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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**:  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EXTERNAL ENTITY SUPPORT NAME**  | **Sponsor** | **Funding Source** | **CRO** | **Drug/Agent/Device/Equipment** |
|  |[ ] [ ] [ ] [ ]
|  |[ ] [ ] [ ] [ ]
|  |[ ] [ ] [ ] [ ]
| **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))

|  |  |  |  |
| --- | --- | --- | --- |
| **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))

|  |  |  |  |
| --- | --- | --- | --- |
| **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**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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) 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: