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| **Section I: Instructions** | | | | | | | |
| **1.** Per OSF HealthCare (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](mailto:OSF.ClinicalResearch@osfhealthcare.org?subject=New%20Research%20Application). | | | | | | | |
| **2.** 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](mailto:HealthCare.Analytics@osfhealthcare.org). Contact [OSF Research Administration](mailto:OSF.ClinicalResearch@osfhealthcare.org?subject=New%20Research%20Application) with questions about this requirement. | | | | | | | |
| **3.** 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](mailto:Michael.J.Hendricks@osfhealthcare.org). Contact [OSF Research Administration](mailto:OSF.ClinicalResearch@osfhealthcare.org?subject=New%20Research%20Application) with questions about this requirement. | | | | | | | |
| **4.** If you are pursuing permission to use an HUD according to its Humanitarian Device Exemption (HDE) indications for *non-investigational* purposes, then DO NOT use this form. Complete and submit the [“HUD Application Form: Non-Investigational”](https://www.osfhealthcare.org/research/investigators-coordinators/forms-templates-guides/). If your research involves use of a Humanitarian Use Device (HUD), then refer to the [“HUD Decision Tree”](https://www.osfhealthcare.org/research/investigators-coordinators/forms-templates-guides/) guide to learn more about investigational use of an HUD. | | | | | | | |
| **5.** Prior to completing and submitting this form, consult with the [Clinical Research Business Office (CRBO)](mailto:OSF.CRBO@osfhealthcare.org) 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/research/investigators-coordinators/forms-templates-guides/) | | | | | | | |
| **6.** Visit the [OSF Research website](https://www.osfhealthcare.org/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 application.  MHA Consultation (If applicable)  IT Feasibility Consultation (If applicable)  OSF Research Application Forms – including any necessary supplemental forms or checklists  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 | | | | | | | |
| **7.** If there are questions regarding the information requested on this application, contact the [OSF Research Administration](mailto:osf.clinicalresearch@osfhealthcare.org?subject=Research%20Application%20Questions) office via email or phone at 309-624-7556. | | | | | | | |
| **8.** 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 II: General Information** | | | | | | | |
| **1. Project/Protocol Number (Assigned by sponsor/investigator):** | | | | | | |  |
| **2. Project/Protocol Acronym:** | | | | | | |  |
| **3. Project/Protocol Title on the IRB Application:** | | | | | | | |
| **4. IRB of Record:** | | | | | | | |
| **5. What is the status of funding for the study?** | | | | | | | |
| Non-Funded | | | | | | | |
| Federal Funding [e.g., NIH (e.g., NCI, NHLBI, NICHD), NSF, DoJ] from:   1. Is OSF receiving funds from this source? 2. Is OSF direct awardee or sub-awardee of federal funding?   Yes: [Notify the Grants Administrator](mailto:OSF.Grants@osfhealthcare.org) if you have not already done so  No  **c.** If OSF is NOT direct awardee or sub-awardee, then  **i.** Who is direct awardee of federal funding?       Award#  **II.** Who is sub-awardee (i.e., source of funds coming to OSF)?       Award# | | | | | | | |
| Industry funding from: | | | | | | | |
| a. Is OSF receiving funds from this source?  b. Is OSF party to a contract or other agreement [e.g., clinical trial agreement (CTA)]?  Yes  No **>** Complete the [Premises Use and Indemnification Agreement](https://www.osfhealthcare.org/research/investigators-coordinators/forms-templates-guides/). | | | | | | | |
| Other Funding [e.g., department grants, private foundations, Community Health Advocacy (CHA), ARCHES]  a. Name of source:  b. Is OSF receiving funds from this source? | | | | | | | |
| **6. Principal Investigator (PI) Information:** | | | | | | | |
| **a. Name:** | | | | **b. Title:** | | | |
| **c. Email:** | | | | **d. Phone:** | | | |
| **e. PI PRIMARY employer:** | | | | | | | |
| OSF  UICOM-P  UICOM-R  Other:   |  | | --- | | **f. PI Employing Department:**  **g. PI SECONDARY employer (if applicable):** | | OSF  UICOM-P  UICOM-R  Other: | | | | | | | | |
| **h. 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  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](mailto:Kimberly.L.Cooley@osfhealthcare.org)]  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: | | | | | | | |
| **i. Is the research being conducted as a school, program or residency requirement?** | | | | | | | |
| No  Yes **>** Name of the school/program/residency: | | | | | | | |
| **7. Primary Study Contact Information (e.g., Study Coordinator):** | | | | | PI is the Primary Study Contact | | |
| **a. Name:** | | | **b. Title:** | | | | |
| **c. Email:** | | | **d. Phone:** | | | | |
| **e. Employing Institution:** | | | **f. Employing Department:** | | | | |
| **Section III: Research Personnel & Conflict of Interest (COI) Disclosure** | | | | | | | |
| **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; * Studying, interpreting, or analyzing identifiable private information or data for research purposes; and/or * Reporting research study results. | | | | | | | |
| No | | | | | | | |
| Yes **>** Complete Item #2  *OPTION: For larger groups, create and submit a standing roster. Applicant is responsible for maintaining*  *currency and attesting to validity of roster.* ***Invalid roster is non-compliance.***  **2. Complete the table below by adding name and employing institution for each study team member.**  **NOTE: This information MUST be identical to CoI information submitted on IRB-specific forms. For**  **EACH person listed, provide the following information:**  *• Do you hold* any *financial interest (e.g., receiving payment for study services, investments, ownership, etc.)*  *that could influence your work or that could be influenced by the outcomes of this particular research study?*  *(Answer* YES *or* NO *in the field titled, “COI?”)*  *• If “Yes,” then describe the financial interest (e.g., type of financial interest, amount, etc.)*  **To create additional rows: Double-Click on the last row, then click on “+” at end of row.** | | | | | | | |
| **Name** | **Email Address** | **Employing Institution** | | | **COI?** | **BRIEF Description of COI** | |
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| **Note:** Changes to the research personnel named above OR on an accompanying standing roster require permission from OSF Research Administration. | | | | | | | |
| **3. Have all research study personnel named above completed the OSF required** [**CITI Program**](http://www.citiprogram.org) **training courses?** | | | | | | | |
| Yes  No **>** Complete the required CITI training courses prior to applying for OSF permission to conduct  human subject research. Refer to the [CITI Training Instructions](https://www.osfhealthcare.org/research/investigators-coordinators/education-training/) for additional information. | | | | | | | |
| **Section IV: Study-Specific Information** | | | | | | | |
| **1. What is the ANTICIPATED date to BEGIN study-related activities at OSF?**  mm/dd/yyyy | | | | | | | |
| **2. What is the ANTICIPATED date to CLOSE ALL study-related activities at OSF?**  mm/dd/yyyy | | | | | | | |
| **3. What is the ANTICIPATED recruitment period?** From mm/dd/yyyy to mm/dd/yyyy | | | | | | | |
| **4. What is the EXPECTED study population size?**  **a.** TOTAL OSF subjects  **b.** TOTAL protocol subjects (when there are subjects across multiple sites)? | | | | | | | |
| **5. Study Description**  **a. Type of Project/Study:**  **b. Other:**    **FOR DATA ONLY STUDIES:**    **a. Will you obtain OSF clinical data through OSF Ministry HealthCare Analytics (MHA)?**  **b. Do you need assistance with statistical analysis from MHA?**  **c. Have you completed initial consult with MHA for assistance in data extraction (See Section I #2)?**  **If “YES,” then what was the date of the initial consult (MM/DD/YYYY)?**  **d. 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.** | | | | | | | |
| **6. 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](http://www.hhs.gov/ohrp/policy/engage08.html)).   |  |  |  | | --- | --- | --- | | **SITE/LOCATION/FACILITY NAME** | **STUDY-RELATED**  **ACTIVITIES** | **SUBJECTS ADMITTED FOR INPATIENT SERVICES?** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | | | | | | | | |
| **8. 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? If unsure, review the** [**HIPAA in Research**](https://www.osfhealthcare.org/research/investigators-coordinators/hipaa/) **page of the OSF website for additional information.** | | | | | | | |
| No (Skip to Item #9) | | | | | | | |
| 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. Disclosure under the  “partial” waiver will require documentation for accounting of PHI disclosure.  To identify/recruit potential participants ONLY. Will request “partial” waiver of HIPAA Authorization.  Investigators will request alteration of HIPAA Authorization due to nature of 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. | | | | | | | |
| **9. Will this project need to be registered on Clinicaltrials.gov? If unsure, reference the** [**OSF Policy on Registration of Clinical Trials.**](https://www.osfhealthcare.org/media/filer_public/7f/71/7f71771b-0afd-4b6a-ba95-5ab5a6ab45f4/registration_of_clinical_trials.pdf) | | | | | | | |
| No  Yes **>** Check all reasons that apply and complete **a.**: | | | | | | | |
| 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). | | | | | | | |
| **a. Is the project currently registered on ClinicalTrials.gov?** | | | | | | | |
| Yes **>** What is the NCT#? NCT | | | | | | | |
| No **>** Complete **b.**: | | | | | | | |
| **b.** **Who will be the responsible party for the ClinicalTrials.gov registration listing?** | | | | | | | |
| The PI for the project | | | | | | | |
| Other Individual/Entity **>** Name: | | | | | | | |
| **\*STOP completing the Research Application Form here if the research is entirely observational.** | | | | | | | |
| *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.*  **10. Does the study involve use of a drug or biologic?** | | | | | | | |
| No  Yes **>** Complete **a.** thru **e.**: | | | | | | | |
| **a. What is the name of the drug/biologic?** | | | | | | | |
| **b. 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/research/investigators-coordinators/forms-templates-guides/). | | | | | | | |
| **c. What is the IND number (if applicable)** | | | | | | | |
| **d. Who is the holder of the IND number (if applicable)** | | | | | | | |
| **e. If no IND, then does this study have IND exemption determination from the FDA?** | | | | | | | |
| *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.*  **11. Does the study involve use of a device?** | | | | | | | |
| No  Yes **>** Complete **a.** through **c.**: | | | | | | | |
| **a. What is the name of the device?** | | | | | | | |
| **b. Has the research sponsor or PI submitted an Investigational Device Exemption (IDE) application to**  **FDA?** | | | | | | | |
| No **>** Complete and attach the [IDE Applicability Form](https://www.osfhealthcare.org/research/investigators-coordinators/forms-templates-guides/). | | | | | | | |
| Yes **>** Provide documentation of IDE determination. | | | | | | | |
| **c. What is the IDE number (if applicable)** | | | | | | | |
| **d. Who is the holder of the IDE number (if applicable)** | | | | | | | |
| **e. If no IDE, then does this study have IDE exemption determination from the FDA?** | | | | | | | |
| **f. 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/> | | | | | | | |
| **12. Does the study involve a procedure that is investigational itself (e.g. surgical technique differing from standard care)?** | | | | | | | |
| No  Yes **>** List all investigational procedures: | | | | | | | |
| **13. Does the research involve a genetic intervention?** | | | | | | | |
| No  Yes **>** Genetic testing language is required. Use [‘Informed Consent – OSF Language’](https://www.osfhealthcare.org/research/investigators-coordinators/forms-templates-guides/) file for wording. | | | | | | | |
| **14. Does the research involve services, support or procedures from other departments?** | | | | | | | |
| No  Yes **>** Complete **a.** and **b.**: | | | | | | | |
| **a. What other ancillary departments and required services will be necessary for the research?** | | | | | | | |
| Radiology Services: | | | | | | | |
| Pharmacy Services: | | | | | | | |
| Laboratory Services: | | | | | | | |
| Pathology Services: | | | | | | | |
| Other Department(s) and Service(s): | | | | | | | |
| **b. 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 research. A letter or email for each department should include the following content:**   * + - 1. **Date of correspondence**       2. **Full title of project/study**       3. **Name of Principal Investigator**       4. **Department leader statements:**          1. **Statement that department leader or designee has knowledge and understanding of the proposal/protocol;**          2. **Statement that department head/chair or designee affirms that the department has the capacity to support the project/study (e.g., materials, space, scheduling, equipment, etc.); and**          3. **Statement that department leader or designee endorses the conduct of the project/study OR change of research.** | | | | | | | |
| **15. Does the study include non-billable tests and/or procedures? (See Section I # 5)** | | | | | | | |
| No | | | | | | | |
| Yes **>** Email [OSF CRBO](mailto:osf.crbo@osfhealthcare.org?subject=Research%20Account%20Inquiry) regarding the potential need to establish a research account. | | | | | | | |
| **16. Will the study sponsor require electronic medical record access for the research?** | | | | | | | |
| No | | | | | | | |
| Yes **>** Complete and attach a [Research Epic Access Request Form](https://www.osfhealthcare.org/research/investigators-coordinators/forms-templates-guides/) | | | | | | | |
| **17. SFMC Only – Is there OSF SFMC Clinical Research Involvement?** | | | | | | | |