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| --- | --- | --- | --- |
| **Section I: Instructions** | | | |
| **1.** Use this form to request OSF permission for all research to be conducted at an OSF HealthCare location, by OSF HealthCare employees, or using OSF HealthCare data. OSF permission is required prior to IRB submission. Complete this form electronically and email it and all required documents to [OSF Research Administration](mailto:osf.clinicalresearch@osfhealthcare.org?subject=New%20Research%20Application). | | | |
| **2.** Visit the [Clinical Research](https://www.osfhealthcare.org/research/) page of the OSF HealthCare website for information on OSF research application procedures, forms, templates, and training requirements. | | | |
| **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. | | | |
| **4.** If there are questions about the investigator having the appropriate hospital privileges for the research, contact the OSF Credentialing Office at 309-655-3215. | | | |
| **Section II: General Information** | | | |
| **1. Project/Protocol Number:** | **2. Project/Protocol Acronym:** | | |
| **3. Project/Protocol Title:** | | | |
| **4. What is the status of funding for the research?** | | | |
| Non-Funded | | | |
| Internal OSF Funding from: | | | |
| External/Private Funding from: | | | |
| Federal Funding from: | | | |
| 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/). | | | |
| **5. Principal Investigator (PI) Information:** | | | |
| **a. Name:** | | **b. Title:** | |
| **c. Email:** | | **d. Phone:** | |
| **e. Employing Institution:** | | **f. Employing Department:** | |
| **g. What institution is the PI conducting the research project on behalf of?** | | | |
| OSF  UICOM-P  UICOM-R  Other: | | | |
| **h. 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)?** | | | |
| Yes **>** Date: | | | |
| No | | | |
| **i. Is the research being conducted as a school, program or residency requirement?** | | | |
| No  Yes **>** Name of the school/program: | | | |
| **6. 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 working on the research, in any capacity, that are not employed by OSF?** | | | |
| No | | | |
| Yes **>** Provide the name and employer of each individual working on the research not employed by OSF: | | | |
| **2. Have all personnel with a role in the research completed the OSF required** [**CITI Program**](http://www.citiprogram.org) **online 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 | | | |
| Yes **>** Complete **a.**: | | | |
| **a. Will a HIPAA Authorization document be signed by subjects?** | | | |
| Yes | | | |
| 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 **>** Complete and attach the [Data Use Form](https://www.osfhealthcare.org/filer/canonical/1503589561/5962/). | | | |
| **7. Are statistician services needed from OSF HealthCare Analytics to assist with the research data?** | | | |
| No | | | |
| Yes **>** Research Administration can connect researchers with appropriate statistician services. | | | |
| **8. Describe how this research aligns with, or adds value to, institution and/or department objectives:** | | | |
| **9. Will this project need to be registered on Clinicaltrials.gov for any of the following reasons? If unsure, reference the OSF Policy on Registration of Clinical Trials.** | | | |
| 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). | | | |
| No | | | |
| Yes **>** Check all reasons that apply and complete **a.**: | | | |
| **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: | | | |
| **10. Is the research solely a retrospective/prospective chart review or data collection?** | | | |
| No | | | |
| Yes**\* >** Complete **a.** through **c.**: | | | |
| **a. Are you requesting HealthCare Analytics Services to pull the research data?** | | | |
| No | | | |
| Yes **>** Research Administration will place the request for you after IRB approval has been verified. | | | |
| **b. Include the data extraction sheet with your Research Application.** | | | |
| **c. When will the data be needed?** | | | |
| ***\**** *If Yes, the research is entirely observational, then you may stop completing Section IV here. Skip to Section V of this form to ensure that all required components of your application are included prior to sending to the Research Administration Department for evaluation.* | | | |
|  | | | |
| **11. Does the research involve use of a drug or biologic?** | | | |
| No | | | |
| Yes **>** Complete **a.** through **c.**: | | | |
| **a. What is the name of the drug/biologic?** | | | |
| **b. Is the research solely a registry study?** | | | |
| No | | | |
| Yes | | | |
| **c. 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/). | | | |
| **12. 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. Is the device currently stocked at OSF?** | | | |
| Yes | | | |
| No **>** Complete **i.**: | | | |
| **i. Has the device been approved by the SFMC New Product Committee?** | | | |
| Yes | | | |
| No **>** For SFMC, Contact the New Product Committee Lead for guidance through the process and/or to access products not stocked at SFMC: [Cynthia.L.Harter@osfhealthcare.org](mailto:Cynthia.L.Harter@osfhealthcare.org?subject=New%20Product%20Committee%20Guidance%20for%20Research%20Application) 309-655-4094. | | | |
| **13. Does the research involve a procedure that is investigational itself (e.g. surgical technique differing from standard care)?** | | | |
| No | | | |
| Yes | | | |
| **14. Will subjects be inpatients at any point during the research?** | | | |
| No | | | |
| Yes **>** At what facilities? | | | |
| **15. 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). | | | |
| **16. Does the research involve other hospital 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: | | | |
| 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 the names of individuals information was sent to and also indicate the educational plan:** | | | |
| **17. Does the research include non-billable tests and/or procedures?** | | | |
| No | | | |
| Yes **>** Email [OSF Research Administration](mailto:osf.clinicalresearch@osfhealthcare.org?subject=Research%20Account%20Inquiry) regarding the potential need to establish a research account. | | | |
| **18. Will the research sponsor require electronic medical record access for the research?** | | | |
| No | | | |
| Yes **>** Complete and attach a [Request for Password for Electronic Medical Records](https://www.osfhealthcare.org/filer/canonical/1496498314/5650/) | | | |
| **19. Does the research involve transferring specimens off-site?** | | | |
| No | | | |
| Yes **>** Complete the appropriate Material Transfer Agreement (MTA) template: If sending specimens to UICOMP, use the [UICOMP MTA](https://www.osfhealthcare.org/filer/canonical/1496498314/5646/). For everything else, use the [General MTA](https://www.osfhealthcare.org/filer/canonical/1496498314/5645/). | | | |
| **Section V: Completion Checklist** | | | |
| **Use the following checklist to ensure that all required components of your application have been addressed.** | | | |
| **OSF Research Application Requirements:** | | | |
| 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 | | | |
| **General IRB Initial Submission Requirements:** | | | |
| 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 | | | |
| **Note:** Initial submission requirements may vary by IRB. Include with your OSF Research Application all information that will be submitted to the IRB of record. | | | |