Informed Consent and the Research Subject Policy

Scope

Applies to Principal Investigators (PIs), their designees, and Study Coordinators (SCs) when obtaining Informed Consent from research participants recruited for Research studies for which Mayo Clinic is the Institutional Review Board (IRB) of Record.

Purpose

To provide instructions to investigators and their designees regarding the informed consent process for research subjects.

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Definitions

Federal Requirements: §46.116 General requirements for informed consent, §46.117 Documentation of informed consent, and 21 CFR 50.25 Elements of Informed Consent

Policy

- It is the policy of the Mayo Clinic Office for Human Research Protection (OHRP) and Mayo Clinic 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 (LAR).

Note: Research personnel must not fill in the date and time.

- The consent document will include the basic elements of informed consent, and the additional elements of informed consent as applicable, as specified in 45 CFR 46.116 - General Requirements for Informed Consent and 21 CFR 50.25 - Elements of Informed Consent.
- Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or in understanding the reasons why one might or might not want to participate in research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
- 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 LAR's understanding of the reasons why one might or might not want to participate
- An investigator will seek informed consent only under circumstances that provide the prospective subject or, when approved by the IRB, the subject's LAR, sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
- If the investigator has a preexisting relationship with a prospective subject, the responsibility for the consent process may be delegated to another qualified member of the study team to avoid the possibility of undue influence to participate in the research.
- The information given to the subject or the LAR will be in language understandable to the subject or the LAR.
- The prospective subject or the LAR 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.
- No informed consent, whether oral or written, will include any exculpatory language through which the subject or their LAR 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.

Posting of Clinical Trial Consent Forms

- Per the 2018 Common Rule requirements effective January 21, 2019, for each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial

on a publicly available Federal Web site that will be established as a repository for such informed consent forms.

- If the Federal department or agency supporting or conducting the clinical trial determines that certain information must not be made publicly available on a Federal Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
- The informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.
- At Mayo Clinic, informed consent form postings for non-cancer clinical trials will be facilitated by the Office of Research Regulatory Support (ORRS). Postings of informed consent forms for cancer clinical trials will be facilitated within the Mayo Clinic Cancer Center.

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Waiver or Alteration of the Consent Process

The provisions for waiver of informed consent do not apply to Food and Drug Administration (FDA) regulated research involving human subjects.

- An IRB may approve a consent procedure which omits some, or alters some or all of the 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, 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:
        - public benefit or service programs
        - procedures for obtaining benefits or services under those programs
        - possible changes in or alternatives to those programs or procedures or
        - 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 that omits some, or alters some or all of the 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, 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 practicably be carried out without the waiver or alteration
- 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
- Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

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Waiver of Documentation of Consent

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 informed consent form for some or all subjects if it finds any of the following:

- The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern
- 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
- 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 or harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- 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

The investigator will develop and maintain a detailed consent process in the research application submitted to the IRB. The following factors may be considered:

- Type of research 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; 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.
- Need for informing subjects of significant or incidental findings resulting from the research.

The consent process must include a description of the following:

- The method(s) for obtaining informed consent, including 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 amount of time planned for the consent process.
- Method(s) for assessment of a subject's capacity to consent, as applicable.
- The protections that are planned to reduce potential subjects' vulnerability to coercion or undue influence during the consenting process.
- Additional safeguards for the specific population, e.g. persons with diminished capacity, language differences, inability to read, limited vision and/or hearing, or other physical considerations.
- The need to include a medical interpreter, LAR, witness, or advocate to be present and observe the discussions within the informed consent process.
- The waiting period between discussion, decision, and enrollment.
- Study team members who will meet with the prospective subject and obtain informed consent. These persons 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.

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Recruitment Plan

To assist in the development of recruitment plans, recruitment, and advertisement materials, Mayo Clinic investigators may contact the Center for Clinical and Translational Science, Service Center, Communications Coordinator-Research Recruitment (507) 255-1943. All recruitment materials used by Mayo Clinic investigators must meet the Brand Standards of Mayo Clinic, and be approved by the IRB. http://intranet.mayo.edu/charlie/brand-standards/

The investigator will:

- Provide a recruitment plan in the research application, including a description of the proposed recruitment method(s), any advertisements, other recruitment materials, or payment arrangements.
- Specify the method(s) and frequency of contacts that will be attempted to engage 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 all recruitment materials to be used in the research. These may include:

- Printed materials, such as flyers, posters, brochures, and postcards.
- Media advertisements such as newspapers, television, radio, and website postings.
- If advertisements will be taped for broadcast, investigators must submit a copy of the audio/video file 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 prior to use or dissemination, to confirm the wording is appropriate and clearly reflects the intent of the research.
- Recruitment letters, phone, or email scripts.
- Direct advertising intended to be seen or heard by potential subjects.
- Payment arrangements, if applicable.

Required content of recruitment/advertisement materials:

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

Optional content of recruitment/advertisement materials:

- A brief list of possible risks and benefits 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 must 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 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 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

The following are prohibited:

- 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, must 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 must 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 must 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.
- 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. Persons may be compensated for blood draws for research up to $50 for each blood draw.

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Use of Social Media for Recruitment

Mayo Clinic investigators using social media (e.g. Twitter, Facebook, YouTube, etc.) as a recruitment method must have the research reviewed and approved by the Mayo Clinic Public Affairs/Center for Social Media. For questions, please contact your site's 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 Principal Investigator (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.
- Investigators at institutions for which the Mayo Clinic IRB is the IRB of record will include within the IRB application documentation of review and approval by the relying organization for the use of social media, or documentation that such review and approval is not required by the institution.

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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, recruitment, 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 nor presents undue influence.
- Reviews the proposed research project and determines that the consent document accurately reflects the purpose, risks, benefits, 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.

The IRB ensures that:

- The research application and related materials (i.e. recruitment/advertisement materials, payments, consent documents, and scripts) as submitted to the IRB are approvable.
- Recruitment locations, 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 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 IRB-approved consent form 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
- Re-consents 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 environments that must be avoided
- Avoids 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 with the prospective subject regarding the research, using the consent document. The investigator (or their delegate) must:
    - 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 population
    - Depending on the subject population, enrollment requirements may include a medical interpreter, witness, advocate, parent(s), spouse or an

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

- Involvement of an LAR in the consent process requires pre-approval by the IRB.
- Involvement of a witness in the consent process may, but does not require IRB pre-approval. The witness must be impartial, such as a subject advocate or someone not affiliated with the research team. The witness must observe the entire consent process, sign the informed consent document, and attest that the subject appears capable of making an informed decision and was given the opportunity to ask questions. See "Documentation of Consent"

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- English-speaking, Legally Blind Prospective Subjects: A person who speaks and understands English, but is unable to read due to low literacy, blindness or other sight issues, can be enrolled in the study by making a mark or signing the consent with assistance. An impartial third party must witness the entire consent process and sign the consent document.
- English-speaking, Physically Unable to Sign Prospective Subjects: A person who speaks and understands 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
  - 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 (has decision making capacity) and
  - is able to indicate approval or disapproval to study entry, they may be entered into the study. The consent form must 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 must 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 or other materials 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 proposed changes to the consent process or consent document(s) to the IRB for review and approval prior to implementation

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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 and includes, 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

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Documentation of Consent

- Informed consent is most commonly 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 LAR. The subject's (and/or the LAR's) signature, 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 Health Insurance Portability and Accountability Act (HIPAA also known as the 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):
    - Persons 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).
    - LAR who may be consenting and signing for the subject, who may be a child, relative, principal, or ward of the state.
    - Parents or guardians who may give permission and sign for the child.
    - Witnesses and/or advocates involved in the consent process. Document involvement of the witness/advocate as follows:

        - When involvement of a witness is pre-planned, the witness should sign on the witness signature line provided on the approved consent form.
        - If involvement of a witness is not planned when preparing an electronic consent form, the study team member must switch the participant signature line to witness signature line in Ptrax (See Research Systems - Ptrax Electronic Signature Process QRG: Continue with the following STEPS whether new Participant or in Consent Prepared status section).
        - If involvement of a witness is not planned when a paper consent form is be used, the study team member will hand write "of Witness" after the Signature under the Participants Name in the signature block and add their initials and date. The witness signs and dates on the written in witness 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 (also known at Mayo Clinic as a 'Consent and Enrollment Note' or 'Research Note'), this will be specified in the IRB approval notification to the PI.
- The PI will maintain the original signed consent document. Documentation of oral consent will also be retained.

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Electronic Informed Consent

- Mayo Clinic offers two methods for obtaining consent/assent/HIPAA authorization signatures electronically:
    - On-Site Electronic Consent: Documentation of informed consent/assent/HIPAA authorization using an electronic device, such as a tablet or other touch screen device, while the consent conversation occurs in the physical presence between the person authorized to obtain consent/assent/HIPAA authorization and the potential subject and/or their Legally Authorized Representative.
    - Remote Electronic Consent: Documentation of informed consent/assent/HIPAA authorization using email for delivery of the form and DocuSign technology to collect signatures while the consent conversation occurs via phone or video or when a consent conversation is not required (replacing mail-out consent).
- Use of Electronic Consent (On-Site or Remote) must be approved by the IRB on a per study basis.
- When determining whether Electronic Consent is appropriate for a study, the IRB considers:
    - The complexity of the study
    - Vulnerability of the research subjects

    - Safety of the research subjects and the persons obtaining consent
- The technical capability for On-Site and Remote Electronic Consent is housed within the Participant Tracking (PTrax) application and is, therefore, available only to studies utilizing PTrax.
- When requesting use of Electronic Consent, Investigators must provide within the IRBe application:
    - Specification of the type(s) of Electronic Consent that will be used (i.e. On-Site and/or Remote)
    - Specification of the documents that will be signed electronically
    - Specification of who will be signing the electronic documents
    - A plan detailing the informed consent process and signature procedure
    - A process for documenting signatures of persons who prefer not to use Electronic Consent
- Investigators must refer to the guidance document, Electronic Consent at Mayo Clinic for specific information required for consent process plans

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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 greater than minimal risk research study, it is important that a copy of the consent form be made available to their health care providers.
- For greater than minimal risk research conducted at Mayo Clinic, it is required that the consent document be scanned into the Electronic Medical Record (EMR).
- The Mayo Clinic 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) EMR.
- The IRB may waive the requirement that the signed consent form is scanned into the subject's medical record for research conducted at Mayo Clinic. When applicable, the IRB will specify the waiver of the scanning requirement in the IRB approval notification to the PI.
- Investigators at institutions for which the Mayo Clinic IRB is the IRB of record will comply with the policies of the relying institution.

Minimal Risk Research

- For research conducted at Mayo Clinic, the IRB may require scanning of consent documents for a minimal risk study into the subject's EMR. If this is required, the IRB will specify this requirement in the IRB approval notification to the PI.

- Investigators at institutions for which the Mayo Clinic IRB is the IRB of record will comply with the policies of the relying institution.
- When the IRB approves waiver of the requirement to obtain a signed written consent form, the PI must consider including the following information in the research study files:
    - Who was approached
    - Name of the study
    - Who explained the project
    - Brief summary of what was explained
    - The subject's expression of understanding of the research project and willingness to participate
    - Questions (if any) were answered to the subject's satisfaction
    - Subject's agreement to participate, and
    - Written information about the project was provided to the subject, if appropriate.
- This note must 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, Sponsor record retention requirements, and/or institutional policy.
- 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 regulatory entities such as the FDA and OHRP.

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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 addresses 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 (if 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 the subject's medical record or other confidential records requiring the subject's consent for purposes related to the study. 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.

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Policy Notes

N/A

Related Procedures

N/A

Related Documents

IRB Consent Form Template and Tools

Informed Consent and Assessment of Capacity to Consent to Research

Informed Consent for Research: A Guide to Assessing a Participant's Understanding

HIMS Scanning

Consent of Non-English Speaking Prospective Subjects to Participate in Research Policy

Special Categories of Research: Children

Electronic Consent at Mayo Clinic

Definitions

Consent Document: A structured, written description in understandable 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 potential participant. It is the document that ensures all regulatory elements are present and communicated to a potential participant. When signed by the potential participant, the consent document is a record of the receipt of research-related information by the participant. It also serves as reference material for the participant as the research project progresses. It is not a contract and is not legally binding, and the participant 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 LAR.

Electronic Informed Consent: Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive, and interactive Web sites, biological

recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.

Enrollment: Occurs when an eligible, informed, potential participant undergoes the initial informed consent process and voluntarily agrees to participate in a research project. Example: You enroll 100 to accrue 25. See also Accrual

Greater than Minimal Risk: The research involves more than minimal risk to subjects.

Informed Consent: An ongoing process of communication between the participant and the study team. Informed consent is a continuing process by which a participant, 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 participant'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 subject's participation in the procedures involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Legally Effective Informed Consent: A potential participant has been provided enough information to make a decision; the potential participant has the capacity to make a decision; the potential participant understands the consequences of his or her decision; and the potential participant 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.

Mayo Clinic: Mayo Clinic refers to Mayo Clinic in Arizona, Florida, and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

Oral (verbal) Consent: A method of presenting the elements of informed consent to the prospective subject or their legally authorized representative, without the requirement of obtaining a signed informed consent document. The presentation may utilize an oral consent script or another format, such as a cover letter. The investigator is required to maintain a record of oral consent activities.

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

References

21 CFR Sec. 50.25 Elements of informed consent

45 CFR 46.116 General Requirements for Informed Consent

45 CFR 46.117 - Documentation of informed consent

Association for the Accreditation of Human Research Protection Programs (AAHRP) Accreditation Standards

Guidance on Institutional Review Board Review of Clinical Trial Websites

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

Office for Human Research Protections (OHRP): Use of Electronic Informed Consent: Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors (December, 2016)

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Owner

Michelle Daiss on behalf of Office for Human Research Protection

Contact

Tamyra Armbrust

Revision History

Date	Synopsis of Change
02/02/2024	Removal of consent of non-English speaking prospective subjects information. Update of witness signature information. Addition of new Consent of Non-English Speaking Prospective Subjects to Participate in Research Policy link. Update of Owner and Contact.
09/01/2021	Minor revision to Documentation of consent section.
01/18/2021	Outside of scheduled review. Updated to current template. Removed Digital Signature Capture section. Updated Electronic Consent Informed Consent to include On-site and Remote. Minor edits by Policy office.
10/06/2020	Minor revision. Clarified consent process. Minor edits to Scope and formatting by Policy office.
01/21/2019	Updated to reflect the 2018 Revised Common Rule including addition of a concise summary, new criteria for waiver of consent and waiver of documentation of consent, posting of clinical trial consent forms on a publicly available Federal web site, and other requirements. Updated definitions and other administrative edits made for clarity.
01/09/2019	Added specification that involvement of an LAR requires IRB approval. Added information regarding involvement of a witness in the consent process. Added section regarding consent of subjects who are unable to read. Changed owner.
09/18/ 2017	Updated to the new policy template. Added section on Electronic Informed Consent, added new key term of Electronic Informed Consent along with related documents Office for Human Research Protections (OHRP): Use of Electronic Informed Consent: Questions and Answers: Guidance for Institutional Review Boards, Investigators, and Sponsors (December, 2016).

08/23/ 2017	Minor revision. Updated the following definitions per Glossary review: Consent Document, Enrollment, Informed Consent, Legally Authorized Representative, Legally Effective Informed Consent, Mayo Clinic, Oral (verbal) Consent, and Recruitment.
04/19/2017	Scheduled review. No changes made.
06/28/2016	Scheduled review. Deleted the following from the 9th bullet under the heading 'After IRB Approval': if possible,
03/04/2015	Scheduled review. No changes made.

Content Information Stamp

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Informed Consent and the Research Subject Policy

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Arizona

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Reviewer(s):

Tamyra L. Armbrust

Approver(s):

Michelle K. Daiss