

DEPARTMENT: Clinical Operations Group – Research	POLICY DESCRIPTION: IRB Review of Research Informed Consent And Its Documentation
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EFFECTIVE DATE: February 22, 2019	REFERENCE NUMBER: COG.IRB.008 (formerly CSG.IRB.008)
APPROVED BY: Ethics and Compliance Policy Committee	

<p>SCOPE: This policy pertains to all Company-affiliated facility-run Institutional Review Boards (IRBs). Nothing in this policy is intended to limit the provision of emergency medical care to the extent required under applicable Federal, State or local law.</p>
<p>PURPOSE: To provide guidance and structure to the IRB in its review of the need for required structure and elements of informed consent and the need for documentation of consent as well as the criteria to waive either of the above for certain circumstances.</p>
<p>POLICY:</p> <ol style="list-style-type: none"> Informed consent is not a single event or simply a form to be signed, but rather an educational process that takes place between the investigator and the prospective subject that lasts from the initial recruitment efforts through the completion of all study procedures and data gathering/review. The basic features of the consent process include: <ul style="list-style-type: none"> Full disclosure of the nature of the research and the expectations of the subject's participation; Adequate comprehension on the part of the potential subject; and The subject's voluntary choice to participate. Unless otherwise waived by the IRB according to strict criteria, no investigator may involve a living human being (or use their identifiable data/biospecimens) as a subject in non-exempt research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. The IRB must review and exercise appropriate authority to approve, require modification in (to secure approval), waive (in part or in whole) or disapprove elements and/or documentation of consents as submitted with the research proposal application. Such consents may not be utilized until approved. In addition to reviewing the physical or electronic form(s), the IRB is charged with approving the process to be used for obtaining consent for each type of study. This process may vary from study to study for reasons such as special patient populations, nature of the test article, or nature of the disease process engaged. The informed consent requirements in this policy are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed in order for informed consent to be legally effective. <p>NOTE: The review of Informed Consent (including the approval, waiver in part or in whole) is a process independent of the approval or waiver of an Authorization to Use/Disclose Protected Health Information. The approval, waiver or partial waiver of one does not automatically imply the other; thus, each should be determined based on their own criteria.</p>

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PROCEDURE:

The IRB must review each research project to determine if adherence to the following FDA, Common Rule and HIPAA Privacy Standards is required, and if so, is met:

1. **Structure Requirements of Informed Consent:** Unless specified otherwise, these structure requirements for Informed Consent apply whether the Informed Consent is written or oral. Note: While an IRB may alter or waive an element of Informed Consent based on such criteria, they may not alter or waive any of these structure requirements.
 - a. Unless otherwise waived in accordance with the criteria for such, an Informed Consent must contain all Required Elements of Consent as well as all Additional Elements of Consent when those Additional Elements apply.
 - b. An investigator shall seek Informed Consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
 - c. The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
 - d. No Informed Consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
 - e. For Federally-Funded studies, pursuant to regulations at 45CFR46.116(a) the following structure requirements are in addition to the above:
 - i. The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
 - ii. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the Informed Consent must be organized and presented in a way that facilitates comprehension.
 - iii. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

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2. **Basic Elements of Informed Consent.** Unless otherwise waived via the approved criteria, in seeking Informed Consent the following information shall be provided to each subject or the legally authorized representative:
- i. **Notification of Research:** The intent is to inform the patient that he or she is participating in research. Informed consent information must include all of the following:
 1. A statement that the study involves research;
 2. An explanation of the purposes of the research;
 3. An explanation of the expected duration of the subject’s participation;
 4. A description of the procedures to be followed; and
 5. Identification of any procedures that are experimental.
 6. For all applicable clinical investigations governed by the FDA initiated on or after March 7, 2012, this exact statement (no deviations or rewording allowed except for translations into languages other than English) is now required by FDA regulation: *“A description of this clinical trial will be available on <http://www.clinicaltrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”* [Note: this required element cannot be altered or waived by the IRB]
 - ii. **Reasonably Foreseeable Risks or Discomforts:** Informed consent must describe any reasonably foreseeable risks or discomforts associated with research. Risks or discomforts that an individual would have experienced absent the research are not risks associated with the research (i.e., risks from conventional care).
 - iii. **Reasonably Expected Benefits to Subjects or Others:** Informed consent information must describe any benefits to subjects or to others who may reasonably be expected to benefit from the research. However, care must be taken not to overstate the benefits and create an undue influence on subjects. Payment to a subject for his or her participation in a research project is not to be considered as a benefit of the research. When there is no intended clinical benefit to the subject, the subject must be made aware of this.
 - iv. **Appropriate Alternatives:** Informed consent information must include a detailed disclosure of any appropriate alternatives to participation in the research, such as procedures or courses of treatment, if any, that may be advantageous to the subject.
 - v. **Protection of Confidentiality:** Informed consent information must describe the extent, if any, to which confidentiality of records identifying the subject will be maintained and,

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for studies on FDA regulated products, specifically that the FDA may inspect records. Research often poses the risk of loss of confidentiality to subjects who participate. Many persons who would not otherwise have access to identifiable, private information about the subject may be engaged in the research process. Consent information should describe any procedures that the research team will use to protect a subject's private records. The IRB must consider the risk of loss of the subjects' privacy compared to the benefit of the research. Suggested consent language for FDA regulated research: *"Because this research involves articles regulated by the Food and Drug Administration (FDA), the FDA may choose to inspect and copy medical or research records that may identify you."*

- vi. **HIPAA Authorization to Use or Disclose PHI:** To the extent the research requires individually identifiable Protected Health Information, the IRB must ensure that the informed consent document includes the following authorization core elements and statements (unless these elements and statements are offered in a separate form). Additionally, the IRB must assure that if there are any State/Local-specific HIPAA preemptions, that the Authorization language is in compliance with both HIPAA and the additional State/Local requirements.
1. A description of the protected health information (PHI) to be used or disclosed;
 2. The name or other specific identification of the person or class or persons authorized to make the requested use or disclosure (e.g., hospital name, physician name);
 3. The name or other specific identification of the person or class or persons to whom the facility may make the requested use or disclosure (e.g., the researcher);
 4. A description of the purpose of the requested use or disclosure (noting that if the purpose is for future unspecified use, the authorization must adequately describe such purposes such that it would be reasonable for the individual to expect that his or her protected health information could be used or disclosed for such future research);
 5. An expiration date or event (e.g., "end of research study" or "none");
 6. A statement that the individual has the right to revoke the authorization in writing and the exceptions to this right (i.e., facility has already taken reliance on authorization);
 7. A statement that if the patient refuses to sign the consent, including the authorization elements, that he/she will not be enrolled in the research protocol;

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<p>8. A statement that the PHI is subject to redisclosure by the recipient and may no longer be protected by federal regulations; and</p> <p>9. The extent to which a patient would be temporarily denied access to their PHI created or obtained in the course of research until the research project was completed. This requirement pertains only to research where patient treatment is involved.</p> <p>vii. <u>Compensation or Treatment for Injury:</u> Informed consent information for research involving more than minimal risk must include explanations regarding:</p> <ol style="list-style-type: none"> 1. Whether any compensation is provided if a research-related injury occurs, and if so what it consists of or where more information about it is available; and 2. An explanation as to whether any medical treatments are available if a research-related injury occurs, and if so what they consist of or where more information about them is available. <p>viii. <u>Contact Information:</u> Informed consent information must include whom to contact for three specific situations (NOTE: Generally, the same contact person/role should not serve for all 3 situations):</p> <ol style="list-style-type: none"> 1. For answers to questions about research. The principal investigator and other members of the research team are appropriate contacts for this information. 2. For answers to questions about the subject's rights. The IRB office or Patient Advocate office are appropriate contacts for this information. 3. In the event a research-related injury occurs. Depending on the nature of the research, the research team, or the study sponsor may serve as appropriate contacts for this information. <p>ix. <u>Voluntary Participation Statement:</u> It is particularly important for subjects and prospective subjects to understand and have complete confidence that their participation is voluntary and without coercion or undue influence. Informed consent provisions must contain clear statements of the following:</p> <ol style="list-style-type: none"> 1. Participation in the research is voluntary; 2. Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled; and 3. The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. NOTE: Use of that exact phrase "no penalty or loss of benefits to which [you] are otherwise entitled" is preferred as opposed to "not affect your <i>treatment at this facility</i>" or other phrase that may be interpreted to imply other limitations.
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x. *[Required **only** of all federally-funded studies but optional for all others]* **One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:**

1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional Informed Consent from the subject or the legally authorized representative, if this might be a possibility; OR
2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

3. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject.

- i. 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 be pregnant) which are currently unforeseeable.
- ii. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
- iii. Any additional costs to the subject that may result from participation by the subject.
- iv. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- v. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue to participate will be provided to the subject.
- vi. The approximate number of subjects engaged in the study.
- vii. For studies involving remuneration to subjects, the form shall have BOTH the amount and schedule of remuneration.
- viii. *[Required applicability to all federally-funded studies and optional for all others]* A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

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- ix. *[Required applicability to all federally-funded studies and optional for all others]* A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- x. *[Required applicability to all federally-funded studies and optional for all others]* For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

4. Documentation of Informed Consent

Unless otherwise waived by the IRB, informed consent must be documented by the use of a single or staged written consent form(s) approved by the IRB that are signed and dated by the subject or the subject’s legally authorized representative at the time of consent. A copy must be given to the person signing the consent. This may be in paper or electronic format.

Any consent form(s) must be provided to the subject or representative before he or she is asked to sign it. The subject or his or her representative may read the consent or have it read to them. It is a best practice to have a version number or date on the consent form.

The consent form may be either of the following:

- a. A single or staged written consent document(s) that contains all non-waived required and additional elements of informed consent. This form(s) may be either read to the subject or the subject’s legally authorized representative, but in any event, the investigator must give either the subject or the representative adequate opportunity to read it before it is signed; OR
- b. A short form written consent document stating that all non-waived required and additional elements of informed consent have been presented orally to the subject or the subject’s legally authorized representative. If the research is federally-funded, this short written form must also describe that the “key information summary” required structure was presented first before other information, if any, was provided. When this method is used, there must be a witness to the oral presentation. Also, the IRB must approve a written summary of what is to be said to the subject or representative. Only the short form itself is to be signed by the subject or their legally authorized representative. However, the witness must sign both the short form and the copy of the summary, and the person obtaining the consent must sign a copy of the summary. A copy of the summary must be given to the subject or their legally authorized representative in addition to a copy of the short form.

5. Approval of the Informed Consent by the IRB

It is extremely important that the IRB members, particularly the non-scientific member, have the time to adequately review the informed consent form(s) and process. The IRB must consider the level of language skills, the nature of the local community, the expected patient population and the need for translation.

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When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards need to be included in the review and consent process to protect the rights and welfare of these subjects. The IRB must be competent to understand these situations pursuant to the regulations.

Thorough review of consent elements and documents must be completed by the IRB. Changes in the consent should be well documented with the rationale for change and then communicated to the Principal Investigator (PI). IRBs should encourage a version control methodology (for example, affixing the approval and/or expiration dates to all approved informed consent documents) and stipulate that copies of these dated documents must be used in obtaining consent.

6. Waiver/Alteration of Elements of Consent

NOTE: Waiver/Alteration of *Elements* of Informed Consent differs from Waiver of *Documentation* of Informed Consent.

NOTE: There are differing criteria in regulations to follow for Emergency Use and/or Planned Emergency Research.

Elements of consent may be waived or altered only in the following limited circumstances:

- a. For public benefit and service programs conducted by or subject to the approval of state or local officials: An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent (but cannot waive or alter the structure of consent) provided that the IRB finds and documents that:
 - i. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
 1. Public benefit or service programs;
 2. Procedures for obtaining benefits or services under those programs;
 3. Possible changes in or alternatives to those programs or procedures; or
 4. Possible changes in methods or levels of payment for benefits or services under those programs; and
 - ii. In addition to the above, the research could not practicably be carried out without the waiver or alteration.
- b. For all other research: An IRB may also approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirements to obtain informed consent provided the IRB finds and documents that:

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<p>i. The research engages not more than minimal risk to the subjects;</p> <p>ii. The waiver or alteration will not adversely affect the rights and welfare of the subjects;</p> <p>iii. The research could not practicably be carried out without the waiver or alteration;</p> <p>iv. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format and</p> <p>v. Whenever appropriate the subjects will be provided with additional pertinent information after participation.</p> <p>c. Waiver/Alteration of Elements of Consent does not automatically imply waiver of Authorization to Use/Disclose Protected Health Information. Both waivers must be evaluated separately based on their respective criteria.</p> <p>7. Waiver of Documentation of Informed Consent</p> <p>NOTE: Waiver of <i>Documentation</i> of Informed Consent differs from Waiver of Informed Consent. NOTE: There are differing criteria in regulations to follow for Emergency Use and/or Research In Emergency Settings.</p> <p>The IRB may waive the requirement for the Principal Investigator to obtain a signed consent form for some or all subjects if it finds <u>and</u> documents (e.g., in the meeting minutes), one of the following:</p> <p>a. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;</p> <p>b. That the research presents no more than minimal risk of harm to the subject and involves no procedures for which written consent is normally required outside of the research context; or</p> <p>c. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects AND provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.</p> <p>In cases in which the documentation requirement is waived, the IRB may require the Principal Investigator to provide subjects with a written statement regarding the research.</p>
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8. Waiver of HIPAA Authorization

In order for the IRB to waive HIPAA Authorizations to Release PHI, the following criteria and documentation must be adhered to:

- a. The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on, at least, the presence of the following elements:
 - i. An adequate plan to protect health information identifiers from improper use and disclosure;
 - ii. An adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research (absent a health or research justification for retaining them or a legal requirement to do so); AND
 - iii. Adequate written assurances that the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.
- b. The research could not practicably be conducted without the waiver or alteration.
- c. The research could not practicably be conducted without access to and use of the PHI.
- d. Required Documentation of IRB Approval of a Waiver: The IRB must provide the Principal Investigator specific documentation of its approval of a HIPAA Waiver. The documentation must include:
 - i. The name of the IRB or Privacy Board (not the names of individual members of the board);
 - ii. The date on which the waiver was approved;
 - iii. The signature of the IRB or Privacy Board chair, or other member designated by the chair;
 - iv. A statement that the IRB or Privacy Board has determined that the waiver satisfies the required criteria;
 - v. A brief description of the PHI that the IRB or Privacy Board has determined is necessary for research purposes; and
 - vi. A statement that the waiver has been reviewed and approved under either normal or Expedited Review procedures and that all applicable procedures were followed.

9. Informed Consent for Non-English Speakers and Persons Who Are Illiterate

Special issues arise when the subjects participating in research do not speak or read English, and great care must be taken to be sure that the individual understands the information about the study. Whenever possible, documentation should take the form of a written consent

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document drafted in language understandable to the subject that embodies all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent information (whether oral and written) written in the subject’s preferred language. The IRB maintains copies of each approved translation. If no IRB member is competent to review the translated forms, the IRB may consider the advice of a consultant or translating person/organization in approving/disapproving the foreign language consent form.

Alternatively, if an oral presentation of informed consent information is used with subjects who do not speak English (or cannot read), in addition to the requirements described above, (i) the oral presentation and the short form written document should be in a language readily understandable to the subject; (ii) the English language informed consent document approved by the IRB may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject. When a translator assists the person obtaining consent, the translator may serve as the witness. The IRB must receive all foreign language versions of the short form document and any other translated documents presented to the subjects as a condition of approval. The IRB recognizes that while the planned enrollment of subjects that do not speak English should have prospectively translated subject-facing documents (i.e., consent forms), from time to time the Investigator may unexpectedly encounter an individual for whom there is not translated documents. Expedited Review of foreign language versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

Illiterate persons who understand English may have the consent form read to them in their native language and make a “mark” on the subject signature line. Signatures of the witness to the consent process and the person conducting the consent interview are required in such situations. The IRB considers illiterate persons as likely to be vulnerable to coercion and undue influence and, therefore, considers whether appropriate additional safeguards are in place when enrollment of such persons is anticipated.

10. Waiver of Consent for Planned Emergency Research Under FDA Regulations

The IRB responsible for the review, approval, and continuing review of the clinical investigation involving planned emergency research may approve such investigation without requiring that informed consent of all research subjects be obtained if the IRB, with the 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, finds and documents each of the following:

- a. The human subjects are in a life threatening situation.
- b. Available treatments are unproven or unsatisfactory.
- c. The collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

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- d. The subjects will not be able to give their informed consent as a result of their medical condition.
- e. The intervention under investigation must be administered before consent from the subject's legally authorized representative is feasible.
- f. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
- g. Participation in the research holds out the prospect of direct benefit to the subjects because:
 - i. Subjects are facing a life-threatening situation that necessitates intervention;
 - ii. Appropriate animal and other pre-clinical studies have been conducted, and the information derived from those studies and related evidence supports the potential for the intervention to provide a direct the individual subjects; and
 - iii. Risks associated with the investigation are reasonable in relation to what is known about:
 - 1. the medical condition of the potential class of subjects;
 - 2. the risks and benefits of standard therapy, if any; and
 - 3. the risks and benefits of the proposed intervention or activity.
- h. The clinical investigation could not practicably be carried out without the waiver.
- i. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator must summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.
- j. The IRB has reviewed and approved informed consent procedures and an informed consent document and determined that these procedures and the informed consent documents must be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation.
- k. Additional protections of the rights and welfare of the subjects must be provided, including, at least:
 - i. Consultations with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;

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- ii. Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;
 - iii. Public disclosure of sufficient information following completion of the clinical investigation, to apprise the community and researchers of the study, including the demographic characteristics of the research population and its results;
 - iv. Establishment of an independent data monitoring committee to exercise oversight of the clinical investigations; and
 - v. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has attempted, if feasible, to contact within the therapeutic window a family member of the subject who is not a legally authorized representative, to ask whether he or she objects to the subject's participation in the clinical investigation. The investigator must summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
- I. The IRB must ensure that procedures are in place to:
- i. Inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of:
 - 1. the subject's inclusion in the clinical investigation;
 - 2. the details of the investigation and other information contained in the informed consent document; and
 - 3. that the informant may now discontinue the subject's participation at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
 - ii. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject must also be informed as soon as feasible.
 - iii. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation must be provided to the subject's legally authorized representative or family member, if feasible.
- m. All records required by this policy must be retained in accordance with the Records Management Policy, EC.014, and must be accessible for inspection and copying by FDA.
- n. The IRB shall verify the IND/IDE covers protocols that may include subjects who are unable to consent (even if an IND for the same drug product or an IDE for the same device already

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APPROVED BY: Ethics and Compliance Policy Committee	

<p>exists for non-emergency settings, a separate one is required for subjects who cannot consent).</p> <p>o. If an IRB determines that it cannot approve the clinical investigation because the investigation does not meet the criteria contained within the FDA regulations' exception from informed consent requirements for emergency research, or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation.</p> <p>11. Authority to Observe the Consent Process</p> <p>The IRB has the legal authority to observe (or have a third party observe) the consent process to protect participants. The IRB should consider this as an option when there is a history of problems with a particular investigator with consenting subjects or if the IRB has reason to believe that the investigators are not consenting subjects appropriately. This observation can be done via record review, personal observation or other appropriate means.</p> <p>REFERENCES:</p> <ol style="list-style-type: none"> 1. IRB Related Definition and Common Acronyms Policy, COG.IRB.001 2. Clinical Operations Group Research Policies in the COG.IRB series (COG.IRB.001 through COG.IRB.011) 3. Records Management Policy, EC.014
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