Title	**Monitoring Informed Consent, HIPAA & Consent Process**
Access	This SOP is intended for use by the RUSH research community.
Policy Type	Standard Operating Procedure
Approval Date	1.15.2019 *(revised 12.16.2020*)
Contact	Stephanie Guzik, Associate Vice President, Office of Research Compliance (ORC)
Applies To	This procedure applies to all Rush University Medical Center and Rush Oak Park personnel obtaining Informed Consent for research subjects. Examples include: • Principal Investigator • Sub/Co-Investigator • Research Nurse • Clinical Research Coordinator • Any personnel responsible for obtaining informed consent from research subjects (e.g., students)
Procedure	Research Compliance monitoring of the Informed Consent Form (ICF), Health Insurance Portability and Accountability Act (HIPAA) Authorization Form (if applicable), Assent and Short Forms (if applicable) are reviewed for compliance with federal regulations and Rush policy. This review includes the Informed Consent Process documentation following the enrollment of research subjects in a new research study *or upon an IRB decision that requires evaluation or re-consenting of past and/or currently enrolled research subjects*. This SOP applies to all IRB approved studies that require an ICF.
Related Documents:	RA-IRB-200 Elements and Documentation of Informed Consent for Research Subjects RA-IRB-202 Enrollment of Subjects Who Do Not Read, Speak or Understand Written or Spoken English RA-IRB-206 Research Involving Children (Minors) RA-IRB-208 Research Involving Adults with Questionable Capacity to Consent OP-661 Mandatory Subject Enrollment in Clinical Trial Management System (CTMS)
Definitions	N/A
Purpose:	1. This SOP is established to assess investigator compliance with regulations and Rush policies related to informed consent (IC). In addition, the SOP is designed to utilize REDCap™ in the review process of the IC between the Institutional Review Board (IRB) and the Office of Research Compliance (ORC). 1.1. This procedure describes the process for assessment of the proper use and execution of the Informed Consent Form (Assent, Short Form, and HIPAA Authorization when applicable) and includes the review of the

	documentation of the informed consent process. 1.2. This review process begins with IRB approval of a new research study that requires an ICF and/or upon the IRB decision to obtain re-consenting of past and/or currently enrolled research subjects. The review process will also include new research personnel.
Procedure:	**Three instances where ORC review is *required*:** **1. IRB Studies that require Informed Consent** 1.1. Starting February 1, 2019 ***all*** new IRB approved studies where there is enrollment of research subjects following the start date of the study. 1.2. This procedure will be completed for the first three (3) study subjects consecutively consented to participate in the study. **2. Consent Form Revision stemming from a new Conflict of Interest (COI) Management Plan** 2.1. Upon receipt of the ORC & Conflict of Individual/Institutional Interest in Research Committee (COIIIR) Management Plan (MP) letter, where: 2.1.1. ICF language is required to be amended, and/or 2.1.2. Re-consenting of previously enrolled subjects with the amended ICF is required, and/or 2.1.3. Consenting of new subjects is required that includes the amended ICF language 2.2. This procedure is to be completed for the first consented study subject after the MP is issued, within 90 days from the issuance of the MP. **3. New Research Personnel consenting research subjects** 3.1. This procedure is to be completed for the first three (3) consecutively consented subjects where consent is obtained by personnel new to research at RUSH. **Two instances where ORC review will occur based on a request from the IRB**: **1. Research Study that requires an IC** 1.1. Upon receipt of the decision/request by the IRB following review of an amendment, continuing review or non-compliance issues by the IRB 1.2. This procedure will be completed for the first two (2) consented study subjects prior to the IRB submission or immediately after the IRB submission depending on the decision of the IRB (unless previously submitted as part of the initial IRB approval process). 1.3. The ICF and accompanying documentation will be reviewed by the ORC within 10 days of the first use of the ICF. **2. Required re-consenting** of a research subject 2.1. Upon receipt of the IRB decision that past and/or currently enrolled subjects must be re-consented and/or must sign a new HIPAA Authorization (if applicable). 2.2. This procedure will be completed for the first two (2) consented study subjects following the IRB decision requiring re-consenting.
Procedure:	**Submissions to ORC:** **1.** The IRB will provide the ORC a list of all newly approved studies and those requiring re-consenting via the IRB's ORC Review Grid.

	2. Research personnel will submit to the ORC all required documentation and information listed below in Section 3 in one of two ways: 2.1. For studies **<u>not</u> requiring coverage analysis nor registered in OnCore™(CTMS),** research personnel will submit the documentation via email to ORC_ICF_Review@rush.edu. 2.2. For **clinical research studies registered in OnCore™ (CTMS)**, the ORC will review all documentation uploaded to the REDCap™ system. Email submissions are not necessary. **3. Procedure Required Documentation** and information will be submitted by research personnel as described above for review by the ORC. 3.1. Copy of the executed Informed Consent Form (ICF) 3.2. Copy of the documentation of the Informed Consent Process (signed and dated by the individual obtaining consent) 3.3. Copy of the executed HIPAA Authorization (when applicable) 3.4. Copy of the executed Short Form (when applicable) 3.5. Copy of the executed Assent Form (when applicable) 3.6. Copy of the Subject's Demographics Page from Epic 3.6.1. For subjects registered in <u>both</u> the REDCap™ system and the Rush electronic medical system (Epic®), this additional document is not necessary. The ORC will cross-check subject demographics. **4. Review process**: 4.1. If the ORC review results in **no findings,** no additional documentation for the particular study will be reviewed by the ORC. 4.2. If the ORC review results in **findings,** the ORC will contact the study staff to address the findings and provide remedial education, as needed. Subject to the nature and severity of the findings, ORC review will continue until satisfactory resolution occurs. 4.3. Communication from the ORC to study staff will be made within two weeks of reviewing the documentation
Criteria for Review	The same criteria used when an Education and Quality Improvement Monitoring (EQuIP) routine audit is conducted by ORC will be used for the review and accompanying recommendations.
Regulatory Elements	45 CFR 46.116: General Requirements for Informed Consent. 45 CFR 46.117: Documentation of Informed Consent. 21 CFR 50 Subpart B: Informed Consent of Human Subjects.
Attachment	Informed Consent Process Documentation template

RUSH UNIVERSITY MEDICAL CENTER

INFORMED CONSENT PROCESS DOCUMENTATION

Subject ID: _____

ORA#	Study Title:
Consent Version Date:	
Approval Date of Consent:	
Expiration Date of Consent:	
Study Principal Investigator(PI):	

Study and consent discussed with: ___ Subject ___ Legally Authorized Representative (LAR) ___ Family Members ___ Other (describe) How was Consent obtained? ___ In person ___ Telephone call ___ Online ___ Other (describe)	If not in-person, how was the subject's identity verified? ___ Full Name (required) AND **Two** additional identifiers (minimum) ___ Date of birth ___ Last four digits of SSN ___ Address ___ Emergency Contact name ___ Other (describe)

Key information presented to subject first?	☐ YES	☐ NO
Purpose of study discussed with subject?	☐ YES	☐ NO
Procedures discussed with subject?	☐ YES	☐ NO
Risks and Benefits discussed with subject?	☐ YES	☐ NO
All of subject's or LAR's questions were answered?	☐ YES	☐ NO
Subject or LAR verbalized understanding of consent?	☐ YES	☐ NO

Subject: ☐ Agrees to Participate ☐ Declined Participation ☐ Wants to meet for further discussion

Consent signed prior to any study related procedures?	☐ YES	☐ NO
A copy of the executed study consent form was given to subject? (Describe how the copy was provided to them in "Comments")	☐ YES	☐ NO
Is the subject currently enrolled in any other study?	☐ YES	☐ NO
Does the subject have any special needs? If Yes, describe in comments section below	☐ YES	☐ NO
Does the subject meet all Inclusion and no exclusion criteria for the study?	☐ YES	☐ NO

Comments:

Signature of Person Obtaining Consent:	Date and Time: