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| **SUBMISSION DETAILS** | |
| Full Study Title  (as provided in the study protocol) |  |
| Study Short Title\* |  |
| Sponsor Protocol Number\*  (as provided by the sponsor) |  |
| Principal Investigator\* |  |
| Submitter\*  (Name only) |  |
| Primary Study Coordinator\*  (Name only) |  |
| IRB Coordinator\*  (Name only) |  |
| Department ID\*  (ex. 23060000) |  |
| OCR #  (if available) |  |
| IRB #  (if available) |  |
| IRB of Record  (IRB01, WIRB, Advarra, etc.) |  |
| NCT ID  (if available) |  |
| OnCore Management Groups |  |

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| **SUBMISSION DOCUMENTS** | **Is This Document Required?** | **Not Applicable** |
| Study Protocol | Required, if not applicable please clarify below |  |
| Informed Consent Form | Required unless a waiver will be requested from the IRB |  |
| Budget | Required for all externally funded projects |  |
| Clinical Trial Agreement;  Funding Agreement;  Grant Award;  Contract; | Required for all externally funded projects |  |
| CMS Pre-Approval (CED/IDE/CAS) | Required for [CED](https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index), [IDE](https://www.cms.gov/Medicare/Coverage/IDE/index), or [CAS](https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Carotid-Artery-Stenting-CAS-Investigational-Studies) studies that will bill insurance (IDE studies cannot begin MCA without Approval Letter) |  |

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| **DRUG, DEVICE AND EQUIPMENT** |  |  |  |
| **Does your study include any of the following?** | **Yes** | **No** | **Notes/Description** |
| **DRUGS**: Named drugs or biologics |  |  | IF YES, INCLUDE [DRUG TABLE](https://clinicalresearch.ctsi.ufl.edu/resources/forms/drug-table/) |
| **DEVICES**: Named devices used with at least one patient |  |  | IF YES, INCLUDE [DEVICE TABLE](https://clinicalresearch.ctsi.ufl.edu/resources/forms/device-table/) |
| **EQUIPMENT**: Equipment provided by an external organization (e.g. iPads, laptops, cameras, e-diaries, wearable devices) |  |  | IF YES, DESCRIBE BELOW\* |
| **EQUIPMENT DESCRIPTION**: | | | |

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| **EXTERNAL ENTITY SUPPORT NAME** | **Sponsor** | **Funding Source** | **CRO** | **Drug/Agent/Device/Equipment** | |
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| **STUDY INFORMATION** | | | | | |
| How will this study be funded?\* | | | | | Choose an item. |
| Does your study involve the VA in any way? | | | | | Choose an item. |
| Will your study team conduct research on the Jacksonville campus? | | | | | Choose an item. |
| Will your study team conduct research in any location other than Gainesville and Jacksonville? | | | | | Choose an item. |
| Is your study [cancer-relevant](https://cancer.ufl.edu/research/clinical-trials-office-2/scientific-review-and-monitoring-committee/what-is-the-srmc/)?\* | | | | | Choose an item. |
| Have you submitted your study to the Cancer Center Scientific Review Committee (SRMC)?\* | | | | | Choose an item. |
| What type of protocol is this?\* | | | | | Choose an item. |
| Is this study a clinical trial? | | | | | Choose an item. |
| What is the study population?\* | | | | | Choose an item. |
| TARGET # of participants to enroll at UF | | | | |  |
| MAXIMUM # participants to enroll at UF | | | | |  |
| # years expected to be open to enrollment at UF | | | | |  |
| # participants for overall study (multisite only) | | | | |  |

# OCR Financial Services

Please provide any details OCR should consider when processing your submission/determining the work flow:

Does your study involve any of the following?

Externally sponsored clinical trials budget

Sponsor invoicing based on subject milestones or enrollment

None of the above (**SKIP TO** [**OCR CONTRACTING SERVICES**](#_OCR_Contracting_Services))

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| --- | --- | --- | --- |
| **BUDGET CONTACT INFORMATION** | **Name** | **Email** | **Phone** |
| **UF** Budget Contact |  |  |  |
| **Primary Unit Admin Contact (PUAC)** for financial management\* |  |  |  |
| **SPONSOR** Budget Contact |  |  |  |
| **BUDGET AND SPONSOR INVOICING** | | | |
| What is the current status of the budget? | | Choose an item. | |
| Will you need OCR to help obtain pricing requests for budget negotiation with sponsor? | | Choose an item. | |
| Date budget was received from the sponsor | | Click or tap to enter a date. | |
| Who will handle sponsor invoicing/payment reconciliation?\* | | Choose an item. | |

# OCR Contracting Services

Does your study involve any of the following?

Contract or master agreement

A sponsor who will provide equipment, drugs, etc.

Outgoing subcontract(s)

Data Use Agreement (DUA), Letter of Indemnification (LOI), Material Transfer Agreement (MTA), MOU, etc.

None of the above (**SKIP TO** [**RESEARCH BILLING COMPLIANCE ASSESSMENT**](#_Research_Billing_Compliance))

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| **CONTRACT CONTACT INFORMATION** | **Name** | **Email** | **Phone** |
| **UF** Contracting Contact |  |  |  |
| **SPONSOR** Contracting Contact\* |  |  |  |
| **CONTRACTING SERVICES** | | | |
| Which Department will handle the contracting for this study? | |  | |
| Does the PI have intellectual property that needs to be protected?\* | | Choose an item. | |
| Who wrote the scientific protocol? | | Choose an item. | |
| What are your expectations regarding the sponsor’s willingness to pay for subject injury costs?\* | | Choose an item. | |
| UFIRST Proposal/Agreement Number (example: PRO0001234/AGR0001234) if already in UFIRST | |  | |

**Research Billing Compliance Assessment**

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| --- | --- | --- | --- | --- |
| **BILLING COMPLIANCE CONTACT INFORMATION** | **Not Applicable** | **Name** | **Email** | **Phone** |
| **UF** Contact for Coverage Analysis Questions |  |  |  |  |

Does your study include any of the following?

Ordering any items or services in Epic

Research-only visits in UF Health

Activities that prolong encounters billed according to time (e.g. OR; anesthesiology; physical therapy)  Services performed by UF Health clinicians

I’m not sure

None of the above (**SKIP** [TO OCR CALENDAR SERVICES](#_OCR_Calendar_Services))

**IF ANY OF THE ABOVE ARE APPLICABLE, PLEASE SUBMIT:**

[**PCR QUESTIONNAIRE FORM**](https://clinicalresearch.ctsi.ufl.edu/resources/forms/)

**OR A**

[**PAPER BILLING GRID.**](https://clinicalresearch.ctsi.ufl.edu/resources/forms/billing-grid/)

|  |  |  |  |
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| **Will your study involve services happening at any of the following locations?** | | | |
| **Ancillary** | **Yes** | **No** | **Notes/Description** |
| **Pathology** |  |  | If yes, please describe below. |
| Describe: IF YES, please include the completed [Pathology PCR form](https://clinicalresearch.ctsi.ufl.edu/resources/research-locations/lab-pathology/) | | | |
| **Shands OR/Anesthesiology** |  |  | If yes, please describe below. |
| Describe: IF YES, please include the completed applicable [OR/Anesthesiology Procedure Coding Request form(s)](https://clinicalresearch.ctsi.ufl.edu/resources/research-locations/or-anesthesiology-surgery/) | | | |
| **Sponsor Central Lab** |  |  | If yes, please describe below. |
| Describe: | | | |
| **Research Space** |  |  | If yes, please describe below. |
| Describe: | | | |

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| **OTHER SERVICE PROVIDERS (DIRECT BILL SERVICES)** | | |
| **Direct bill** services: select all that apply  (**NOTE**: Direct bill service estimates should be obtained by the study team) |  | Investigational Drug Service (IDS) |
|  | CTSI Clinical Research Center (CRC) |
|  | McKnight Brain Institute (MBI) |
|  | Other service provider (please list below) |
|  | None of the above |
| Please describe all **direct bill** services: | | |

# OCR Calendar Services

Which of the following apply to your study?

Patient-level services will be generated in Epic

Budget is visit-based

None of the above (**SKIP TO** [**RECRUITMENT SERVICES**](#_Recruitment_Services))

Are there any other details about the SOE/Calendar that you want to share?

|  |  |  |  |
| --- | --- | --- | --- |
| **CALENDAR SERVICES** | | **Notes/Description** | |
| Does your protocol include a schedule of events? Note: The schedule of events should be in the form of a table listing the study visits as a timeline, and the procedures and events associated with each visit. | Choose an item. | If the schedule of events is not in a table, one must be submitted using the [OCR SOE template](https://clinicalresearch.ctsi.ufl.edu/resources/forms/schedule-of-events). Please download, complete, and attach. | |
| **CALENDAR BUILD INSTRUCTIONS** | **Yes** | **No** | **Notes/Description** |
| Are there portions of the protocol that our site is NOT participating in? |  |  | If yes, please describe below. |
| Description: | | | |
| **EPIC CONFIGURATION INFORMATION** | | | |
| **UF** Contact for Charge Review Questions (Person Indicated ***MUST*** have an Active Epic User Account) |  | | |
| **Email** Address for Epic Generated Study-Funded Bills/Statements or Questions about the study |  | | |
| Should Research-Related Results (labs, procedures, etc.) be released to a patient’s MyChart (Yes/No) | Choose an item. | | |
| If no, what are the reasons for not releasing the results for this study? | Restricted (i.e. to protect the integrity of the data)  Double blinded  Single blinded  Other: Please explain if so. | | |
| Duration of the release restriction? | What is the duration of the restriction:  Always  While the patient is active on the study  While the study is active | | |
| Adverse Event Tracking in Epic? (Yes/No) | Choose an item. | | |

# Recruitment Services

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| **Do you plan to use any of the following for recruitment?** | **Yes** | **No** | **Next Steps** |
| **myChart** |  |  | If YES, please submit an IT Build request at <https://idr.ufhealth.org/services/analyst-data-support-services/idr-data-request-form/> |
| **CTSI Recruitment Center** |  |  | IF YES, someone from the CTSI Recruitment Center will contact you |
| Notes (optional): | | | |

# Other Applicable UF Health Policies

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **Next Steps** |
| **Supply Chain:** Will Shands need to purchase, receive, or store any device or equipment for this study? |  |  | IF YES, UF study team must notify **UF Health Shands Supply Chain Services** about any study device or equipment that will be purchased, received or stored by Shands Hospital.  For details, see <https://clinicalresearch.ctsi.ufl.edu/resources/uf-health-research-contacts/shands-supply-chain/> |
| **Clinical Engineering:** Will your study involve the use of non-Shands-owned clinical equipment in a Shands clinical location (e.g. ECG machines, etc.)? |  |  | IF YES, UF study team must contact **Shands Clinical Engineering** for inspection of any clinical equipment that will be used in Shands locations.  For details, see <https://clinicalresearch.ctsi.ufl.edu/resources/uf-health-research-contacts/shands-clinical-engineering-research-equipment-inspections/>  In addition, if using any non-Shands-owned **radiologic devices/equipment** in Shands locations, contact Jennifer Sirera ([bardej@shands.ufl.edu](mailto:bardej@shands.ufl.edu)) in Shands Radiology. |
| **UF Health Physicians Clinical Safety Committee:** Will your study involve use of investigational research drugs in a UFHP clinic? |  |  | UF study team must contact **UFHP Clinical Safety Committee** for approval of any investigational drug research activities in a UFHP clinic.  For details, see <https://clinicalresearch.ctsi.ufl.edu/resources/uf-health-research-contacts/ufhp-clinical-safety-committee/> |
| **Shands Nursing Impact Committee (RCIC):** Will your study involve any additional approval by the Shands Nursing Impact Committee? |  |  | The RCIC provides research implementation support for studies that requires resources from a Shands nursing team.  For details, see: <https://clinicalresearch.ctsi.ufl.edu/resources/uf-health-research-contacts/shands-nursing-impact-committee/> |

# **Anything Else**?

Provide any other details that you want us to know about your study: