|  |
| --- |
| **1.** Per OSF HealthCare (OSF) [policy](https://x.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies), investigators and research staff must comply with CITI education requirements PRIOR to submitting a study proposal for institutional permission. Refer to [“Forms, Templates & Policies”](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies) webpage for additional information.  |
| **2.** Per OSF policy, permission by OSF Research Administration is required prior to IRB submission for all research studies to be conducted at an OSF location, by OSF employees, or using OSF data. To request permission, complete this form electronically and email all required documents to OSF Research Administration. |
| **3.** If your research study involves obtaining clinical data through Ministry HealthCare Analytics (MHA), then you must complete an MHA Consultation PRIOR to submitting study materials for permission. To schedule a consultation, send your request AND a copy of your study proposal/protocol to Healthcare Analytics. Contact OSF Research Administration with questions about this requirement. |
| **4.** If your research study involves developing, deploying and/or optimizing technology and applications, then you must complete a feasibility consultation with OSF Information Technology PRIOR to submitting study materials for permission. To schedule a consultation, send your request AND a copy of your study proposal/protocol to OSF Information Technology. Contact OSF Research Administration with questions about this requirement. |
| **5.** If you are pursuing permission to use a Humanitarian Use Device (HUD) according to its Humanitarian Device Exemption (HDE) indications for *non-investigational* purposes, then DO NOT use this form. Complete and submit the [“Humanitarian Use Device (HUD) Application”](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies) form. If your **research** involves use of an HUD, then refer to the [“Humanitarian Use Device (HUD) Decision Tree”](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies) guide to learn more about investigational use of an HUD.  |
| **6.** Prior to completing and submitting this form, consult with the Clinical Research Business Office (CRBO) IF: (1) You plan to conduct study-related activities in a clinical setting; (2) The research study has funding from OSF, non-OSF sponsor or NIH grants; and/or (4) The research involves a contract or other legal agreement (e.g., Research Services Agreement). Find the CRBO forms [here](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies). |
| **7.** Visit the [OSF Research website](https://www.osfhealthcare.org/patients-visitors/clinical-research) for information on OSF research application procedures, forms, policies, templates, and training requirements. Use the following checklist to ensure inclusion of required/applicable documents with this OSF Research Application Form. [ ]  MHA Consultation (If applicable) [ ]  IT Feasibility Consultation (If applicable)  [ ]  Contracts and Agreements (e.g., CTA, LOI, MTA) – available draft versions, if not previously provided [ ]  Department, Committee and/or Facility Approvals – available approvals obtained prior to this application [ ]  IRB Initial Review Submission Form [ ]  Final Protocol [ ]  Investigator’s Brochure / Package Insert [ ]  Device Manual / Device Instructions for Use [ ]  Informed Consent and/or Parental Permission & Assent Forms, and HIPAA Authorization Form [ ]  Conflict of Interest Information [ ]  Recruitment Materials [ ]  Study Related Materials not incorporated into the protocol |
| **8.** If there are questions regarding the information requested on this application, contact the OSF Research Administration office via email or phone at 309-624-7556. |
| **9.** If there are questions about the investigator having the appropriate hospital privileges for the research, contact the OSF Credentialing Verification Office at 309-308-5050. |

Section I: Project/Protocol Identification

|  |
| --- |
| 1. **Project/Protocol Title (Full/Official):**
 |
| 1. **Short Title (if applicable):**
 |
| 1. **Protocol Number (Assigned by Sponsor):**
 |

Section II: Principal Investigator (PI) Information

|  |  |  |  |
| --- | --- | --- | --- |
| 1. **Last Name:**

      | **First Name:**      | **Degree(s):**       | **Job Title:**      |
| 1. **Employing institution(s) and department(s):**
 |
| 1. **PREFERRED Email Address:**
 |
| 1. **PREFERRED Phone Number:**
 |
| 1. **Download, complete, and submit OSF** [[**Research Significant Financial Interest Disclosure Form**](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies) (RSFIDF)](https://osf-p-001.sitecorecontenthub.cloud/api/public/content/7c4a25bd7626496c803c7b3eaee3a38c?v=b11406df) for an OSF employed PI. Non-OSF employed PI should submit with this application conflict of interest (CoI) documentation required by employing institution. (NOTE: If PI’s institution does NOT require formal submission of CoI documentation, then complete the OSF RSFIDF and submit with this application.)
2. **Is the PI a trainee (i.e., resident, fellow, or student) or nurse?**

**NOTE: If anticipated PI is a trainee, then confirm eligibility with appropriate academic department.** **[ ]  No (Skip to next** **section) [ ]  Resident [ ]  Fellow [ ]  Medical Student [ ]  Other Student** **[ ]  Nurse [NOTE: Nursing Administration Professional Practice Council (PPC) must review projects that Nursing staff and/or leadership** **propose.** **Contact Kim Cooley** **[ ]  Nursing Student > Complete i. and ii.:** **i. Provide the name of nursing student’s advisor:**       **ii. Has the research been approved by appropriate faculty (SFCN) or New Knowledge and**  **Innovation Committee (SACN/SAMC)? [ ]  No [ ]  Yes > Date:**  **Is the research being conducted as a school, program or residency requirement?****[ ]  No [ ]  Yes > Name of the school/program/residency:**       |

Section III: Primary Contact

|  |
| --- |
| 1. **Is the PI the Primary Contact? [ ]  Yes [ ]  No: If “no”, then complete remainder of section.**
 |
| 1. **Name:**
 | **PREFERRED** **Email Address:**       | **PREFERRED** **Phone#:**       |
| 1. **Employer:**
 |
| 1. **Role in this study (e.g., Investigator, Coordinator):**
 |

Section IV: Investigators and Staff Roster

|  |
| --- |
| 1. **Will this study have a team/staff supporting the PI by performing any of the following activities:**
* Providing substantial and/or substantive contributions to study conceptualization and/or design;
* Obtaining information about living individuals by intervening or interacting with them for research purposes.
* Obtaining identifiable private information about living individuals for research purposes;
* Obtaining the voluntary informed consent of individuals to be subjects in research;
* Accessing, studying, interpreting, or analyzing identifiable private information or data for research purposes;
* Reporting research study results.

NOTE: For assistance with determining who needs to be added to the study team, contact the Human Subject Protection Program (HSPP) team. [ ]  **No, there is not any study staff supporting the PI.**  **[ ]  Yes, study staff support the PI. (Complete the table below OR provide Delegation of Authority log.)**Complete the OSF [Research Significant Financial Interest Disclosure Form](https://x.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies) (RSFIDF) for EACH OSF employed team/staff member supporting the PI. Non-OSF employed study staff should submit with this application conflict of interest (CoI) documentation required by employing institution. (NOTE: If other employing institution(s) does/do NOT require formal submission of CoI documentation, then complete the OSF RSFIDF and submit with this application. |

**NOTE: To add rows, click on the final row to visualize “+,” then click on “+.”**

**ADD ROWS BEFORE YOU BEGIN DATA ENTRY.**

**NOTE: If referencing below the “Delegation of Authority Log” (DoA Log), then you should provide a copy of the DoA Log.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Email Address** | **Employer** | **Role in Study** | **Responsibilities/Tasks** | **Listed on FDA Form 1572?** |
|      |       |       |  |       |  |
|      |       |       |  |       |  |
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|      |       |       |  |       |  |

Section V: Proposed IRB of Record

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| --- |
| 1. **Proposed IRB of Record:**
 |
| 1. **Has PI/study team completed appropriate IRB application/submission form and included the completed form with this application? [ ]  Yes [ ]  No If “No”, then explain:**
 |
| 1. **Has the proposed IRB of Record provided the study team with reliance-associated documents (e.g., Reliance Agreement template, Local Context Questionnaire)? [ ]  Yes (Complete and submit documents with this form) [ ]  No (Explain:**      **)**
 |

Section VI: Sponsorship and Funding

|  |
| --- |
| 1. **Sponsor Name:**
 |
| 1. **Sponsor Type: [ ]  Investigator [ ]  Institution [ ]  Industry [ ]  Federal Agency**

 **[ ]  Cancer Cooperative Group (e.g., Alliance, SWOG) Other:**       |
| 1. **Funding**

 **[ ]  Non-funded**  **[ ]  Federal Funding [e.g., NIH (e.g., NCI, NHLBI, NICHD), NSF, DoJ]** **Name of agency:**       **Is OSF receiving funds? [ ]  Yes [ ]  No [ ]  Unknown** **Is OSF direct awardee or sub-awardee of federal funding?**  **[ ]  Yes: Notify** **the Grants Administrator** **[ ]  No** **Name of direct awardee:**       **Award#: [ ]**  **Name of sub-awardee (i.e., source of funds coming to OSF):**       **Award#:**       **[ ]  Industry funding**  **Name of sponsor:**       **Is OSF receiving funds? [ ]  Yes [ ]  No [ ]  Unknown** **Is OSF party to a contract or other agreement [e.g., clinical trial agreement (CTA)]?** **[ ]  Yes: Contact the Research Administration Clinical Research Business Office (CRBO)**  **[ ]  No > Complete the Premises Use and Indemnification Agreement.** **[ ]  Other Funding [e.g., department grants, private foundations, Community Health Advocacy (CHA),**  **ARCHES]** **Name of source:**       **Is OSF receiving funds? [ ]  Yes [ ]  No [ ]  Unknown**  |

Section VII: Project/Study Description and Plan

|  |
| --- |
| 1. **Project/Study Type:**  **Other:**       **Multi-center? [ ]  Yes [ ]  No**
 |
| **FOR DATA ONLY STUDIES (i.e., NO INTERVENTION OR INTERACTION WITH LIVING SUBJECTS)****Complete Ministry HealthCare Analytics Consult, as needed (See #7 below)****Identify below sources/locations of data (e.g., SAMC, MSG Bloomington Clinic, Ministry-wide)**Ministry-wide: [ ]  Yes [ ]  No Hospital(s):       Clinic(s):       Other (e.g., registries):       |
| 1. **Phase (if applicable):**  **For assistance with definitions/descriptions click** [**here**](https://www.fda.gov/patients/drug-development-process/step-3-clinical-research#collapse1)**.**
 |
| 1. **Anticipated start date (mm/dd/yyyy):**
 |
| 1. **Anticipated recruitment period: From (mm/dd/yyyy):**       **To (mm/dd/yyyy):**
 |
| 1. **Anticipated study duration (i.e., from enrollment to closure; in number of months):**
 |
| 1. **Subject Population**

 **Anticipated accrual for entire project/study:**       **Accrual to-date across ALL sites/centers:**       **Anticipated accrual at OSF site(s)?**       **If multiple OSF sites, then specify accrual goal per site (e.g., SFMC/2; SAMC/3):**       **What is enrollment plan to ensure accrual at OSF site(s)?**       **Are there competing studies for the above population? [ ]  Yes [ ]  No** **If yes, then describe plans to ensure adequate accrual:**       |
| 1. **Ministry HealthCare Analytics (MHA) Consult**

**OSF requires investigators to complete an MHA consult when the study plan/protocol includes obtaining/using OSF clinical data with MHA assistance. Examples include, but are not limited to:*** **List of eligible patients to assist recruitment**
* **Data-only studies**
* **Mixed-methods studies**

 **Will you obtain OSF clinical data through OSF MHA?** **Do you need assistance with statistical analysis from MHA?** **Have you completed initial consult with MHA for assistance in data extraction?**  **If “YES,” then what was the date of the initial consult (mm/dd/yyyy)?**      **A data extraction sheet including all data needed for the project MUST accompany this Research****Application Form. If MHA will not/cannot provide all listed data elements, then highlight those****elements you plan to obtain through MHA. An Excel file is recommended.** |

Section VIII: PHI and HIPAA Compliance.

|  |
| --- |
| 1. **Does the study involve accessing OSF Electronic Health Records (EHR) or other sources (e.g., clinical registry) of OSF protected health information (PHI) in order to look at/collect PHI?**

 **[ ]  No** **[ ]  Yes>** Indicate below type of PHI access/use/disclose and form of authorization: **[ ]** To identify/recruit potential participants ONLY. Will request “partial” waiver of HIPAA Authorization.  Investigators will obtain signed HIPAA Authorization to enroll participants in study. NOTE:  Disclosures under a waiver require tracking for accounting purposes ([Guides; “HIPAA: Accounting of](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies)  [Disclosures”](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies)). HSPP will provide appropriate support for tracking disclosures.   [ ]  To identify/recruit potential participants ONLY. Will request “partial” waiver of HIPAA Authorization.  **Investigators will request alteration of HIPAA Authorization for the “main” study.**  Describe the alteration and its justification:       [ ]  To identify potential participants and for collection as research data for the study. NO HIPAA  Authorization will be obtained for the study. Will request “partial” and “main study” (i.e., “full”) waivers  of HIPAA Authorization.  [ ]  Will seek and obtain Limited Data Set (LDS) using Data Use Agreement (DUA). NO waivers required  for this use/disclosure. |
| **\*\*\*STOP completing the Research Application Form here if the research is DATA ONLY\*\*\*** |

Section IX: Study Location and Ancillary Departments

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. **Which study-related activities will occur at which sites/locations/facilities?**

**Note:** Study-related activities include, but are not limited to: Recruitment; intervening or interacting with any living human subject; obtaining informed consent; obtaining identifiable private information or biological specimens from any source for the research; housing or administering investigational procedures or products; using, analyzing, cataloging and/or sharing identifiable information about subjects; and/or receiving an award through a grant/contract (i.e. awardee institutions). **NOTE: To add rows, click on the final row to visualize “+,” then click on “+.”****ADD ROWS BEFORE YOU BEGIN DATA ENTRY.**

|  |  |  |
| --- | --- | --- |
| **Site/Location/Facility Name** | **Study-related Activities** | **PROTOCOL-PRESCRIBED****Admission to Hospital?**  |
|       |       |  |
|       |       |  |
|       |       |  |

 |
| 1. **Ancillary Departments**

|  |  |  |
| --- | --- | --- |
| **Name of Department** | **Services & Personnel Provided** | **Department Leader** |
|  Cardiology |       |       |
|  Pharmacy |       |       |
|  Lab Services |       |       |
| Radiology |       |       |
| Radiation |       |       |
| Respiratory Therapy |       |       |
| Rehabilitation Services |       |       |
| Other:       |       |       |
|  Other:       |       |         |

**The above ancillary departments must receive information on the protocol, approve the procedures to take place, and indicate how staff will be informed about the study. Provide documentation of approval for all ancillary departments that will be necessary for the study.** |

Section IX: ClinicalTrials.gov Registration

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| 1. **Will this project need to be, or is it already, registered on** [**ClinicalTrials.gov**](https://clinicaltrials.gov/)**? If unsure, then reference the** [**“Registration of Clinical Trials” policy**](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies)**.**

 [ ]  No  [ ]  Yes **>** Check all reasons that apply and complete [ ]  The project is an applicable clinical trial (ACT) as defined by 42 CFR Part 11. If unsure, review the  [Checklist for Evaluating Whether a Clinical Trial or Study is an ACT](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf). [ ]  The project is a clinical trial funded in whole or in part by the National Institutes of Health (NIH). If  unsure, review the [NIH Policy on the Dissemination of NIH-funded Clinical Trial Information](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm). [ ]  The project is a Qualifying Clinical Trial (QCT) per the Center for Medicare and Medicaid Services  (CMS). If unsure, review the [Medicare National Coverage Determination (NCD) Manual](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending) [ ]  The project is a clinical trial per the International Committee of Medical Journal Editors. If unsure,  review the [ICMJE Clinical Trial Registration Policy](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).1. **Is the project currently registered on** [**ClinicalTrials.gov**](https://clinicaltrials.gov/)**?**

[ ]  Yes: NCT#:        [ ]  No: Who will serve as Responsible Party for registration? Name:       Role/Relationship to study:       |
| **\*\*\*STOP completing the Research Application Form here if the research is OBSERVATIONAL\*\*\*** |

Section X: Drug/Biologics and Device Trials

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| *Note: The Investigational New Drug (IND) information required below will be found in study protocol and/or FDA letter. Consult study sponsor for additional information.* **1. Does the study involve use of a drug or biologic?** [ ]  No [ ]  Yes **>** Complete **a.** thru **e.**1. **What is the name of the drug/biologic?**
2. **Does the study involve an off-label use of an approved drug/biologic?**

[ ]  No [ ]  Yes **>** Complete and attach the [IND Applicability Form](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies)1. **What is the IND number (if applicable)**
2. **Who is the IND holder?**
3. **If no IND, then does this study have IND exemption determination from the FDA?**       **NOTE:** **Provide copy of FDA exemption letter when available.**
 |
| *Note: The Investigational Device Exemption (IDE) information required below will be found in (1) study protocol and/or (2) FDA letter. Consult study sponsor for additional information.***2. Does the study involve use of a device?**  [ ]  No [ ]  Yes **>** Complete **a.** through **f.**1. **What is the name of the device?**
2. **Has the research sponsor or PI submitted an Investigational Device Exemption (IDE) application to FDA?**

[ ]  No **>** Complete and attach the [“IDE Applicability”](https://www.osfhealthcare.org/patients-visitors/clinical-research/investigators-coordinators/forms-templates-policies) form[ ]  Yes **>** Provide documentation of IDE determination1. **What is the IDE number (if applicable)**
2. **Who is the holder of the IDE number (if applicable)**
3. **If no IDE, then does this study have IDE exemption determination from the FDA?**        **NOTE: Provide**

 **copy of FDA exemption letter when available.**1. **Has the device been approved by the OSF New Product Committee for use in this research project?**

[ ]  Yes **>** Provide documentation of the Product Committee approval to use the device for this research project.[ ]  No **>** All devices being used for research projects should be approved by the OSF New Product Committee.  Request New Product Committee review here: <https://app.lumere.com/providers/osf/requests/add/> |
|  |

Section XI: Safety/Risk

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| --- |
| 1. **Safety/Risk Assessment/Management**

**Indicate plans for Data Safety Monitoring:****[ ]  Sponsor has established external DSMB****[ ]  Cooperative group DSMB****[ ]  No DSMB required (i.e., less than minimal risk)** **Sponsor monitoring plan? [ ]  Yes [ ]  No [ ]  Unknown** **Will sponsor require electronic medical record access for research? [ ]  Yes [ ]  No** **If “Yes,” then complete and submit** [**Research Epic Access Request Form**](https://osf-p-001.sitecorecontenthub.cloud/api/public/content/crbo_epic_research_access_request__v5_322022.docx?v=a120f2a1)**.** **Other risk/safety considerations (Select all that apply):** **[ ]  Recombinant/synthetic DNA/RNA (requires Institutional Biosafety Committee review)**  **[ ]  Other high-risk agent or experimental intervention [e.g., radiation exposure (e.g.,**  **radioisotopes, increased x-ray exposure), experimental surgical intervention]:** **[ ]  Vulnerable patient population (children, pregnant women, prisoners, etc.)****Are there any special considerations or circumstances that should be considered for this study? *(i.e.******PK sampling outside the normal business day, or an EKG machine would be required to complete******this study compliantly)*** **[ ]  Yes Describe/explain:** **[ ]  No** |

Section XII: Recruitment and Epic Information

|  |
| --- |
| **Please complete the following required section if this is a clinical trial.**1. **Epic Patient Facing (subject to IRB approval)**

**Study Name:** **Description:** **A screenshot of a medical research institute  Description automatically generated**1. **Does this Project/Protocol have any test and/or procedures?**

**[ ]  Yes** **[ ]  If “NO,” do you intend to utilize the Epic Research Functionality as an enrollment log?** **[ ]  Yes [ ]  No (You have finished this section)**1. **Do you want an Epic tool that will help identify patients for your Project/Protocol?**

**[ ]  No****[ ]  If “Yes,”** **Please provide desired Inclusion/Exclusion criteria to be used. (attached document is acceptable):****Please note if enrollment is time sensitive. (e.g. emergency department):**1. **Do you intend to send recruitment requests, in Epic MyChart, to this subject population?**

**[ ]  Yes (Continue below) [ ]  No (You have finished this section)****Do you want to get a Recruitment Notification for the following:****Interested?****[ ]  No [ ]  If “Yes,”****[ ]  Coordinator;****[ ]  PI; or****[ ]  Coordinator & PI****Declined?****[ ]  No [ ]  If “Yes,”****[ ]  Coordinator;****[ ]  PI; or****[ ]  Coordinator & PI****Do you want to require provider approval before sending recruitment requests? [ ]  Yes [ ]  No** |