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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 projects 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.** Visit the [OSF HealthCare 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 that all required components of your application are addressed:  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 Assent Forms  Conflict of Interest Information  Recruitment Materials  Study Related Materials not incorporated into the protocol | | | | | | |
| **3.** 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. | | | | | | |
| **4.** 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:** | | **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 research?** | | | | | | |
| Non-Funded | | | | | | |
| Internal OSF Funding from: | | | | | | |
| External/Private Funding from: | | | | | | |
| Federal Funding from: | | | | | | |
| Oncology/Federal/Cooperative Group Funding from: | | | | | | |
| Industry Sponsor Funding from:       **>** Complete **a.**: | | | | | | |
| **a.** **Is OSF party to the clinical trial agreement (CTA)?** | | | | | | |
| Yes  No **>** Complete the [Premises Use Agreement](https://www.osfhealthcare.org/filer/canonical/1496498314/5649/). | | | | | | |
| **6. Principal Investigator (PI) Information:** | | | | | | |
| **a. Name:** | | | **b. Title:** | | | |
| **c. Email:** | | | **d. Phone:** | | | |
| **e. Employing institution the PI is conducting the project on behalf of:** | | | | | | |
| OSF  UICOM-P  UICOM-R  Other: | | | | | | |
| **f. Employing Department:** | | | | | | |
| **g. Is the PI a resident, fellow or nurse?** | | | | | | |
| No  Resident  Fellow  Nurse **>** Complete **i.** and **ii.**: | | | | | | |
| **i. Provide the name of the nurse’s/nursing student’s advisor:** | | | | | | |
| **ii. Has the research been approved by the Nursing Research Committee (Peoria) or Research and Evidence Council (Rockford)?**  No  Yes **>** Date: | | | | | | |
| **h. Is the research being conducted as a school, program or residency requirement?** | | | | | | |
| No  Yes **>** Name of the school/program: | | | | | | |
| **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** | | | | | | |
| **1. Will there be personnel involved in conducting the research in addition to the PI? Involvement includes:**   * 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; and * studying, interpreting, or analyzing identifiable private information or data for research purposes. | | | | | | |
| No | | | | | | |
| Yes **>** List all personnel involved in conducting the research: | | | | | | |
| **Name** | **Employing Institution** | | | **Name** | | **Employing Institution** |
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| **Note:** Changes to the research personnel named above require permission from OSF Research Administration when Peoria IRB is not the IRB of record. | | | | | | |
| **2. Have all research 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 the research. Refer to the [CITI Training Instructions](https://www.osfhealthcare.org/filer/canonical/1496498314/5644/) for additional information. | | | | | | |
| **Section IV: Research Information** | | | | | | |
| **1. When is the research expected to start?** mm/dd/yyyy | | | | | | |
| **2. When is the research expected to end?** mm/dd/yyyy | | | | | | |
| **3. What is the planned recruitment period?** From mm/dd/yyyy to mm/dd/yyyy | | | | | | |
| **4. What is the target number of OSF subjects to be enrolled?** | | | | | | |
| **5. At what facilities will the research be conducted (i.e. facilities engaged in the research)?** | | | | | | |
| **Note:** Research conduct includes: intervening or interacting with any human subject, including obtaining informed consent; obtaining identifiable private information or biological specimens from any source for the research; housing or administering investigational procedures or products; and receiving an award through a grant/contract (i.e. [awardee institutions](http://www.hhs.gov/ohrp/policy/engage08.html)). | | | | | | |
| **6. Does the research involve using or disclosing protected health information (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 **>** Proceed to **#7** | | | | | | |
| Yes **>** Complete **a.**: | | | | | | |
| **a. Will a HIPAA Authorization document be signed by subjects?** | | | | | | |
| Yes **>** Use the [HIPAA Authorization for Research](https://www.osfhealthcare.org/media/filer_public/20/4c/204c2387-2160-46a1-a157-1a8bf1e8f077/template_osf_healthcare_hipaa_authorization_for_research_adult_version_10-version_date_041019_041219.docx) when authorization is not included in the informed consent. | | | | | | |
| No **>** Complete **b.**: | | | | | | |
| **b. Will a request for full waiver of HIPAA Authorization be submitted to the IRB?** | | | | | | |
| Yes **>** When PHI is disclosed outside of OSF under a waiver of HIPAA Authorization, such PHI disclosures must be accounted for. Review the [OSF Guidance: HIPAA Accounting of Disclosures](https://www.osfhealthcare.org/filer/canonical/1517583353/6651/) for additional information. | | | | | | |
| No | | | | | | |
| **7. Will this project need to be registered on Clinicaltrials.gov? If unsure, reference the OSF Policy on Registration of Clinical Trials.** | | | | | | |
| 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/grants/guide/notice-files/NOT-OD-16-149.html). | | | | | | |
| 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#? | | | | | | |
| 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: | | | | | | |
| **8. Is the research solely retrospective/prospective data collection?** | | | | | | |
| No  Yes**\* >** Complete **a.** and **b.**: | | | | | | |
| **a. Are you requesting OSF Ministry HealthCare Analytics (MHA) to pull some or all of the research data?** | | | | | | |
| No | | | | | | |
| Yes **>** Research Administration will place the request to MHA after IRB approval has been verified. | | | | | | |
| **b. A data extraction sheet including all data needed for the project is required with your Research Application. Highlight/identify the specific data elements being requested from MHA.** | | | | | | |
| **\*STOP completing the Research Application Form here if the research is entirely observational.** | | | | | | |
| **9. Does the research involve use of a drug or biologic?** | | | | | | |
| No  Yes **>** Complete **a.** and **b.**: | | | | | | |
| **a. What is the name of the drug/biologic?** | | | | | | |
| **b. Does the research involve an off-label use of an approved drug/biologic?** | | | | | | |
| No  Yes **>** Complete and attach the [IND Applicability Form](https://www.osfhealthcare.org/filer/canonical/1503589561/5963/). | | | | | | |
| **10. Does the research 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/filer/canonical/1503589562/5964/). | | | | | | |
| Yes **>** Attach a copy of documentation from the FDA approving the IDE. | | | | | | |
| **c. 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/> | | | | | | |
| **11. Does the research involve a procedure that is investigational itself (e.g. surgical technique differing from standard care)?** | | | | | | |
| No  Yes **>** List all investigational procedures: | | | | | | |
| **12. Will subjects be inpatients at any point during the research?** | | | | | | |
| No  Yes **>** At what facilities? | | | | | | |
| **13. Does the research involve a genetic intervention?** | | | | | | |
| No  Yes **>** [Genetic testing language](https://www.osfhealthcare.org/filer/canonical/1496498314/5648/) is required in the informed consent form (ICF). | | | | | | |
| **14. Does the research involve services, support or procedures from other departments?** | | | | | | |
| No  Yes **>** Complete **a.** and **b.**: | | | | | | |
| **a. What other 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 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 departments that will be necessary for the research.** | | | | | | |
| **15. Does the research include non-billable tests and/or procedures?** | | | | | | |
| 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 research sponsor require electronic medical record access for the research?** | | | | | | |
| No | | | | | | |
| Yes **>** Complete and attach a [Research Epic Access Request Form](https://www.osfhealthcare.org/filer/canonical/1603368505/11585/) | | | | | | |