	<b>Human Research Protection Program</b> Good Clinical Practice <b>Informed Consent Process</b>	
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## 1. INTRODUCTION AND PURPOSE

The ethical conduct of clinical investigations is based upon the voluntary consent of the subject who has been appropriately informed about a study's risks and benefits. It is the responsibility of the investigator to ensure that all federal regulations have been met through the language of the informed consent document, and that informed consent itself has been properly obtained from the subject or the subject's legal representative.


Documentation of the informed consent process is required to establish that the subject was accurately and adequately informed and that no study-related procedures were initiated prior to obtaining informed consent. Informed consent is a process for information exchange that takes place between the potential subject and the investigator, before, during and sometimes after the study.

This standard operating procedure (SOP) describes the steps for fulfilling the regulatory and ethical requirements for developing the informed consent document, submitting it for IRB approval, and for appropriately obtaining the subject's informed consent. It applies to obtaining consent under general requirements or routine circumstances as well as identifies the specialized procedures for obtaining informed consent from vulnerable populations. This SOP also specifies the conditions for exceptions from the general requirements for obtaining informed consent.

## 2. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109	IRB review of research
45 CFR 46.109	
21 CFR 50.25	Elements of informed consent
21 CFR 56.111	Criteria for IRB approval of research
45 CFR 46.111	
21 CFR 312.54	Emergency research under §50.24 of this chapter
21 CFR 312.60	General responsibilities of investigators
21 CFR 312.62	Investigator recordkeeping and record retention
45 CFR 46.116	General requirements for informed consent
	FDA Internal Compliance Program Guidance Manual, 1994: 7348.811: Clinical Investigators
FDA Information Sheets, October, 1995	Frequently asked questions, A Guide to Informed Consent Documents, Informed Consent and the Clinical Investigator, The Belmont Report and Declaration of Helsinki
May 9, 1997	International Conference on Harmonisation: Good Clinical Practice: Consolidated Guideline
FDA website:	<a href="#">U S Food and Drug Administration Home Page</a>
OHRP website:	<a href="#">HHS - Office for Human Research Protections</a>
ICH website:	<a href="#">ICH</a>

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### 3. PROCEDURES

#### A. Drafting or adapting the written informed consent form

Based upon the protocol and investigator's brochure\*, prepare an informed consent form and/or use the [Informed Consent Template](#) provided by the IRB, **or**

Adapt an informed consent document provided by the sponsor.\*

Ensure that the point(s) of care Health Insurance Portability and Accountability Act (HIPAA) authorization form(s) utilized does not conflict with the Informed Consent Form.

Verify that all required and additional elements (protocol specific) of the informed consent form are incorporated and insert the appropriate language as required by the IRB by reviewing against the [Informed Consent Checklist](#).

Verify that all HIPAA required elements are incorporated or attached by reviewing all of the elements against the [HIPAA Authorization Required Elements](#).

Submit the informed consent form and IRB application, for review and approval.

Make modifications as requested by the IRB and submit any required changes to the sponsor.\*

After the informed consent document has been approved by the IRB, file the original IRB approval letter and stamped and dated informed consent form in the regulatory file.

Send copies of both documents to the sponsor\* and other collaborating departments as requested.

#### B. Obtaining written consent from the subject (or the legal representative)


Obtain written informed consent from the study subject (or the legal representative). In some cases an impartial witness signature may be required. All consent signatures must be collected prior to initiating any study related procedures. See [Guidance for Investigators- Obtaining Informed Consent](#)

Ensure that the most recent, stamped and dated, version of the IRB-approved consent form is used.

Review the informed consent form with the subject (or the legal representative) in a location that provides as much privacy as possible.

Allow the subject (or the legal representative) time to read the document and ask questions. Encourage input from family members and other care providers, if appropriate.

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If the subject is unable to give written informed consent, provide the above information to the subject's legally authorized representative for a definition of who is an authorized representative in the State of Maine see MMC Policy "Privacy and Confidentiality of Patient Information Appendix A Definitions" for the [State of Maine Definition of Legally Authorized representative](#).

### **Special circumstances or needs:**

Subjects who do not understand English should be presented with an informed consent document written in a language understandable to them. A translator may also be used to assist in the consent process.

Ensure that both the subject (or the legal representative) and an impartial witness (when required) sign and date the informed consent document that has been translated into the language of the subject and approved by the IRB.

Subjects that cannot read may have the informed consent document read to them unless prohibited by the protocol.\*

### **C. Documenting the informed consent process**

After consenting to participate in the clinical study, ensure that the subject (or the legally authorized representative) and impartial witness (when required) signs and dates the document in the required sections of the consent form.

It is highly recommended that the time of consent be noted adjacent to the signature and date on each signature line of the consent form.

Provide a signed copy of the informed consent form document to the subject (or the legally authorized representative).

Document and date the procedure for obtaining written informed consent in the subjects' record

Place a signed copy of the consent form in the subject's medical record.


### **D. Revisions to the informed consent form**

Assess the need for revising the informed consent form based on changes to the protocol, events occurring within the study which increase risk to the study subjects, or as directed by the sponsor.\*

Submit the revised informed consent form with changes requested by the sponsor\* and/or investigator to the IRB for approval.

When directed by the IRB or sponsor, re-consent previously enrolled subjects with the revised, IRB approved version of the informed consent form.

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Follow all procedures for obtaining and documenting the original informed consent process as outlined above.

## **E. Exceptions from general requirements for informed consent**

### **1) Verbal informed consent using a short form and summary sheet**

As an alternative to standard written informed consent documents, oral presentation of informed consent information may be used.

In such cases, the subject must be provided with both:

- A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative; and
- A written summary of the information that is to be presented orally.

Refer to [MMC IRB SOP, Informed Consent General Requirements and Documentation](#).

Using the IRB-approved short form read the document to the subject or the legally authorized representative. If the subject (or the legally authorized representative) does not speak English, ensure that the information is presented in the subject's native language and that the translation has been approved by the IRB.

Ensure that the person obtaining consent signs and dates the summary sheet and request that a witness sign both the summary sheet and the short form to document that the informed consent process was properly implemented.

Ensure that the subject (or the legally authorized representative) signs the short form.


Provide the subject (or the legally authorized representative) with a copy of both the short form and the summary sheet.

### **2) Waivers and exemptions of informed consent**

The IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent (such as written documentation). The IRB may waive the requirement to obtain informed consent if the IRB finds that the research meets specific criteria.

The IRB/Privacy Board may also waive the requirements to obtain authorization for Use of Disclosure of Protected Health Information if it finds that the research meets specific criteria.

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Refer to the [MMC IRB SOP, Informed Consent and Authorization Exemptions](#)

- [Waiver or Alteration of Authorization for Use or Disclosure of Protected Health Information](#)
- [An Emergency Situation Prior to IRB Review and Approval](#)

## **F. Vulnerable populations**

### **1) Consent of children**

Consult with the IRB regarding state and local laws for the consent of minors. Refer to the [MMC IRB SOP, Vulnerable Populations, Children](#).

If the subject is considered to be a legal minor, obtain consent from one or both parents, or legal guardian.

Obtain consent from the legal minor if they turn 18 years of age during the duration of the study.

Follow all procedures for obtaining and documenting the informed consent process as outlined above.

Provide a copy of the informed consent form to the parent(s) or legal guardian(s).

Consult with the IRB regarding their requirements for the assent of minors.

Refer to the [MMC IRB SOP, Assent](#) .

Develop a form to be used by children for their verbal or written consent for their participation in the study that describes the risks and benefits in age-appropriate language.


Follow all procedures for obtaining and documenting the informed consent process outlined above.

Provide a copy of the informed consent form to the child and parent(s) or legal guardian(s).

### **2) Prisoners**

If an investigator indicates in the study submission application that prisoners will participate in the research, or that subjects may reasonably be expected to be incarcerated at some point during the study, additional requirements will apply to the IRB review. Refer to the [MMC IRB SOP, Vulnerable Populations, Prisoners](#) .

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### 3) Pregnant Women and Fetuses

The following may be involved in research if certain conditions are met and not prohibited by the protocol:

- pregnant women or fetuses prior to delivery
- fetuses after delivery
- fetuses of uncertain viability
- nonviable fetuses

Refer to the [MMC IRB SOP, Vulnerable Populations, Pregnant Women and Fetuses](#)

### 4) Cognitively impaired

Studies involving subjects who are decisionally impaired may take place over extended periods taking into account the study's anticipated length and the condition of the individuals to be included (i.e.; subjects with progressive neurological disorders) periodic reassessments and re-consenting of individuals should be considered to ensure that:

- a subject's continued involvement is voluntary.
- decision-making capacity has not diminished.

## 5. LINKS AND RESOURCES

[Informed Consent Checklist](#) (Link)

[Guidelines for obtaining informed consent Attachment A](#)

[Informed Consent Template](#) (Link)

[State of Maine Definition of Legally Authorized representative.](#) (link)

[MMC IRB SOP, Informed Consent General Requirements and Documentation](#) (Link)

[MMC IRB SOP, Informed Consent and Authorization Exemptions](#) (link)

[MMC IRB SOP, Vulnerable Populations, Children](#) (Link)

[MMC IRB SOP, Assent](#) (Link)

[MMC IRB SOP, Vulnerable Populations, Prisoners](#) (Link)

[MMC IRB SOP, Vulnerable Populations, Pregnant Women and Fetuses](#) (Link)

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