Banner):daniel.silvain@bannerhealth.com; sydney.goosen@bannerhealth.com  |

### Institutional Biosafety Committee (IBC) Review

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| --- | --- | --- | --- |
| **Meeting Frequency** | **Turnaround Time** | **Required Documents** | **Notes** |
| Once monthly3rd Wednesday | 3 business days | Protocol, IB, tracked ICF radiation risk language, IBC submission forms | Email submission to:rlss-help@email.arizona.edu; rlss-committee-support@email.arizona.edu  |

### ICF Review & Finalization

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| **Meeting Frequency** | **Turnaround Time** | **Required Documents** | **Notes** |
| N/A | varies | ICF template | ICF is first tracked by the IRB/Regulatory coordinator (inserts required UA/Banner language), then is reviewed and approved by RLSS, UAHS Finance team, and sponsor/CRO.Note: multiple ICF reviews by the Sponsor will likely be required prior to final approval as Finance routinely provide required ICF edits/language at different points in the review process***Spanish translations are requested due to UAHS’s high volume of Spanish-speaking subjects.*** |

## Simultaneous Prep & Submissions

### UA IRB Submission

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| --- | --- | --- | --- |
| **Meeting Frequency** | **Turnaround Time** | **Required Documents** | **Notes** |
| Expedited Chair Review:*For deferral to central IRB*Reviewed by IRB staff in the order receivedFull Committee Review:  *For trials with UA IRB as IRB of record*Twice monthly2nd Tuesday,4th Tuesday | 1 – 2 weeksDependent on pre-review questions | Protocol, IB, final tracked ICF, subject materials, TRRW approval, RLSS/RSC approval, Banner feasibility approval, UA IRB applicationU of Arizona IRB, FWA: 00004218 | **Christine Melton-Lopez**Director, Human Subjects Protection Program1618 E. Helen StreetTucson, AZ 85721Phone: (520) 626-8630Email: melton1@arizona.edu Central Email: VPR-IRB@email.arizona.edu Website: <https://rgw.arizona.edu/compliance/human-subjects-protection-program> Submit at least 2 weeks prior to meeting. Pre-review edits must be complete 1 week prior to meeting.Expedited Chair Review Fee = $1,000; Full Committee Review Fee = $2,500 |

## Central IRB (WCG or Advarra) Submission

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| --- | --- | --- | --- |
| **Meeting Frequency** | **Turnaround Time** | **Required Documents** | **Notes** |
| Twice weekly | WCG: 1 week or lessAdvarra: 2 – 3 weeks | Protocol, IB, final tracked ICF, Subject Materials, UA IRB deferral approval | WCG IRB1019 39th Ave, SE Suite 120Puyallup, Washington 98374-2115Telephone: 855-818-2289Email: researchquestions@wcgirb.com UACC is required to submit on behalf of the site PI rather than sponsor/CRO central submission.UACC typically requests Spanish translations from WCG unless the sponsor/CRO has a preferred vendor. |

## SIV

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| --- | --- | --- | --- |
| **Meeting Frequency** | **Turnaround Time** | **Required Documents** | **Notes** |
| N/A | N/A |  | **Required approvals**: **Finalized CTA/budget, Central IRB approval, SRC approval** |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Version Number** | **Revision Date** | **Author** | **Changes** |
| 1.0 | 1/27/2023 | Gustavo C. | Drafted |
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