Procedure Name: Informed Consent Procedure	**Number:** SOP 13 v3.0
Subject: Clinical Research	**Effective Date:** July 01,2004
Linked Policy: Clinical Research Operations & Compliance Policy	**Revised Date:** April 18, 2023

PURPOSE:

This SOP establishes the procedure for developing an informed consent form (ICF)/ research subject authorization form (RSAF), when applicable, obtaining IRB approval of ICF/RSAF, administering the approved ICF/RSAF, and obtaining informed consent and research subject authorization from subjects, or their legally authorized representative, prior to performing and research related procedures at George Washington University MFA.

SCOPE:

This SOP applies to research team members responsible for conducting informed consent on subjects for clinical research studies conducted at GWU MFA.

RESPONSIBILITY:

The Principal Investigator (PI) is responsible for developing the informed consent form (ICF), which should include a research subject authorization (HIPAA Authorization) for studies involving the use and/or disclosure of Protected Health Information (PHI); obtaining IRB approval of the ICF processes; and subsequently obtaining written, or electronic consent/authorization from the subject or his/her Legally Authorized Representative (LAR) (when allowed) unless the PI has delegated one or more of these responsibilities to a designated research team member as documented on the Delegation of Authority Log. A sponsor template may be used, but must be reviewed and modified to be consistent with GWU MFA approved wording (i.e., subject injury language, contact information, and/or HIPAA Authorization language).

PROCEDURES:

Protocol Review

Review the protocol prior to drafting a study specific ICF to assure that the ICF will accurately reflect study purpose and procedures. The review should concentrate on the following:

- Study purpose;
- Inclusion and exclusion criteria;
- Number of subjects who are expected to be enrolled;

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- Required study procedures;
- Length of study and number of required visits; and
- Potential risks and benefits.

Draft Informed Consent Form (ICF)

When no template has been provided by the Sponsor/ CRO a draft ICF may be written by the PI or designee.

When needed, draft an ICF that includes all pertinent information obtained from the protocol review and all of the following, unless the PI has requested and the IRB approved waiver of or alteration to informed consent for a particular study:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of all reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others, which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, which may be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that records may be available to FDA and other government agencies, the IRB, and study sponsor;
6. For research involving more than minimal risk, an explanation as to whether compensation will be provided and an explanation as to whether ant medical treatments (or medical coverage) are available if injury should occur;
7. An explanation of whom to contact for information regarding research subject's rights and whom to contact in the event of a research related injury to the subject; and
8. Explanation that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. Include the following additional information in the ICF, where appropriate:
    - A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which is currently unforeseeable;
    - Anticipated circumstances under which the subject's participation may be terminated by the investigator, the FDA, or the sponsor without regard to the subject's consent;
    - Any additional costs to the subject that may result from participation in the research;

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- The consequences of the subject's decision to withdraw from the research. In addition, the procedures for orderly termination of participation by the subject must be included;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

Submit the draft ICF or revised/redlined Sponsor template consent to the Sponsor/CRO for review and approval prior to submission to the IRB.

Obtain IRB Approval of Informed Consent Form (ICF) and file original, IRB approved consent in Regulatory Binder.

Administer Consent

1. Ensure that the most recent version of the IRB-approved informed consent is used (e.g., use of an expired ICF is prohibited);
   - Prior to any study procedures, determine whether a potential subject has legal capacity to provide consent/authorization
   - If a subject is deemed to have capacity to consent, follow the steps outlined below.
   - If a subject is deemed not to have capacity to consent, provide the information to the subject's LAR or legal guardian and follow the steps outlined below.
2. Provide a copy of the IRB-approved ICF to the subject or his/her LAR to read in an environment that provides privacy;
3. Explain the study to the subject or his/her LAR. This explanation should include the study purpose, procedures, risks and benefits, study drug/device and alternative;
   - Provide adequate time for the subject or LAR to ask questions;
   - Answer all questions posed by the subjects or LAR or get answers from the appropriate person;
   - Assess the subject's or LAR's understanding of what is being asked of them as a study participant;
   - Ensure subject and/or LAR signs and dates ICF at the time consent is given;
   - Ensure that person obtaining the consent signs and dates ICF at the time consent is given;
   - ICF is conducted and in the subject's language.
4. Record in the source document the date of signature. The source document should state that informed consent was obtained prior to the initiation of any study related procedure; and

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5. If a child's Assent document is to be used in a study, the assent should be administered and signed as descried above (in addition to obtaining the parent's permission to enroll their child in a study).
6. In cases where potential subjects are not proficient in English, the IRB approved consent form should be translated into the language understood by that participant.
    - GWIRB requires a Translator/Back-Translator Form to be completed and submitted with the English version, translated version, and back-translated version.
    - In cases where a potential subject speaks English, but is unable to read or write (Vulnerable Population), the consent should be read to the subject and the may make their mark on the consent document. An impartial witness must attest to the adequacy of the consent process and also sign the consent.

Electronic Consent

GWU MFA utilizes Florence as the e-consent platform. The primary study contact will:

- Submit the Google Form (located on the OCR website).
- The Google Form will be routed to the Site Admins and they will enter the information provided in the Google Form.
- Site Admins will assign the role of Study and Staff Editor to the primary study contact and they will complete e-consent registration process and delegate roles to other research team members.
- Follow the Florence specific e-consent SOP, guidance document and workflow for a more detailed explanation of the Florence e-consent system.

Distribute Consent

1. Provide the subject or LAR with a copy of the administered, signed consent document.
2. Retain the original, signed consent document in a secured binder.
3. Document on the source document that a copy of the informed consent was given to the subject and/or their LAR

Waiver of Informed Consent in Emergency Situations

- PI must verify that the subject is in a life-threatening situation, and available treatments are unproven or unsatisfactory.
- PI must verify that informed consent cannot be obtained from a subject for **ALL** of the following reasons:
- Informed consent cannot be obtained from the study subject as a result of their medical condition;

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- The intervention under investigation must be administered before consent from the subject's legal representative if feasible; and
- There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
- If feasible, obtain concurrence from an independent uninvolved physician that the subject is in a life-threatening situation. If time does not permit the concurrence of a second physician, the test article may nevertheless be administered. If this use occurs, documentation of the action taken should be submitted to a non-involved second physician for review and evaluation.
- Immediately, within no more than five working days of the emergency use, inform the IRB of the use via documentation from the investigator and the second physician.
- Notify the Sponsor, if applicable, to the test article as soon as possible.

Exception from Obtaining Informed Consent for Emergency Research

1. PI must document and the IRB (with concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) must find:
    - Subjects are in a life-threatening situation, that available treatments are unproven or unsatisfactory and knowledge gained from the study will be used to determine the safety and effectiveness of the intervention;
    - Informed consent is not feasible because the subject cannot consent due to their medical condition and the intervention must be administered before consent from the subject and/or LAR is feasible;
    - The investigation could not be carried out without the waiver of informed consent;
    - Risks to study subjects are reasonable and subjects may directly benefit from the research study;
    - The PI has defined the length of the potential therapeutic window and has committed to attempt to contact a LAR for each subject within the therapeutic window and, if feasible, ask for consent within that window rather than proceeding without consent. If consent is not feasible and a LAR is not available, provide a family member with an opportunity to object to the subject's participation in the investigation within the therapeutic window, if feasible; and
    - There is an approved ICF and procedures available for those situations in which consent of a subject or a LAR is feasible.

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Re-Consenting Previously Consented Subjects

Whenever a study modification requires revisions to a currently approved ICF because the modification affects the risk to benefit ration and/or may affect the subject's willingness to participate in the study, the PI must:

- File the revised modification request with the Sponsor for approval prior to submitting to the IRB, when required or not initiated by the Sponsor;
- Promptly send the revised ICF to the IRB for review and approval along with any other revised study documents, e.g., protocol, recruitment materials, IB.
- Store the updated consent in the regulatory binder on top of the version it replaced
- Discuss the revised ICF with the subject or subject's LAR at the next study visit after it as been approved by the IRB
- Administer the revised consent to all subject's currently active in the study (as outlined in the Administer Consent Section of this Document); and
- Distribute consent copies

Note: Consent revisions made due to IND Safety Reports may change the risk section of the ICF and may require that the site notify every patient who ever received study drug.

Draft and Administer HIPAA Research Subject Authorization (RSA)

- All subjects enrolled in research after April 14, 2003, that involve protected health information (PHI) must sign a (RSA) Form that has been approved by the IRB unless the IRB has waived this requirement.
- The RSA must specify all uses and disclosures of PHI that will be used, collected, or created in the study.
- The RSA should be submitted to the privacy officer for review and approval.
- Unless required by the Sponsor, the RSA will be incorporated into the main ICF.
- Administer the RSA to all subjects in the study as outlined above, and;
- Distribute authorization copies

Sample Consent Language

For consent templates and guides, please visit the Office of Human Research website.

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Review and Revision
This SOP shall be reviewed every 2 years. This SOP may be reviewed more frequently if it does not reflect current operations.

Attachments
Sample HIPAA Language
Sample Forte Language
Sample ICF Checklist

REFERENCES:

21 CFR 50.20	General requirements for informed consent.
21 CFR 56.109	IRB review of research.
ICH E6 (R2)	Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2)
21 CFR 312.60	General responsibilities of investigators.
21 CFR 812.40	General responsibilities of sponsor.
21 CFR 814.42	FDA and IRB approval.
21 CFR 812.43	Selecting investigators and monitors.
21 CFR 812.100	General responsibilities of investigators.
21 CFR 812.110	Specific responsibilities of investigators.
GWU, OHR Investigator Guidance Documents and IRB policies/SOPs	Investigator Guidance Documents and IRB policies/SOPs

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GWU MFA Clinical Research SOPs	SOP 02- Research Team Responsibilities SOP 04- Research Team Communication/Interactions with IRB

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Sample HIPAA Language

How will my privacy and health information be protected?

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form

The use and release of protected health information is for the purpose of collecting data for this study.

Protected Health Information to be shared: *[list all PHI that will be used or disclosed for this specific study]*

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:

Hospitals: <List by name>
Clinics: <List by name>
Other Providers: <List by name>
Health Plan: <List by name>

And from hospitals, clinics, health care providers, and health plans that provide health care to you during the study *[NOTE: Delete types of CE's that do NOT apply to this study]*

By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team;
- Other healthcare providers such as labs which are part of the study;
- A safety monitoring board {include only if applicable};
- Institutional officials who are responsible for compliance;

Some of the tests in this study would have been done as part of your regular care. These test results will be used both to treat you and to complete this research. The test results will be recorded in your medical record. These study results will be included in your medical record. Results of tests and studies done solely for this research study and not as part of your regular care will *[also] OR [not]* be included in your medical record.

[or use this alternative statement:]

All tests are being done only because you are in this study. The study results will *[not]* be *[given to you to send]* OR *[sent]* to your physician to include in your medical record

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Once your health information has been disclosed to others outside of the hospitals and medical practices *[customize this part of the phrase to fit this study*], the information may no longer be covered by the federal regulation that protects privacy of health information.
Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study.
This Authorization does not have an expiration date.
However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have about you; however, no new health information or new biological specimens will be collected from you after you cancel your permission.
To cancel your permission, you will need to send a letter to *[name Principal Investigator]* stating that you are canceling your authorization. This letter must be signed and dated and sent to this address: *[enter the name and address of the Principal Investigator*].
[Include for research involving prisoners. Otherwise delete]. If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

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Informed consent template language for use of the Forte payment system.

Include if the study is utilizing Forte Participant Payments to manage the payments. Otherwise delete, either as part of the full study informed consent form or as a stand-alone consent form for payment.

The research team will use a system called Forte Participant Payments to manage payments to research participants. The system offers 3 payment options:

1. Reloadable debit / credit cards. When selected, funds are available on the same business day. If you choose to receive a reloadable debit/credit card, as per the cardholder agreement, there are some restrictions on the use of the card.
2. Electronic deposits into your bank account. You define your bank account via a banking portal provided to you via email. When selected and appropriately defined, the funds are available within 3 business days. To use this method you will need to provide your bank account information to Forte.
3. Paper check mailed to you. You define this method via a banking portal provided to you via email. When selected and appropriately defined, a paper checks require 3 days to process plus delivery time.

All three options require the collection of your name, date of birth and gender. If you choose payment option 2 or 3 you will need to provide your email address to the research team.
The payment method selected will be associated with your participant record. If you enroll in other studies at the university (or the GW Medical Faculty Associates) that use the Forte Participant Payment system, payments from those other studies will be made using the same payment method (same card, bank account information or paper check mailing address) that you choose.

If the total amount of payment you receive from the George Washington University (or GW Medical Faculty Associates) meets or exceeds $450.00, a research team member will contact you to provide you with a tax form to complete. This tax form will request your social security number.
If you receive $600 or more from the university (or the GW Medical Faculty Associates), GW must report the amount you receive to the Internal Revenue Service (IRS) on the form 1099-MISC. This form tells the IRS that payment was made to you, but it does not say that you were paid for taking part in this research study. You should talk to your tax advisor regarding the proper use of this form 1099-MISC.

If you choose to use a reloadable card, Forte Participant Payments may disclose information to third parties about the card or the transactions you make:
(1) Where it is necessary for completing transactions;

(2) In order to verify the existence and condition of the card for a third party, such as a merchant;
(3) In order to comply with government agency, court order, or other legal or administrative reporting requirements;
(4) If you consent by giving us your written permission;
(5) To our employees, auditors, affiliates, service providers, or attorneys as needed; or
(6) Otherwise as necessary to fulfill our obligations under the card holder agreement (provided separately)

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Subject Injury Language Guidance Document

Updated January 11, 2024

The purpose of this Guidance Document is to provide the Informed Consent Model Subject Injury Language . This is not required for non-interventional studies or expanded access.

MODEL LANGUAGE

You may have medical problems or side effects from taking part in this research study. If you have any side effects after taking the study drug or are injured during the study, tell your study doctor right away. Once you tell your study doctor, he will either provide you with or refer to you proper medical treatment.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- George Washington University Hospital (GWU Hospital) and/or the George Washington University Medical Faculty Associates (GWU MFA); or
- your physician; or
- treatment center of your choice.

The study sponsor, _____ will provide payment for the reasonable medical expenses needed to diagnose and treat the research-related injury if the injury or illness is directly related to the *(study drug, placebo, name of comparator, etc.)* or the study procedures **and** your injury was not caused by**:**

- Failure by *GWU Hospital*, GWU MFA, the study doctor, or study staff to follow the sponsor's written instructions, the study protocol, or applicable laws, guidance, and regulations; or

- The negligence or misconduct of *GWU Hospital*, GWU MFA, the study doctor study or study staff.

- A standard of care procedure that you would have undergone even if you were not participating in the study;

- The normal progression of your disease or condition; and/or a pre-existing condition not made worse by the study drug or study procedures

  There are no plans for *GWU*, GWU Hospital and/or the GWU MFA to pay you for any injuries or illnesses. By signing this form you will not give up any legal rights.

If the sponsor covers these expenses they will need to know some information about you such as your name, gender, date of birth, Medicare Claim Number (if you have one), and social security number (if you do not have a Medicare Claim Number). This information will be used to check to see if you receive Medicare, and if you do, report the payment they make to Medicare. This information may be collected directly from you, or from the study doctor, study staff, or other health care providers who treated your illness or injury. This information may be shared with others, including the sponsor's representatives and the Centers for Medicare & Medicaid Services (the government agency responsible for administering the Medicare program). The sponsor and its representatives will not use this information for any other purpose.

Office of Clinical Research

DOCUMENTATION OF INFORMED CONSENT

Protocol ID: _____ IRB Number: _____ PI: _____

Subject ID:		**Subject Initials:**	__ __ __
ICF Version:	v.	**ICF Approval Date:**	
Date of Subject Signature: (DD/MMM/YYYY)		**Time Subject Signed:** **24 hour Clock**	:
Is this the most recent IRB Approved ICF version?	☐ Yes ☐ No		
Verification that no research activity has taken place before the subject has signed the consent:	☐ Yes ☐ No		

Person Obtaining consent should check below to indicate completion of each task for the Informed Consent Process:	
☐	The subject was given the opportunity to read over the consent
☐	The subject had the opportunity to ask any questions about the research being conducted and their involvement
☐	The consent was obtained in the subject's language
☐	The subject verbalized their understanding of the informed consent
☐	The subject was reminded they can withdraw at any time without fear of repercussion
☐	A copy of the signed consent was given to the subject
Additional Comments:	

Printed Name of Person Obtaining Consent:		**Date:**
Signautre of Person Obtaining Consent:		