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Informed Consent

1 Goals

Upon completion of this module, the learner will be able to:

- Comprehend the underlying ethical requirements of informed consent
- Describe the eight basic elements and the six additional elements of informed consent
- Illustrate the appropriate method of documenting informed consent
- Define the special circumstances and requirements associated with obtaining the informed consent of vulnerable populations for participation in research
- Describe the conditions under which obtaining and/or documenting the subject's consent may be waived

2 Introduction

Becoming involved in human research is an undertaking that requires serious thought and commitment on the part of the researcher as well as the willing participant.

The desire to gain scientific knowledge through human subject research must be balanced with ethical concerns at all times.

Participants must be provided information regarding the nature of the research as well as risks, benefits and expected outcomes. This should be communicated during a dialogue (the informed consent "process") as well as in writing (the informed consent "document").

The participants must be fully informed before agreeing to enroll in a research project and kept updated on new information that becomes available that might affect their willingness to continue participation.

3 Informed Consent Process

Informed consent is the primary ethical requirement and foundation of human subject research. It reflects the basic principle of respect for persons.

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In addition to being the morally correct thing to do, obtaining informed consent of subjects is required by Federal law and University policy. Failure to obtain proper informed consent may result in revocation of research funding, disbarment or criminal prosecution at the Federal level and sanctions ranging from reprimand to dismissal by the University. Investigators may also be subject to civil suits arising from violations of Federal law and/or University policy. The University is not obligated to defend an investigator if laws or policies were violated.

It should always be remembered that providing information and educating the subject is not a single event but an ongoing process. The informed consent process is designed to provide prospective subjects with all relevant information so that they can decide whether or not to participate. Investigators have a contractual and ethical responsibility to keep research subjects fully informed of any new information that might affect their willingness to continue study participation. The process should permit the potential research subject to ask questions and to exchange information freely with the study investigators.

No investigator may involve an individual in a research study unless the investigator has prospectively obtained the legally effective, written informed consent of the individual or the individual's legally authorized representative (unless the IRB has specifically granted a waiver of the consent process or the requirement for written informed consent). See section on "Waiver of Informed Consent" which is addressed later in this chapter.

The investigator must seek informed consent under circumstances that give the individual sufficient time to consider whether or not to participate in the research study and that minimize possible coercion or undue influence.

Informed consent to participate in a research study should be sought at a time separate from obtaining informed consent required for standard medical care/treatment purposes. Participants might be overwhelmed with forms to sign for their medical care and not realize that they are agreeing to participate in research.

4 Basic Elements of Informed Consent

Both the FDA regulations (Title 21 Part 50) and the Federal Policy regulations (Title 45 Part 46.116) outline the requirements for obtaining and documenting informed consent.

Both define the eight basic elements of informed consent that must be included in the informed consent document. They are as follows:

4.1 A statement that the study involves research.

This description/statement should include information such as:

- An explanation of the purpose of the research
- The reason why the potential subject is being asked to participate

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- The expected duration of study participation
- A description of the procedures that will be performed
- Identification of any procedures which are experimental.

It is important to explicitly state that the individual is being asked to participate in a research study so as to clearly differentiate:

- The relationship between patient-physician from the relationship between subject-investigator; and
- Informed consent for participation in research from informed consent for invasive clinical procedures.

The consent process (and document) must clearly describe all of the procedures that will be performed for research purposes. Procedures that are experimental should be clearly distinguished from standard medical procedures used for screening or follow-up.

Procedures that are performed solely as part of the subject's routine medical care should not be included.

4.2 A description of any reasonably foreseeable risks or discomforts.

The risks of all procedures performed for the purpose of the research should be explained. The explanation of risks should be communicated in such a way that the information is honest, factual and does not minimize reported adverse effects. Statements should not imply that an experimental intervention is safe when the purpose of the study involves a determination of safety.

Risks of all medications should be outlined, including risks of approved drugs that will be administered to facilitate a research procedure. For example, if a commonly used topical anesthetic will be used, e.g., lidocaine, in order to implement a study procedure, the risks of lidocaine must be addressed.

The subject should be provided with information that addresses not only the nature and severity of the risks, but also their expected frequency.

4.3 A description of any benefits to research subjects or to others that may reasonably be expected from the research.

The description of potential benefits should be clear and not overstated. If there is no potential for direct benefit to the research subject, this should be explicitly declared. If applicable, it may be stated that future patients who are afflicted with this same problem might benefit from the current research. Statements should not imply that an

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experimental intervention is effective when the purpose of the study is to evaluate its effectiveness.

Note: Remuneration for participation in research study is not considered a benefit. Remuneration should be addressed in the Costs and Payments section of the consent form.

4.4 A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the potential research subject.

To enable a rational choice to participate in a research study, potential research subjects must be aware of the full range of treatment options. Thus, the informed consent discussion (and document) should briefly address any treatments currently available as alternatives to study participation. For many research studies, the only alternative to study participation is not to participate and this should also be stated in the consent form document.

4.5 A statement describing the extent to which confidentiality of records identifying the subject will be maintained

The subject should be informed of measures in place to protect their privacy and the confidentiality of research data, e.g., using identity codes instead of names, storing files in locked cabinets and protecting computerized information with passwords.

If records will be maintained in such a manner that it might be possible to link the results of the study with subject identifiers, this must be explicitly stated. If any other entity, such as the sponsor of the research study, an applicable regulatory agency (e.g., FDA or OHRP), and/or hospital billing departments, requires access to the study records, the potential research subjects must be so informed. Additionally, a statement should be included that the Research Conduct and Compliance Office of the University of Pittsburgh may audit the research study records for quality assurance purposes.

Any possible exceptions to maintaining confidentiality of the research records should also be addressed (e.g., required reporting of child or elder abuse and subpoena of records by the court).

In cases where data are being collected about sensitive issues such as illegal behavior, alcohol abuse, drug abuse, sexual practices or genetic information, a Federal Certificate of Confidentiality may be obtained. These certificates are designed to protect data from the possibility of subpoena by the courts. Certificates are issued sparingly and are appropriate only when the research information gathered is of a sensitive nature and protection is deemed necessary to achieve the research objectives while protecting the study subjects' confidentiality and privacy.

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4.6 For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs; and, if so, what they involve, or where further information may be obtained.

This explanation may be omitted from the informed consent document for minimal risk protocols (e.g., psychosocial studies) where injury associated with study participation is unlikely.

4.7 A statement that participation is voluntary; that refusal to participate will involve no penalty or loss of benefits to which the potential research 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.

If the research study involves patients, the statement should specify that refusal to participate in or withdrawal from the research study will have no effect on the individual's current or future care at a UPMC facility. Likewise, if the research study involves recruiting primarily University students, the statement should specify that refusal or withdrawal would not affect current or future academic standing.

4.8 An explanation of whom to contact for answers to pertinent questions about the research and the rights of research subjects, and whom to contact in the event of a research-related injury to the subject.

The Voluntary Consent Statement should explain that the subjects should contact the principal investigator or a member of the research staff with questions regarding any aspect of the study. The first page of the consent form must list the principal investigator and all co-investigators. Include either an address and phone number for each listed investigator or a common departmental address and phone number, if applicable.

For studies with risk of physical harm, emergency contact information must be provided on the first page of the consent document. The subject must be able to reach a member of the research team within two phone calls at any time. Therefore, emergency instructions must be provided on audex messages and a "real person" must answer and triage the call to the research team who is familiar with the protocol and study intervention. Note that it is unacceptable to have a "physician on call" who is not familiar with the protocol address the call.

The number for the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668), should also be included in the Voluntary Consent Statement.

The Compensation for Injury Section should instruct the subjects that, if they believe they have been injured as a result of the research procedures, they are to notify the principal investigator.

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5 Six Additional Elements of Informed Consent

In addition to the required eight basic elements of informed consent, six additional elements should be communicated to the subject and addressed in the consent form, if applicable to the design of the study

5.1 The approximate number of subjects to be involved in the study.

If the number of subjects in a study is material to the individual's decision to participate, the potential research subjects should be told not only the approximate number of subjects involved in the study but also why this information is important. For example, a Phase I study may involve a few individuals who are the first human subjects to receive the investigational agent. This information might be significant in making the decision to participate.

5.2 A statement that the particular treatment or procedure might involve risks to the subject (or to the embryo or fetus, if the subject is pregnant or becomes pregnant) that are currently unforeseeable.

Investigators should ensure that individuals who agree to enter a study fully understand the potential risks that the study poses. Potential research subjects, both women and men, need to understand the danger of receiving any investigational agent, of which effects on the fetus are unknown. If measures to prevent pregnancy are warranted, contraception should be fully explained.

5.3 Anticipated circumstances under which a subject's participation might be terminated by the investigator without regard to the individual's consent.

Examples of specific reasons for termination by the investigator should be provided, i.e.,

- Deleterious effect of participation on the subject's health or welfare,
- Failure to comply with instructions to effectively implement study activity, and/or
- Failure to maintain appointment schedule.

5.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

When withdrawal from a research study might have deleterious effects on the subject's health or welfare, the informed consent document should explain any withdrawal procedures that are necessary for the subject's safety and welfare. For example, gradual

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discontinuation of a medication and monitoring during the weaning process might be indicated rather than an abrupt discontinuation of the drug. Another example might be a subject's decision to terminate an investigational life-sustaining device. In this case, the possibility of death as a result of his or her decision must be clearly explained.

5.5 A statement that significant new findings developed during the course of the research which might relate to the subject's willingness to continue participation will be provided to the subject.

This statement might not be applicable to certain research studies (e.g., psychosocial studies) and may be omitted from the respective informed consent document. However, if the study involves an investigational drug or device, any new information about additional side effects that are revealed during the course of the study must be communicated to the enrolled subjects.

- For subjects already enrolled and actively participating in a research study, new information may be communicated via a written consent form addendum. This addendum is an abbreviated form that specifically addresses the new information. It also should contain a reiteration of the voluntary consent and right-to-withdraw statements and must be signed by the subject or subject's legally authorized representative and the person obtaining the consent. It must be submitted and approved by the IRB prior to implementation. Once implemented and signed, the addendum should be filed with the original consent form, a copy given to the subject and a copy placed in the subject's medical chart if hospitalized.

- For prospective new subjects, the previously approved consent form and protocol should be modified to integrate the new information.

- All modifications to the protocol, consent form document, and addenda must be submitted and approved by the IRB prior to their implementation.

5.6 Any additional costs to the subject that might result from participation in the research.

Potential research subjects should be clearly informed if they, or their third-party insurance providers, will be billed for any procedures associated with their participation in the research study.

Potential research subjects should also be informed that certain third-party insurance providers might not fund care that is delivered as part of a research study and that, under such circumstances, the subjects will be held directly accountable for the charges.

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6 Important Points to Remember

- Information given to potential research subjects must be understandable to them. Technical and medical terminology should be avoided or, if used, explained in lay terms. Short and concise sentences are often most effective. Acronyms should be spelled out in full the first time they are used. It is helpful to have an individual unfamiliar with the research area read and comment on the consent form prior to submitting it for IRB approval.

- Deferred consent is not permitted. This means that obtaining informed consent may not be postponed to a time after research activities or screening procedures have already been performed.

- Phone consent is not permitted. (Please refer to the section on Waiver of Informed Consent and Waiver to Document Informed Consent for possible exceptions to this rule.)

- The principal investigator must retain the original signed informed consent document in the research records. A copy of the informed consent document must be given to the research subject or subject's legal representative. For hospitalized subjects, a copy of the signed informed consent document must also be included in the subject's medical chart.

- The informed consent document may not include exculpatory language through which the potential research subject is made to waive or appear to waive any legal rights or releases, or appears to release the investigator, the sponsor, the institution or their agents from liability for negligence.

- The investigator should establish procedures to ensure that only the current IRB-approved version of the consent form is being used.

- Informed consent is an ongoing process and subjects must be kept informed of any new information that may influence their decision to continue study participation.

7 Documentation of Informed Consent

It is the policy of the University of Pittsburgh IRB that the subject or the subject's legal representative and the person obtaining their consent must sign the consent form document.

Note that, if the study involves a drug, device or surgical procedure, the person obtaining the consent must be an investigator listed on the first page of the consent document who is also an appropriately credentialed physician.

All individuals must sign and date the consent form in their own hand. No one may date the signature of another.

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If a legal representative signs the consent form, the relationship to the subject should also be documented.

To ensure that the subject (or subject's legal representative) has read and discussed each page, a space should be provided on the bottom right-hand corner of every page of the consent form for the subject (or legal representative) to initial. Initials are not required on the signature page.

It is good clinical practice to include a progress note in the subject's case history that the subject has been properly informed of the details of study participation. This note should include highlights of the consent process dialogue and include:

- who was present for the discussion
- that the risks were presented and discussed
- that all questions were answered
- that the subject appears to understand the conditions of the study and agrees to participate by signing the informed consent document.

This note should be signed and dated by the person making the entry. It is also good clinical practice to include in the narrative note the "time" that consent was obtained, especially if research procedures will be performed on the same day.

7.1 Verification of Explanation

In cases where assent is obtained from children or from adult subjects who are decisionally impaired but capable of executing some judgment of the nature of the research and their participation in it, a statement should be included in the subject's progress notes or medical record to indicate that the investigator has discussed the study in detail with the subject, answered all questions, and that the subject has provided affirmative agreement (i.e., assent) to participate in this research study. Any child or decisionally impaired adult who is able to provide a signature may sign an assent statement.

7.2 Parental Certification

In cases where minor subjects are to be enrolled in a research study, the parent(s) or legal guardian(s) must also sign the consent form agreeing to allow the child to participate. The IRB has the authority to determine if one or both parents must sign for a minor child.

7.3 Witness Signature

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A witness signature is required when the prospective subject is physically unable to sign the consent document. In those instances, the subject should "make their mark" and a witness must sign verifying that the named individual made the mark.

Note that a witness signature is also required when enrolling non-English speaking subjects or decisionally impaired adults. This will be addressed in the applicable sections.

Refer to the IRB Reference Manual, Chapter 8, for more detailed information regarding required signatures.

8 Screening Tests and Interviews Prior to Subject Enrollment

Screening procedures (including interviews) that are performed solely for the purpose of determining if individuals are eligible for participation in a research protocol are subject to regulations governing human subject protections, including the requirement for written informed consent.

With respect to screening interviews/surveys, written informed consent must be obtained prior to conducting the interview/survey if:

- the interview/survey is being performed for research purposes;
- the recorded responses to the interview/survey could place the individual at risk of civil or criminal liability or be potentially damaging to his/her employability, insurability, or reputation; and
- subject identifiers are retained with the recorded interview/survey responses.

If a separate consent for "screening procedures" is prepared, it must include the eight basic elements of informed consent.

Note that for "phone" screening interviews, a waiver for "written" informed consent may be granted by the IRB with appropriate justification and documentation. See the section on “Waivers” later in this chapter.

Medically proven and accepted procedures that are performed for the standard clinical care of a prospective research subject and which would have been performed whether or not study entry was contemplated (e.g., procedures consistent with the diagnosis or treatment of a disease or medical condition) may be performed and the results subsequently used for determining research study eligibility. However, the protocol and consent document must indicate that historical medical information will be documented in the research records.

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9 Informed Consent of Non-English Speaking Subjects

Research subjects who do not speak English should be provided with a "short form" consent document, written in the subject's native language, that summarizes the basic elements of informed consent. (Copies of such "short form" consent documents, translated into several commonly encountered foreign languages are available from the IRB Office.)

The standard (i.e., IRB-approved, full-description) informed consent document should be presented verbally to the subject in his/her native language and all questions answered. UPMC maintains a staff of interpreters that may assist with this interaction. The International Patient Relations Center may be contacted by calling 412-648-6262. Be advised that arrangements with this office must be made well in advance of subject enrollment.

When enrolling a non-English speaking subject, consideration and arrangements should be made for communication with the subject for the consent process as well as throughout the course of the research study. The consent process for this population must be witnessed and the collection of accurate information regarding the subject's status and recording of adverse events is imperative.

Refer to the IRB Reference Manual, Chapter 6, and contact the IRB for guidance if the study involves a non-English speaking population or subject.

10 Informed Consent of Vulnerable Populations

10.1 Children as Research Subjects

In Pennsylvania, children are defined as persons < 18 years of age who have not attained the legal age or status to consent for treatment or procedures involved in research.

Note that the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects, effective October 1998, requires that children be included in all human subject research conducted or supported by the NIH unless there are scientific and ethical reasons not to involve them.

When enrolling children into a protocol, the consent of one or both parents or guardians must be obtained as well as the assent of the child.

Under Pennsylvania law, neither foster parents nor Children and Youth Services (CYS) may provide the informed consent to enroll a foster child in a research study. Only the birth parent or a person adjudicated as an adoptive parent can provide consent.

If a legal guardian provides consent, the court order or legal authorization should be copied and included in the research records with the consent document.

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For detailed instructions pertinent to the enrollment of children, the requirements and exceptions, please refer to the IRB Reference Manual, Chapter 6, and/or 45 Part 46, Subpart D at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartd

10.2 Pregnant Women and Fetuses

Special research protections for pregnant women and fetuses have been in existence since 1975. The informed consent of the pregnant woman should be obtained in accord with the standard regulatory provisions for informed consent if the research hold out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit to both the pregnant woman and the fetus, or no prospect of direct benefit for the pregnant woman nor fetus when the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means.

The informed consent of the pregnant woman and the father shall be obtained in accord with the standard regulatory provisions for informed consent if the research holds out the prospect of direct benefit solely to the fetus; except the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity, or if the pregnancy results from rape or incest.

For detailed instructions pertinent to the enrollment of pregnant women and fetuses, pregnant children or research involving neonates, please refer to the IRB Reference Manual, Chapter 6 and/or 45 Part 46, Subpart B at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartb

10.3 Prisoners

The IRB committee reviewing and approving a protocol that will include prisoners must include a prisoner representative. Once the protocol is approved by the IRB and Department of Health and Human Services (DHHS), prisoners enrolled in the research must provide informed consent. Prisoners enrolled in research must also be informed that their participation will have no effect on their parole.

If a research subject becomes incarcerated during his/her participation in a study, the IRB must be notified immediately. The subject may be withdrawn with full disclosure of the reason for such action or the protocol must be resubmitted to the IRB. The IRB will re-review the protocol in accordance with the listed requirements for research involving prisoners.

For detailed instructions pertinent to the enrollment of prisoners, please refer to IRB Reference Manual, Chapter 6, and/or 45 Part 46, Subpart C at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#subpartc

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10.4 Persons with Decisional Impairment

As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that would impair reasoning or judgment. Mental illness or cognitive impairment alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of the individual's incapacity to understand and to make a choice before being deemed unable to consent.

If the research is determined to involve greater than minimal risk and does not provide direct benefit to the participant, the research must bear some direct relationship to the cause of the subject's decisional impairment, i.e., Alzheimer's disease. The need for proxy consent must be justified and the methods in place to obtain proxy consent must be explained in the protocol. The IRB may require additional safeguards where appropriate for a given protocol.

The individual who may sign as the subject's legally authorized representative reflects Pennsylvania State Law and details may be found in the IRB Reference Manual, Chapter 6.

If a person with decisional impairment is capable of exercising some judgment concerning the nature of the research and their involvement, the investigator should obtain the subject's assent in addition to the consent of the legally authorized representative. The subject's verbal objection to participate is binding and the subject must not be enrolled.

Note that the proxy consent and assent of a decisionally impaired adult must be witnessed and the consent document signed by the witness.

A narrative note describing details and circumstances of obtaining proxy consent should be documented in the research records. Please refer to the IRB Reference Manual, Chapter 6, for further guidance when the research involves decisionally impaired adults.

10.5 Traumatized and Comatose Persons

Research involving patients undergoing emergency care differs from clinical research in other settings because the patient's capacity to provide consent is often severely compromised, and decisions about participation in research might have to be made too quickly to obtain permission from the patient's legally authorized representative.

In these cases, a waiver of informed consent may be necessary. Please refer to the section of this chapter that addresses "Waiver of Informed Consent for Research Involving Emergency Care" or to the IRB Reference Manual, Chapter 6.

If the subject recovers and is capable of making a decision, the research study must be explained to him/her (informed consent process), and s/he must provide his/her written informed consent to remain in the study.

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10.6 Terminally Ill Patients

Research involving terminally ill patients presents additional concerns in that potential subjects tend to be more vulnerable to coercion or undue influence, and the research is likely to present greater than minimal risk. As a result, special attention should be given to the informed consent process. The following elements must be emphasized:

- Accurate information concerning eligibility for participation (i.e., diagnosis and prognosis) and risks and benefits should be conveyed clearly and in a manner that will not either engender false hope or eliminate all hope.

- Patients should be fully informed of the availability of treatment alternatives, including at what point their participation in the research study should or might be terminated to permit a treatment alternative (e.g., discontinuation of participation in a drug trial to permit organ transplantation), and information that another alternative might be no additional treatment.

- Any costs to the subject associated with research study participation should be stated explicitly.

11 Waiver of Consent

There are circumstances in which an investigator may petition the IRB to waive the requirement for informed consent or for documentation of informed consent. The categories of studies and the requirements for each are described below.

11.1 Waiver of Informed Consent for Minimal Risk Research Studies

The IRB can approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or may waive the requirement to obtain informed consent provided that each of the following criteria is met:

1. The research involves no more than minimal risk to the subjects.
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.
3. The research could not practicably be carried out without the waiver or alteration.
4. Whenever appropriate, the subjects will be provided with additional pertinent information after enrollment.

An example of a research protocol that meets these criteria would be a study that involves surveys and questionnaires presented to adolescent subjects being seen at a clinic that provides information and treatment for sexually transmitted diseases. For research studies, enrollment of children under the age of 18 requires parental consent. However, in this case, a waiver of the requirement for parental consent may be appropriately justified based on the fact that the State of Pennsylvania permits adolescents to seek treatment and education regarding sexually transmitted diseases without their parents' consent. To require consent of the parents for the adolescent's participation in the research study would result in a disclosure of his/her attendance at the clinic and would be in opposition to the State's policies.

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To be considered for such a waiver, the principal investigator must address each of the above criteria, including a justification of its applicability to the proposed research. This information should be included in the recruitment section of the IRB protocol as well as in a cover letter. Be advised that the full Institutional Review Board reviews all requests for a waiver of consent. These requests are considered seriously and must have indisputable justification before a waiver can be granted.

11.2 Waiver of Informed Consent for Research Involving Emergency Care

The Federal Policy and FDA regulations permit individuals to be enrolled, without their legally effective informed consent (or the consent of their authorized representatives), in research studies directed at the evaluation of emergency care interventions provided that certain basic conditions are met:

1. Potential subjects are in a life-threatening situation and:

    - available treatments are unproven or unsatisfactory; and
    - collection of scientific data is required to determine the safety and effectiveness of the experimental intervention.

2. Obtaining informed consent is not feasible because:

    - the potential subject is not able to consent due to his/her medical condition;
    - the intervention must be administered before consent from the potential subject's authorized representative is feasible
    - there is no reasonable way to prospectively identify potential eligible subjects.

3. Participation in the research study holds the prospect of <u>direct</u> benefit to the subjects because:

    - the subjects are facing a life-threatening situation;
    - appropriate pre-clinical and prior clinical research studies support the potential for direct benefit; and
    - the risks associated with the research are reasonable relative to the risks of the subjects' condition and the risk/benefit ratio of standard therapy for the condition.

4. The research could not be practicably carried out without the waiver.

In addition to meeting the above basic conditions, there are multiple additional requirements that must be addressed before the IRB can grant a waiver of the informed consent requirement for research involving emergency care procedures. Investigators involved in the implementation of such research studies, wherein a waiver of informed consent is an anticipated necessity, are advised to engage the assistance of the IRB Office as early as possible in the implementation process.

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11.3 Waiver of Requirement to Obtain a Signed Informed Consent Document

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if either:

1. 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;

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

    Note: If a waiver is granted based on this criterion, each subject must be asked whether s/he wants documentation linking her/him with the research, and the subject's wishes will govern.

To be considered for such a waiver, the principal investigator must address, in the recruitment section of the IRB protocol submission, the criterion under which s/he is requesting the waiver and provide a justification of its applicability to the proposed research.

Note that if the IRB grants a waiver of the requirement to obtain a signed consent form, this does not eliminate the requirement to obtain the informed consent of the subject for study participation. Thus, accompanying this waiver request should be a script of the information that will be provided to potential subjects in obtaining their verbal consent for study participation. This verbal consent process should include all of the basic and additional, applicable elements of informed consent. The waiver request should also address the mechanism that will be used by the investigators to document that the verbal consent of subjects has, in fact, been obtained.

This process is frequently used for the initial phone screening for prospective subjects. The phone screening presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. To apply for a waiver to document consent for the phone screening, the investigator must justify the request, include a script that includes the eight basic elements of consent and provide the list of screening questions that will be presented to the prospective subject during the phone screening,

Refer to the IRB Reference Manual, Chapter 8, for additional guidance.

12 Additional Waivers

It is possible to obtain waivers of consent for other research endeavors. For example, a researcher may apply for a:

- Waiver of consent when performing record review that is "preparatory to research"

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- Waiver of consent to use medical records information (PHI) when the researcher is also the health care provider for the prospective subject
- Waiver of the HIPAA Authorization for sharing contact information for the purpose of recruiting subjects
- Waiver for the retrospective review of medical records.

Please refer to the IRB Reference Manual, Chapter 8, for details regarding the necessary justification and documentation requirements to apply for any of these waivers.

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