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Topics in Research Consent
Promoting Compliance

Kathy O'Connor, RN – Associate Director, Research Audit
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Consent questions can also be directed to:

The iRIS Support Team
Office of Human Research Affairs
Albert Einstein College of Medicine
Email: iris-support@einsteinmed.org
Phone: 718-430-2237

Topics

- Planning your research consent process
- Research consent roles
- Essential research consent documentation
- Reconsent
- Self-audit of your consent process

Steps to Take as you Plan Recruitment and Consent Workflow

1. Review your approved IRB application to confirm the risk level assigned to your protocol by the IRB
   - Consent documentation requirements are slightly different for “Minimal Risk” vs “Greater than Minimal Risk Research”
2. Review the recruitment and consent process as described in the IRB application and protocol. Particularly review the answers to the following questions in the IRB application:
   - Have you requested a “Waiver of Informed Consent/HIPAA Authorization to Review Records for Recruitment Purposes”?
   - “When and where will the informed consent take place?”
   - “How and when will subjects be approached for this study?”
   - “List the names of key personnel who will conduct the consent process.”
3. Develop a written study specific consent process that all research personnel will follow. The procedure must be consistent with the consent procedure described in your IRB application and protocol. Procedures and study personnel can be updated and changed by submitting an amendment to the IRB.

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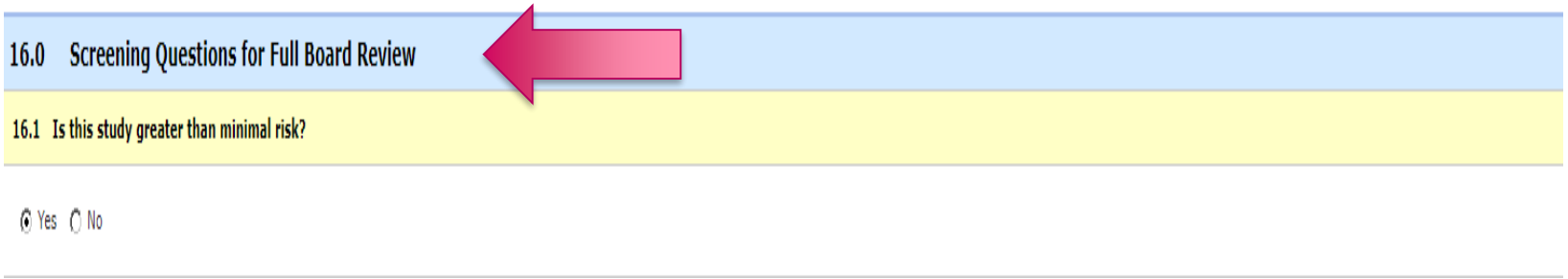

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30.0 Waiver of Informed Consent/HIPAA Authorization to Review Records for Recruitment Purposes

30.1 Confirm that all of the following are true:

The review of medical/clinical records involves no more than minimal risk to the subjects.

The waiver of consent/authorization does not adversely affect the rights and welfare of the subjects.

The review of medical/clinical records could not practicably be carried out without the requested waiver.

The plan to protect confidentiality (including protection of identifiers from improper use and a plan to destroy identifiers, where appropriate) is described in the confidentiality section of the application.

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.

The PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

The research team will be accessing records that contain health information that may also include some or all of the 18 HIPAA identifiers.

30.2 Are all of the preceding statements true?

(•) Yes ( ) No

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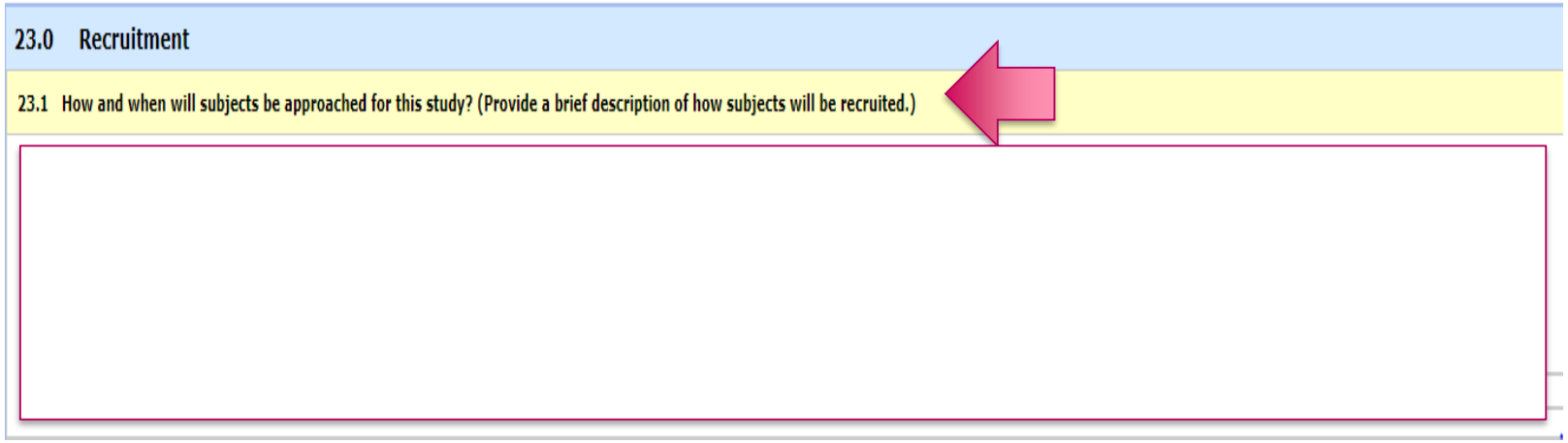

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22.0 Informed Consent Process

22.1 *Informed consent is a process that takes place between the potential subject and the researcher/research team, before, during and sometimes after, the study. Participants are required to receive a full explanation of the research protocol and all the required elements of informed consent. They are to be provided the opportunity to ask questions and have their questions answered by a knowledgeable member of the research team. Non-English speaking subjects are required to have a translator present during the consent process. The consent process is subject to monitoring.*

22.2 When and where will the informed consent process take place?

22.3 Does this study involve research activities for which maintaining privacy would be a concern or expectation for subjects or potential subjects? (e.g., studies on illegal activities, sexual activity or any stigmatized behavior or disease)

○ Yes ◉ No

If "Yes", describe how subjects and potential subjects privacy is maintained during the recruitment process as well as throughout the study.

22.4 List the names of the Key Personnel who will conduct the informed consent process:

All personnel who will be consenting subjects must be listing in the "Key Personnel and Project Contacts" section of the Application. See section 3.0 of the Application.

22.5 Do you expect to enroll a significant number of subjects who speak a common language other than English or Spanish?

○ Yes ◉ No

If "Yes," which languages?

If "Yes," who will serve as the translator?

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Pitfalls to Avoid:

- Misremembering how the consent process was described in the IRB application/protocol and carrying out a consent process that may be reasonable but is not what was approved.
- Alteration of the consent process without amending your IRB application/protocol to reflect the changes
- Failure to create a written workflow process that is distributed to all research staff

Research Consent Roles

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Research Consent Roles

- Principal Investigator
  - Responsible for ensuring staff is properly trained and knowledgeable about the research and related consent policies
  - With IRB approval, the PI may formally delegate consent tasks to other study team members, but the PI remains responsible for ensuring that adequate informed consent is obtained from each subject enrolled in the protocol

- Subinvestigators who are (1) Licensed Independent Providers (example MD/NP), (2) have been trained and added to the study with the IRB and (3) are listed on the study Delegation of Authority Log

- Research Coordinators who have (1) have been trained and (2) added to the study with the IRB and (3) are listed on the study Delegation of Authority Log

Pitfall to Avoid:

- Inadequate PI oversight of consent process and related documentation. May lead to patterns of error in procedure and documentation that are not addressed in a timely fashion. It's important to ensure that signed consent forms and other consent process documents are reviewed on a regular basis so that problems can be identified and addressed.

Required Documentation
Reference: Einstein IRB Policy "Required Documentation for the Conduct of Research Involving Human Subjects"

All Research:

1. All IRB correspondence, including original IRB application, all IRB submissions, and all IRB approvals.
2. All versions of the protocol and all amendments (protocol signatures where required)
3. Subject Identification and Enrollment Log
4. Screening Log
5. All original signed consent and assent forms
6. Completed Data Collection forms or Case Report forms
7. Completed Adverse Event Logs
8. Completed Protocol Deviation Logs
9. All monitoring reports (if 3rd party monitoring is performed)
10. All substantive communication with the study sponsor - all emails should be printed (if applicable)
11. Documentation of IATA training (if biological samples are shipped)

Additional Requirements for Greater than Minimal Risk Research:

12. Delegation of Authority Log
13. Documentation that shows the PI or qualified sub-I reviewed all entry criteria and approved subject entry into the study
14. Informed Consent Note for each subject enrolled
15. Data Safety Plan and Reports

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Minimum Documentation Requirements:

- All Research:
  - Subject Identification and Enrollment Log
  - Screening Log
  - All original signed consent and assent forms
- Greater than Minimal Risk Research:
  - Delegation of Authority Log
  - Informed Consent Note for each subject enrolled

Minimum Documentation Requirements:

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Subject Identification and Enrollment Log

A single document that identifies all subjects who have signed a consent to participate and have been entered into the study

- The log must identify the individuals and establish a link to their study number

Subject Identification and Enrollment Log

Investigator Name:	Protocol:	Site Number:

MRN	Subject ID	Date of Consent	Consent Version	Eligible Y/N	Date of Enrollment		

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Missing Log – Example and Outcome:

40 women consented to complete a survey related to autoimmune symptoms.

Each survey contained the subject's study number, but no other identifier.

Each consent contained the subject's signature, but no study number.

Upon review, 40 completed surveys and 38 signed consent forms were found.

There was no Subject Identification and Enrollment Log created so it was not possible to determine which two consent forms were missing.

The investigator was not permitted to use any of the data collected.

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Screening Log

Subject Consent – Yes. PHI may be included on Screening Log

Screening Log

Investigator Name:	Protocol:	Site Number:

Date of Consent	MRN	DOB	Screening Number	Eligible Y/N	Enrolled Y/N	Comments

Subject Consent – No. PHI may not be included on Screening Log

Prescreening Log

Investigator Name:	Protocol:	Site Number:

Sex M/F	Age	Diagnosis	Date records Reviewed	Participation Offered?	Comments

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Q: I need to keep a record of patients who have declined to be screened or participate. I don't want to approach the same patient again if they have already said they are not interested. How can I do this?

A: You may keep a list of patients who have declined (including their name/MRN). However, this information should not be included in your study records. PHI about these individuals should not be shared with monitors or others and should not be included in data analysis.

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  - Delegation of Authority Log
  - Informed Consent Note for each subject enrolled

Original Signed Consent and Assent Forms

For most interventional research, Investigators are now required to scan signed consent forms into EPIC.

Please remember that you are required to keep the original signed forms in your study files.

These are original source documents and should never be shredded or discarded after scanning.

If your approved consent plan involves a consent discussion over the phone with the signed consent form emailed or faxed to you- the fax, pdf or photo of the signature is your original source document. It should not be shredded.

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DELEGATION OF AUTHORITY AND SIGNATURE LOG

Principal Investigator: _____ **IRB #:** _____ **Sponsor:** _____

Study Title: _____

PRINT NAME	TITLE	SIGNATURE	INITIALS	*STUDY TASKS	START DATE	END DATE	PI INITIALS/DATE

List individual delegated study related tasks (ICH GCP 4.1.5). Update this log in a timely manner as new personnel are added and/or study roles change.

*Delegated Study Tasks:
1. Informed consent discussion (General)
2. Obtain Medical History
3. Perform Physical Exam
4. Assess Eligibility Criteria
5. Mix/compound study drugs
6. Administer study drugs
7. Clinical supervision of research procedures
8. Approve discharge after study visits
9. Evaluate adverse events
10. Coordinate IRB and FDA submissions
11. Maintain required regulatory documentation
12. Scan signed consent forms into EPIC
13. Consent documentation Quality Assurance

*When tasks are delegated by an investigator, the investigator is still responsible for those tasks and for providing the necessary level of supervision of those to whom tasks are delegated.

PI Signature: _____ **Date:** _____

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Informed Consent Note

Date the consent document was signed: _____ Participant: _____

The individual named above has agreed to participate in protocol #_____ entitled:
_____
_____
_____

The purpose, risks, benefits, and alternative treatments were explained to the participant by _____ and all questions were answered. A copy of the Informed Consent Document was given to the participant by _____.

The Informed Consent Document was signed prior to any study procedures being performed. **Please describe any special circumstances:**

- ☐ Subject not English Speaking (Non-English speaking subjects may **not** be enrolled using an English language consent form. Generally, a fully translated consent **should** be used; please contact the IRB for guidance regarding short forms).
  - Subject's Language: _____
  - Interpreter: _____
- ☐ Subject hard of hearing/deaf.
- ☐ Subject illiterate/low literacy/visually impaired/without reading glasses. (Witness required when consent information presented verbally to subject.)
- ☐ Subject able to consent, but not sign, due to physical impairment.
- ☐ Subject does not have capacity to consent. (Do **not** obtain consent from Health Care Proxy/Legally Authorized Representative unless specifically authorized by the IRB.)
  - Subject's Proxy/LAR: _____
  - Relationship to Subject: _____

Comments (e.g. how special circumstances were addressed):
_____
_____
_____
_____

Name of person completing this form	Signature of person completing this form	Date/Time

☐ Consent scanned into EPIC

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- Q: Where is the Informed Consent Note you just showed us filed?

- A: You can develop a consent note template in EPIC and chart in EPIC directly. Alternately, you can complete a paper note and scan into EPIC with the consent form. Or the paper Informed Consent Note can be filed in your study binder.

Q: Do I need to reconsent continuing subjects each time a I receive a new stamped consent version with the progress report? The text of the form has not changed.

A: No

Q: A subject has signed a consent form and I realize it expired two days ago. There was a new version in iris but I didn't see it until after the subject left. The text of both forms is the same. What do I do?

A: This is a deviation that meets the Einstein IRB reporting criteria for a Reportable Event. Report the event in iris and plan to ask the subject to sign the current form at the next visit.

Q: A subject has signed a consent form and I realize it expired two days ago. There was a new version in iris but I didn't see it until after the subject left. The new version contains information not found in the version signed by the subject. What do I do?

A: This is a deviation that meets the reporting criteria for a Reportable Event. Call the subject and discuss the new information, document the call, confirm continued agreement to participate, mail the subject a copy of the current consent form, report the event and plan to ask the subject to sign the current form at the next visit.

Q: The IRB approved my amendment with changes to the consent form. How do I know if I must reconsent continuing subjects?

A: If the changes to the consent form are relevant to the participant, they should be asked to sign the new form. For example, if changes are made to visit 3 procedures, subjects who have not yet had visit 3 should be asked to sign the new consent form.

Q: Does the IRB provide direction as to when reconsent is required pursuant to an amended consent?

A: Yes, the amendment approval letter should indicate if reconsent is required.

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FWA #00009807
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FWA #00000140

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1300 Morris Park Ave., Belfer 1002
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West Campus IRB
Montefiore Medical Center
3308 Rochambeau Avenue
Bronx, NY 10467
718.798.0406 fax 718.798.5687

https://www.einsteinmed.org/irb

Notification of Amendment Approval

Date: April 15, 2021

Principal Investigator: [redacted]

Study Title: [redacted]

IRB #:	[redacted]	**Reference #:**	074696
Amendment Approval Date:	04/14/2021	**Study Expiration Date:**	06/21/2021

This amendment was reviewed and approved at the IRB meeting held on 04/14/2021.

This submission was approved with the following stipulations:

- Use only IRB stamped copies of the consent form(s). Do not use expired consent forms.
- A fully translated foreign language informed consent document must be approved by the Einstein IRB prior to enrolling non-English speaking participants.
- Currently enrolled subjects must be re-consented at their next study visit with the updated consent.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to Study Assistant – My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

Reminders

All changes to a study must receive IRB approval before they are implemented. The only exception to the requirement for prior IRB review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(b)(4), 21 CFR 56.108(a)). In such cases, report the actions taken as a reportable event.

Reportable Events must be reported to the IRB in compliance with the Einstein IRB policy.

Expiration Notice: IRB approval for this study is limited to the period specified above. In order to gain re-approval, you must submit a Progress Report prior to the expiration of the study. When the research is

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Q: The study PI has changed and this is reflected in the new approved consent. Do I need to reconsent participants?

A: It is important that participants have the current PIs contact information. Typically, subjects are asked to sign the updated consent form. Subjects who are no longer making study visits can be notified by letter. Your amendment should indicate how you intend to notify subjects.

Self Audit Tool (Example)

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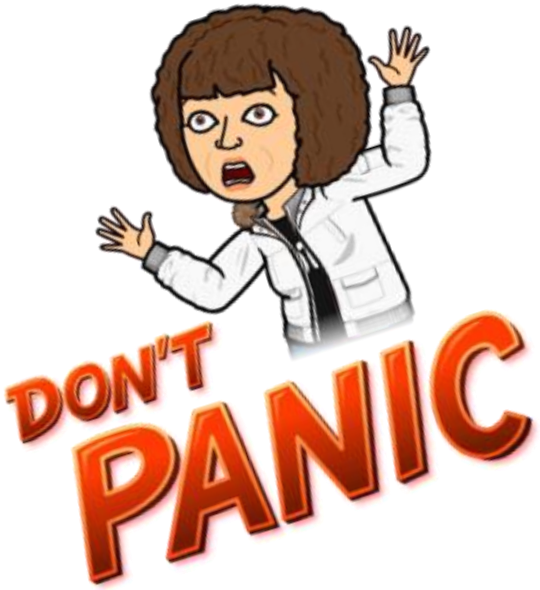
	Subject 1	Subject 2	Subject 3	Subject 4	Subject 5
Were the recruitment and consent procedures consistent with the procedures described in the approved research plan (application and protocol)?					
Were all individuals involved in the consent process added to the study with the IRB and assigned this role on the Delegation of Authority Log?					
Did the subject give written consent and/or reconsent by personally signing and dating the ICF?					
Was the consent form cosigned and dated by research staff?					
Were any differences in the dates of subject/staff signatures explained?					
Was the correct (current) IRB-approved consent version utilized?					
Did the subject sign consent the consent form prior to the first study intervention?					
Is there a Consent Note that explicitly states that a copy of the consent form was provided to the subject?					
If the subject is not proficient in English, were appropriate consent procedures followed?					
Was the consent scanned into EPIC?					

Q: I have reviewed my consent forms and have identified a significant problem. What should I do?

A: Contact Kathy O’Connor for instructions.



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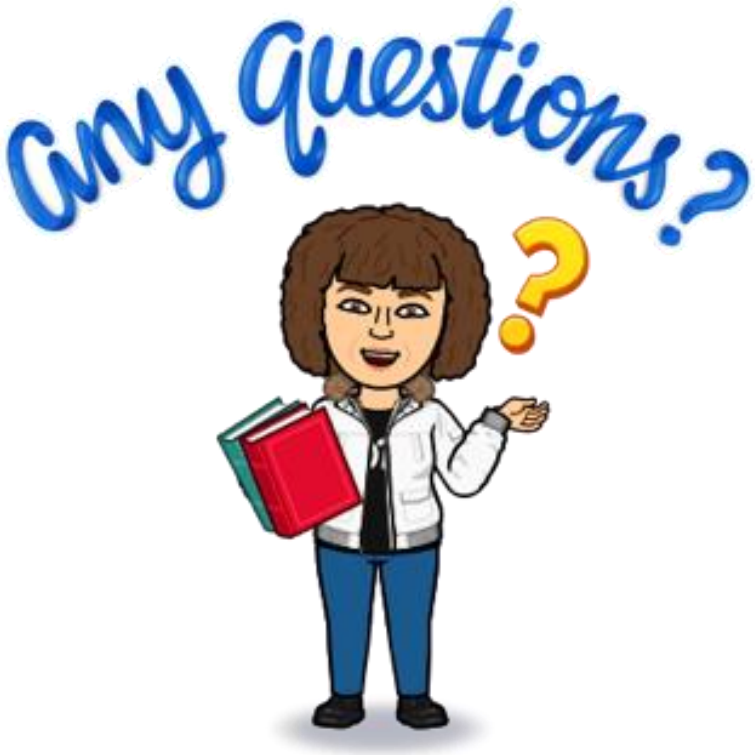

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