Informed Consent and the Research Subject

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Federal Requirements: 45 CFR 46.116, 45 CFR 46.117 and 21 CFR 50.25

Content Applies To

Mayo Clinic Human Research Protection Program

Purpose

The purpose of this policy is to provide guidance to investigators regarding the informed consent process for research subjects.

Policy

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It is the policy of the Mayo Clinic Office for Human Research Protection Institutional Review Board (IRB) that investigators will not involve human beings as subjects in research unless the investigator has obtained the legally effective informed consent of

the subject or the subject's legally authorized representative. Exception to this policy requires that the IRB grant a waiver of the informed consent requirement.

Unless waived by the IRB, consent will be documented by the use of an approved, written consent form. The form will be signed and dated (including the time) by the prospective subject or the prospective subject's legally authorized representative. Note: research personnel may not fill in the date and time.

The consent document will include the basic elements of informed consent as specified in 45 CFR 46.116 - *General Requirements for Informed Consent* and 21 CFR 50.25 - *Elements of Informed Consent*.

An investigator will seek informed consent only under circumstances that provide the prospective subject or, when approved by the IRB, the subject's legally authorized representative sufficient opportunity to understand and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the subject or the representative will be in language understandable to the subject or the representative.

No informed consent, whether oral or written, will include any exculpatory language through which the subject or their 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.

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Key Terms

Consent Document: A structured, written description in lay terms of relevant research project information. The written consent document is not 'consent' itself; it is the 'record' of what has been communicated to a prospective subject. It is the document that ensures all regulatory elements are present and communicated to a potential subject. When signed by the potential subject, the consent document is a record of the receipt of research-related information by the subject. It also serves as reference material for the subject as the research project progresses. It is not legally binding and the subject may choose to withdraw consent at any time.

Documentation: Documentation of informed consent includes use of a written IRB-approved consent document, signed and dated by the prospective subject or the prospective subject's legally authorized representative.

Enrollment: Occurs when an eligible, informed, prospective subject undergoes the initial informed consent process and voluntarily agrees to participate in a research project.

Informed Consent: An ongoing process of communication between the subject and the investigator. Informed consent is a continual process by which a subject, after having been informed, voluntarily confirms his or her willingness to participate in a research project and can demonstrate understanding of all aspects of the research project that are relevant to the subject's decision to participate.

Legally Authorized Representative (LAR): An individual, or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the prospective subject's participation in the procedure(s) involved in research (45 CFR 46.102).

Legally Effective Informed Consent: A subject has been provided enough information to make a decision; the subject has the capacity to make a decision; the

subject understands the consequences of his or her decision; and the subject can communicate that decision.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Oral (verbal) Consent: A spoken presentation of the elements of informed consent to the prospective subject or their legally authorized representative.

Recruitment: Recruitment is the process of distributing or presenting information which describes the research project and eligibility criteria so that a prospective subject may consider enrollment.

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Waiver or Alteration of the Consent Process

The provisions for waiver of informed consent do not apply to FDA regulated research involving human subjects.

- An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:
    - 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: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
    - The research could not practicably be carried out without the waiver or alteration.
- 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 requirement to obtain informed consent provided the IRB finds and documents that:
    - The research involves no more than minimal risk to the subjects;
    - The waiver or alteration will not adversely affect the rights and welfare of the subjects;
    - The research could not be practicably carried out without the waiver or alteration; and
    - Where appropriate, the subjects will be provided with additional pertinent information after participation. (45 CFR 46.116)

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Waiver of Documentation of Consent

The provisions for waiver of documentation of informed consent do not apply to FDA regulated research involving human subjects.

The IRB will review the research proposal to determine if waiver of documentation of informed consent is appropriate. The IRB may waive the requirement for an investigator to obtain a signed consent form for some or all subjects if it finds that either:

- The only record linking the subject and the research would be the consent form 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; or
- That 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.
- In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
- When the IRB considers waiving the requirement to obtain written documentation of consent, the IRB reviews a written description of the information that will be provided to subjects via an oral consent script, contact letter, phone script or similar document.
- If a waiver of written consent is granted by the IRB, the IRB will determine whether the investigator must document the oral consent in research study files and/or the subject's medical record.

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Consent Process Plan

The investigator will develop a detailed consent process plan for the initial research proposal submission to the IRB. The following factors should be assessed and used to develop the plan:

- Type of research project being conducted, for example, biomedical research, behavioral/social science research, health services research.
- Risk to subjects, including procedures, devices, drugs, or biologics.
- Vulnerable categories of subjects, for example children; adults lacking decision-making capacity; prisoners; pregnant women and fetuses; persons who are non-English speaking, economically or educationally disadvantaged, terminally ill, or students or employees of the organization.
- Characteristics of subjects such as age or health status that may influence health literacy and the consenting process.
- A plan for informing subjects of significant or incidental findings resulting from the research.

The plan must include a description of the following:

- Recruitment and advertising activities.
- Payment arrangement, if any.
- The method(s) for obtaining informed consent, including where or how communication will take place.
- The amount of time planned for the consent process.

- Method(s) for assessment of a subject's capacity to consent.
- The protections that are planned to reduce potential subject's vulnerability to coercion or undue influence during the consenting process.
- The waiting period between discussion, decision, and enrollment.
- Study team members who will meet with the prospective subject and obtain informed consent. These individuals must be sufficiently trained, knowledgeable about the research project in order to answer questions posed by the subject, and must have IRB approval to obtain consent.
- If the investigator has a preexisting relationship with a prospective subject, the responsibility for the consent process will be delegated to another qualified member of the study team to avoid the possibility of undue influence to participate in the research.

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Recruitment Plan

To assist in the development of recruitment plans and recruitment and advertisement materials, contact: the Mayo Clinic Center for Translational Science Activities, Service Center, Communications Coordinator-Research Recruitment (507) 255-1943 or internal (77) 5-1943. All recruitment materials must meet the Brand Standards of Mayo Clinic. http://mayoweb.mayo.edu/brand-standards/index.html

The investigator will:

- Provide a recruitment plan in the project proposal, including a description of the proposed recruitment method(s), advertisements, and if applicable, any payment arrangements.
- Specify the maximum number of contacts that will be attempted to contact a prospective subject (i.e., number of telephone calls, voicemail messages, emails, letters, etc.).
- Describe the extra protections for prospective subject populations that may be vulnerable to coercion or undue influence.
- Describe the source of prospective subjects.
- Ensure that recruitment methods, advertisements, payment arrangements are not misleading, inaccurate, exculpatory, or violate the equitable selection of subjects; and do not place prospective subjects at risk of coercion or undue influence.
- Ensure that subject privacy and confidentiality are protected.
- Consider a prospective subject's stress level or health status.
- Consider the timing of recruitment discussions with a prospective subject, for example, in relation to a subject receiving a diagnosis and ensure the readiness of a prospective subject to understand information being discussed.

The investigator will submit copies of the following recruitment information, including advertisements or payment arrangements to the IRB for review:

- Printed materials, such as flyers, posters, brochures, postcards.

- Media advertisements such as newspapers, television, radio, and internet website postings.
- If advertisements will be taped for broadcast, investigators should submit a copy of the audio/video tape or the text / script for review.
- If final copies of recruitment or advertising materials are not available at the time of initial IRB submission, draft versions may be submitted. When the final copy becomes available, it must be submitted to the IRB for review and approval to confirm the wording is appropriate and clearly reflects the intent of the research.
- Recruitment letters, phone or e-mail scripts.
- Telephone call scripts.
- Direct advertising intended to be seen or heard by potential subjects.
- Payment arrangements, if applicable.

Required content of recruitment/advertisement materials:

- Name and address of the investigator and research facility.
- The purpose of the research or the condition under study.
- A summary of the criteria that will be used to determine eligibility for the research project.
- The person or office to contact for further information.
- The voluntary nature of participation.

Optional content of recruitment/advertisement materials:

- A brief list of prospective benefits and risks to subjects, if any.
- The estimated time or other commitment required of the subject.
- A statement that remuneration will be provided, without emphasis on the payment or amount.

Recruitment/advertisement materials should **not** contain:

- Claims of safety, equivalence or superiority to treatment.
- Phrases such as “new treatment”, “new medicine”, or “new drug”.
- The term “free” in reference to treatment procedures.
- Overestimations of benefits and underestimations of risks.
- Payment or the amount to be paid in large or bold type.

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Recruitment Materials Posted on Websites

- IRB review and approval of listings of clinical trials on the internet is not required when the system format limits the descriptive information provided to basic trial information, such as: the title; purpose of the study; protocol summary; basic eligibility criteria; study site location(s); and how to contact the site for further information.
- Examples of clinical trial listing services that do not require prospective IRB approval include www.clinicaltrials.gov and the Mayo Clinical Trials listing.

- Information exceeding the basic trial information, such as descriptions of clinical trial risks and potential benefits or solicitation of identifiable information, requires IRB review and approval before posting on websites.

Individual or Institutional Recruitment Incentives

Mayo Clinic prohibits:

- Payments to professionals in exchange for referrals of potential participants ("finder's fees").
- Payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") unless they are judged not to interfere with providing prospective participants with sufficient opportunity to consider whether to participate and do not increase the possibility of coercion or undue influence on investigators or participants.

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Payment/Reimbursement of Research Subjects

Research subjects may be paid, however the payment of participation is not considered a benefit, but rather a reimbursement for time and effort. All payments to subjects in research must be fair and equitable. Participation in a clinical trial offered by a sponsor may not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

Principle of Reasonable Compensation: The IRB will review and determine the amount is reasonable and not so large as to unduly induce participation. All information concerning payment, including the amount and schedule of payment, should be clearly stated in the application and reflected in the consent documents. When the IRB evaluates the selection of subjects, it considers the influence of payments to subjects. While the federal regulations do not specifically state how much researchers should pay subjects or what that payment should look like, the IRB will apply a principle of reasonable compensation as it reviews subject payment for time, effort and inconvenience.

Pro-Rated Payment and Bonuses: Payment for participation in research should not be contingent upon the subject completing the entire study but rather be prorated as the study progresses to insure voluntary participation. While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable providing that such an incentive is not coercive. If a bonus is given at the completion of the trial it should not be more than one half of the total reimbursement.

Department of Defense - Recruitment and Payment

When research involves U.S. military personnel, the additional protections to minimize undue influence for military research participants include:

- Officers are not permitted to influence the decisions of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.

- When recruitment involves a percentage of a unit, an independent ombudsman is present.

When research involves U.S. military personnel, the limitations on dual compensation prohibit an individual from receiving pay of compensation for research during duty hours. An individual may be compensated for research if the participant is involved in the research when not on duty. Individuals may be compensated for blood draws for research up to $50 for each blood draw.

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Use of Social Media (Twitter, Facebook) for Recruitment

Research projects using social media as a recruitment method must be reviewed and approved by the Mayo Clinic Public Affairs/Center for Social Media. For questions please call your local Public Affairs/Center for Social Media office.

- New projects proposing the use of social media as a recruitment method will contain a statement from the PI in either the IRBe application or the research project proposal that the use of social media for recruitment of research subjects has been reviewed and approved by the Mayo Clinic Public Affairs/Center for Social Media.

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Enrollment Plan

When planning enrollment the Investigator must address the following:

- Amount of time needed for reading or reviewing the consent document
- Amount of time needed for the prospective subject to make a decision
- The location or methods of communicating and the related privacy needs for the initial and on-going discussions (e.g. in-person, mail, telephone)
- The need for including a medical interpreter, Legally Authorized Representative, family member(s), witness, or advocate who may need to be present and observe the discussions within the informed consent process.

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Non-English Speaking Prospective Subjects who are Not Specifically Targeted for the Research Project *(see below for* targeted non-English speaking subjects)

If enrollment of a prospective non-English speaking subject is considered when a research project does not specifically target this population, the investigator must:

- Have an independent medical interpreter provide an oral explanation (in person or by phone) of the entire content of the English version of the approved consent document to the prospective subject or the subject's legally authorized representative.
- In conjunction with the oral presentation, use the IRB's written Short Form / Authorization to Use and Disclose Protected Health Information form, stating that the elements of informed consent have been presented orally. The short form must be translated into a language understandable to the subject. Translated short forms in several different languages can be found on the IRB home page under the Forms and Procedures tab, Forms and Templates.

- There must be a witness to the oral presentation. The witness must be conversant in both the English language and the language of the prospective subject. The interpreter may serve as the witness.
- Assure that the prospective subject or their representative has signed the translated Short Form/Authorization to Use and Disclose Protected Health Information form.
- Assure that the witness has signed both the translated Short Form and a copy of the English consent document.
- Assure that the person obtaining consent has signed a copy of the English consent document.
- A copy of the translated Short Form and a copy of the English consent document must be given to the prospective subject or the prospective subject's representative.

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Non-English Speaking Prospective Subjects who are Specifically Targeted for the Research Project

If a research project targets non- English speaking persons of a specific language, then all printed study materials that are provided to the subject must be translated in that language and approved by the IRB prior to enrolling potential subjects. To do this, the investigator must:

- Submit English versions of the documents to the IRB for review and approval.
- Send the final English versions, which have been approved by the IRB, to an external translation vendor or to Mayo Clinic Written Translation Services for translation for the intended targeted population. For questions regarding Mayo Clinic translation services, contact the Translation Coordinator at (77) 8-0372 or e-mail to translation@mayo.edu.
- Submit the translated documents to the IRB via the IRB electronic system together with the *Certificate of Authenticity* provided by the translation service.

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Guidelines for the Use of Interpreters

A Mayo Clinic interpreter or Mayo-contracted telephone interpreter will be utilized when obtaining informed consent for research from a non-English speaking prospective research subject or the subject's legally authorized representative. This will assure complete, accurate, impartial, and confidential communication. Study staff designated to obtain consent and fluent in the language of the prospective research subject may also serve as interpreters.

Telephone interpreting is provided when an interpreter is unavailable for a face-to-face encounter, unable to arrive within a reasonable amount of time, or when Mayo Clinic Language Services does not have an interpreter on staff for a requested language. Telephone interpreting is used as a back-up, not as a replacement for an in-person interpreter.

Family members and friends may not serve as interpreters during the research consent process except in an emergency situation and only until a Mayo Clinic or contracted telephone interpreter is available. Additionally, adult family members or friends may

serve as interpreters if the prospective research subject declines Mayo interpreter services AND if the use of that person does not compromise the effectiveness of care or violate confidentiality. To ensure accuracy, the investigator should request that a Mayo Clinic interpreter be present when a family member or friend is interpreting.

Minor children may not serve as interpreters for the research consent process.

An interpreter contracted by the investigator for the purpose of a specific study may, with IRB approval, be utilized. Approval by Mayo Clinic Language Services may also be required.

- To request an interpreter, contact Mayo Clinic Language Services during office hours (below). After hours, contact the Mayo Clinic Operator.
    - Language Services

    Office Hours: Monday – Friday, 7:00 am – 6:00 pm

    Phone: (77) 4-2741

    http://intranet.mayo.edu/charlie/international-services/language-services/rochester/
- Mayo Clinic Institutional Policy
    - Communication Assistance – PC.6

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IRB Submission and Review

The IRB reviews the application and attached documents including (but not limited to) the research protocol, consent forms, scripts and recruitment and advertising materials, and payment arrangements. The IRB:

- Determines whether the consent process is appropriate for the proposed research activities and if revisions to the consent process or document are necessary.
- Determines the amount of payment and the proposed method and timing of disbursement is neither coercive or presents undue influence.
- Reviews the proposed research project and determines that the consent document accurately reflects the purpose, risks, benefits and procedures, and payments as outlined in the research protocol and contains all the required elements of consent disclosure.
- Determines whether documentation of informed consent is appropriate for the proposed research activities, the subject population and the level of risk.
- Determines if revisions to the consent process or consent document are necessary.

The IRB will ensure that:

- The research project proposal and related materials (i.e. recruitment/advertisement materials, payments, consent documents, scripts) as submitted to the IRB via IRBe are approvable.
- Recruitment sites, recruitment methods, advertising materials and payment arrangements do not place subjects at risk of coercion or undue influence or cause inequitable selection.

- The consent process minimizes the possibility of coercion or undue influence and maximizes continued legally effective informed consent. When prospective subjects are vulnerable to coercion or undue influence due to their status, condition or situational vulnerability, the IRB review will ensure that the informed consent *process* is appropriate for that population.
- The consent document has the requisite regulatory and institutional information and is written in language that is understandable to the research project population.
- The consent documents accurately describe the risks and benefits initially approved by the IRB and at the time of research project modifications, continuing review, submission of reportable events or other safety-related information.
- Significant new findings or alterations to the risks and benefits that may relate to the subject's willingness to continue participation will be provided to the subject.

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After IRB Approval

Investigator Responsibilities - Enrollment

During the enrollment phase of a research project, the investigator:

- Adheres to the IRB-approved research project and uses the current approved consent form (in IRBe) and consent process plan as approved by the IRB
- Ensures that delegated activities are performed by authorized and qualified staff as listed in the IRB application
- Submits all proposed research project modifications and revised documents to the IRB for review and approval prior to use
- Documents and retains consent records as directed by the IRB
- Reconsents subjects as directed by the IRB
- Assesses a prospective subject's physical and emotional state to determine his/her capacity for decision making
- Stops or reschedules the enrollment process if a prospective subject is unable to engage in the discussion or comprehend the research project information due to their physical or emotional state or if they appear reluctant or decline participation. The investigator (or their delegate) must never try to convince a prospective subject to participate in a research project
- Conducts the enrollment discussion with consideration given to the physical environment where enrollment activities will take place
    - Privacy and confidentiality issues may arise when enrollment activities take place in areas that are not private
    - Environments such as procedural rooms with multiple staff present or a waiting room lobby may introduce peer pressure, increase anxiety, foster intimidation, or present undue pressure to make an immediate decision
    - Waiting rooms with other patients nearby, exam rooms after being gowned, or patients lying on a gurney in a hallway are environmental conditions that must be avoided

- Avoids if possible, having the enrollment discussion immediately before surgery or clinical procedures or when prospective subjects are deprived of their glasses, hearing aids, clothing, or have been pre-medicated for a procedure
- Conducts a conversation regarding the research and the consent document with the prospective subject. The investigator (or their delegate) should:
    - Repeat important information to enhance subject recall
    - Use plain, nonmedical language whenever possible
    - Pause often for clarification, questions and answers
    - Spend time listening to the prospective subject
- Verbally reminds the prospective subject that their decision to participate or not participate will not affect their clinical care
- Provides private and ample time for the subject, their family members and/or their LAR to assess, evaluate, and discuss the information they have been given before asking them for their decision
- Discusses the research project in a way that is culturally and linguistically appropriate to the research project population
    - Depending on the subject population, enrollment requirements may include a medical interpreter, witness, advocate, parent(s), spouse or a LAR to be present to support the subject, to communicate information, to ensure impartiality of the discussion, and to contribute to documentation of the prospective subject's decision
    - Non-English-speaking Prospective Subjects: A Mayo Clinic medical interpreter will be used for communication assistance whenever engaging a non-English speaking subject in the informed consent process, including the discussion and confirmation that the subject understands the consent document. See "Guidelines for the Use of Interpreters".
    - English-speaking, Illiterate Prospective Subjects: A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document. A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into a study if they are competent and able to indicate approval or disapproval by other means. If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally (still competent) and (2) is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. An impartial third party should witness the entire consent process and sign the consent document.

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Participation

Investigator Responsibilities - Participation

During the participation phase of a research project, it is the responsibility of the investigator (or their delegate) to:

- Take opportunities to increase or enhance a subject's understanding of the research project
- Provide opportunities for subjects to ask questions; confirm participation or withdraw from the research project
- Remind the subject that research project team contact information is provided in the consent document and may be used for research project related questions
- Provide the subject with a medical contact for clinical issues that may arise
- Keep research project team contact names and telephone numbers up to date and submit the updated consent to the IRB for review and approval
- Notify the IRB when there are significant changes in the research project and/or when information about the research project provided up to that point is no longer sufficient for maintaining legally effective informed consent. The IRB may determine that notification of subjects is necessary
- Verify the subject's willingness to continue in the research project

  Submit changes to the consent process or form to the IRB for review and approval

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Investigator Responsibilities - Study Completion and Last Contact

The informed consent process ends at the point of last contact with the subject.

The investigator will determine when the final communication with the subject is anticipated or scheduled. Final communication can occur at any time but is not limited to:

- The signing of the consent form
- After a single procedure
- As a planned oral expression of appreciation after multiple visits
- As follow-up mailings at the end of the research

Documentation of Consent

- Most commonly informed consent is documented by the use of a written consent document which has been approved by the Mayo Clinic IRB and signed by the subject and/or the subject's legally authorized representative (LAR). The subject's (and/or the LAR's) signature and date and time of their consent are required on the consent document to verify that consent has been obtained.
- When a consent document incorporates the HIPAA (Privacy Rule) language, regulations require that the subject must be given a copy of the signed consent document.
- Other signatures on the consent document may include (as appropriate):

- Individuals interacting with the subject to obtain consent (i.e. investigator or research study staff identified on the research study application as approved to obtain consent).
- Legally Authorized Representative who may be consenting and signing for the child, relative, principal or ward of the state.
- Parents or guardians who may give permission and sign for the child or relative.
- Witnesses and/or advocates involved in the consent process.
- If a subject is unable to physically sign the consent document but is capable of consenting to participate in the study, a witness will be present to observe the consent process. The witness should use the margin of the document to record a brief statement indicating the observation of the consent process and the subject's voluntary participation, and sign and date the note. The witness will then sign the written consent document on behalf of the subject and writes the subject's full name on the signature line.

- The date should include the month, day and year using the mm/dd/yyyy format.
- The time should include 'A.M.' or 'P.M.'or be in a 24-hour "military" format.
- If the IRB requires documentation of oral consent in the subject's medical record as a 'Consent and Enrollment Note', this will be specified in the IRB approval notification to the Principal Investigator (PI).
- The PI will maintain the original signed consent document in the study file. Documentation of oral consent will also be retained in the study file.

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Consent Forms and the Subject's Medical Record

Greater than Minimal Risk Research

- When a research subject is a patient or becomes a patient receiving medical care while participating in a research study, it is important that a copy of the consent form be made available to their health care providers via the electronic medical record (EMR) for clinical care purposes.
- Scanning of the signed consent document into the subject's EMR is required for all greater than minimal risk studies. The investigator or their designee must submit a photocopy of the signed consent document to the Mayo Clinic Health Information Management Services (HIMS) Scanning Department for inclusion into the prospective subject’s (patient’s) electronic medical record (http://mayoweb.mayo.edu/scanning/).
- The IRB may waive the requirement that the signed consent form is scanned into the subject's medical record. The IRB will specify this requirement in the IRB approval notification to the Principal Investigator.

Minimal Risk Research

- The IRB may require scanning of consent documents (i.e. written consent form /HIPAA authorization) for a minimal risk study into the subject's EMR, and if this

is required, the IRB will specify this requirement in the IRB approval notification to the Principal Investigator [removed to be consistent with 6. above].

- When the IRB approves waiver of the requirement to obtain a signed written consent form, the Principal Investigator should consider including the following information in the research project files:
    - Who was approached
    - Name of project
    - Who explained the project
    - Brief summary of what was explained
    - The subject expressed an understanding of the research project and willingness to participate
    - Questions (if any) were answered to the subject's satisfaction
    - Subject agreed to participate, and
    - Written information about the project was given to the subject, if appropriate.
- This note should be signed and dated by the person obtaining consent.

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Study Record Retention Requirements (Investigator):

- The investigator will retain all written consent documents per Federal regulations, Mayo Clinic IRB and Sponsor record retention requirements.
- Study records related to research, including consent documents, must be retained for a minimum of 3 years after the completion of the research.
- FDA-regulated studies may require longer retention periods.
- The records must be accessible for inspection and copying by authorized representatives of the FDA and the Office of Human Research Protection (OHRP).

Subject Withdrawal and Data Retention

- When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.
- An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.
- The investigator must obtain the subject's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB must approve the consent document.

- If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the participant collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

Related Documents and Websites

IRB Consent Form Template and Tools

HIMS Scanning website: http://mayoweb.mayo.edu/scanning/

Special Categories of Research: Children

References

Association for the Accreditation of Human Research Protection Programs (AAHRP), version 1/2012

Office for Human Research Protections (OHRP) Obtaining and Documenting Informed Consent of subjects Who Do Not Speak English, November 9, 1995

Guidance on Institutional Review Board Review of Clinical Trial Websites (http://www.hhs.gov/ohrp/policy/clinicaltrials.html

Federal Regulations

45 CFR 46.116 General Requirements for Informed Consent:

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

45 CFR 46.117 - Documentation of informed consent:

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.117

21 CFR Sec. 50.25 Elements of informed consent:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=50.25

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