AAHRPP Site Visit 2021: 
Interview Guide for Administrators

Accreditation

AAHRPP, or the Association for the Accreditation of Human Research Protection Programs, will conduct an accreditation site visit at Einstein/Montefiore Medical Center, spring of 2021. AAHRPP is an international, independent nonprofit organization that reviews and accredits an institution’s human research protections program. “AAHRPP accreditation offers assurances—to research participants, researchers, sponsors, government regulators, and the general public—that a Human Research Protection Program is focused first and foremost on excellence.” Einstein/MMC is seeking its first AHRPP accreditation.

AAHRPP has been provided with a written description of the Einstein/MMC Human Research Protection Program Policies and Procedures and resources, as well as with a list of all active IRB protocols. During the site visit, representatives from AAHRPP will conduct interviews and review records to ensure that the policies and procedures have been implemented effectively and are being adhered to throughout the institution.

As a research administrator, you are an integral part of the Einstein/MMC HRPP. During the site visit, AAHRPP will select approximately 75 individuals to be interviewed. Anyone who has a role in human research may be selected for an interview. A number of administrators will be interviewed.

AAHRPP will provide a list of individuals selected for interviews approximately three weeks prior to the site visit. If selected for an interview by AAHRPP, you will be notified closer to the visit date and will be provided with additional information.

We anticipate each session will take between 20-45 minutes. Sessions will be in the form of individual or group interviews. We expect questions to be focused on regulatory and ethical issues related to research with human participants, but questions may also relate to your impressions of the Einstein/MMC HRPP and the Einstein IRBs. We recommend that you respond directly to the question asked. If a question seems unrelated to the type of work you do, please let the interviewer(s) know.

Preparing for the Site Visit

This document is provided to help you prepare should the visit team select you for an interview. You may be familiar with the information included, however, this guide is intended to refresh your understanding. Information is also available on the OHRA website—AAHRPP Accreditation Visit. Each section of this document is followed by a list of questions that you may be asked. This document includes sections on the following topics:

- Section 1: General Tips
- Section 2: Einstein/MMC HRPP Policies and Procedures
- Section 3: Ethical Conduct of Research and Federal Regulations
- Section 4: Minimizing Risks and Protecting Participants’ Rights and Welfare
- Section 5: Compliance with IRB and Other Review Unit Requirements
- Section 6: Obtaining and Documenting Informed Consent
- Section 7: Conflict of Interest Disclosure
Section 1: General Tips

- Einstein/MMC accreditation depends largely on these interviews. You will be expected to:
- Understand the Einstein/MMC Human Research Protection Program’s (HRPP) structure
- Clearly describe your role and contribution in supporting the protection of research participants
- Be familiar with the Einstein/MMC HRPP Policies and Procedures and where to access them
- Understand the AAHRPP accreditation process
- Understand and describe the ethical aspects, the purpose, and the value of your work
- Know the process for non-compliance reporting at Einstein/MMC
- Know human research training requirements and resources at Einstein/MMC
- Know IRB application, iRIS submission, terminology
- Understand what constitutes conflict of interest at all levels (i.e., staff, IRB, institution)
- Understand how a conflict of interest is managed at Einstein/MMC

Possible General Questions

- What is the role of the IRB?
- What does the IRB do?
- What is the IRB’s reputation on campus?
- What do you think about the IRB and its efforts to protect human subjects? Why does Einstein/MMC value AAHRPP accreditation? What do you think of it?

Section 2: Einstein/MMC HRPP Policies and Procedures

The following sections are taken from the Einstein/MMC HRPP Policies and Procedures available on the Office of Human Research Affairs (OHRA) website. Key elements of the policy are provided for your review.

The Executive Dean at Einstein, Edward Burns, and the Director of the Office for Research at MMC, Victor Hatcher, serve as the Institutional Officials (“IOs”) for Einstein and MMC respectively. In practice, Edward Burns has assumed responsibility for the overall Human Research Protection Program. The IO’s have the authority, but are not limited, to take the following actions:

- Suspend or terminate IRB approval of research
- Place administrative sanctions on investigators for non-compliance, such as
Suspending or terminating of research privileges
Requiring investigators or research staff to undergo additional training as condition of continuing research
Appointing an independent person to monitor ongoing research

- Ensure that the HRPP has sufficient resources, including IRBs appropriate for the volume and types of Human Research to be reviewed, so that reviews are accomplished in a thorough and timely manner
- Determine what IRBs the organization will rely upon
- Ensure that the research review process is independent and free of undue influence
- Encourage participant outreach activities to further the understanding of and support for human research

The Institutional Officials may delegate their authority to representatives including the Assistant Dean for Academic Affairs, the Associate Dean for Administration and Finance, the Office of Human Research Affairs, and IRB Chairs, as appropriate.

Melissa Epstein is the Director for the Einstein Office of Human Research Affairs, the central administrative office for the HRPP. This office serves as the central repository of all information affecting the protection of human subjects in research. The OHRA is responsible for the management and oversight of the Einstein Institutional Review Board (IRB). The Einstein IRB is responsible for the review of all human subjects research conducted at Einstein and MMC.

The Einstein/MMC HRPP is supported by:

- The Office of Human Research Affairs (OHRA) and the Einstein IRB, Einstein/MMC Conflict of Interest (COI) Committee, the Office of Clinical Trials (OCT), the MMC Office of Research and Sponsored Programs (ORSP), the Einstein/MMC Institutional Biosafety Committees (IBC), the Einstein Institute for Clinical and Translational Research (ICTR), the Einstein Office of Grant Support, the MMC Research Compliance Office, Protocol Review and Monitoring Committee, MMC Research Pharmacy, and the Einstein Office of General Counsel.

- Academic departments and centers to which faculty, staff, and trainees engaged in human research are appointed

To ensure the highest standards of human subject protections, Einstein and Montefiore have developed and supported a Human Research Protection Program. Einstein and MMC pride themselves on their commitment to excellence in all research activities and recognize the institutional responsibility for the ethical conduct of research. Such standards are vital for the success of the research enterprise, participant safety and public trust.
Possible Questions About HRPP Policies and Procedures

- Who are the institutional officials responsible for research at Einstein/MMC?
- Who is the organizational official responsible for the Einstein/MMC Human Research Protection Program?
- What is the Einstein/MMC Human Research Protection Program (HRPP)?
- What is your role in the Einstein/MMC HRPP?
- What research is under your purview?
- What is the mission of the HRPP at Einstein/MMC?
- What does your division/department do to support human research activities?

Section 3: Ethical Conduct of Research and Federal Regulations

Einstein/MMC fosters a research environment that promotes respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of Einstein/MMC. All members of the Einstein/MMC community involved in human research are expected to comply with the highest standards of ethical and professional conduct in accordance with applicable federal and state regulations as well as the institutional and IRB policies governing research involving humans.

The review and conduct of research at Einstein/MMC is guided by principles set forth in the Belmont Report and performed in accordance with Department of Health and Human Services (DHHS) regulations (45 CFR 46 or the “Common Rule”), and Food and Drug Administration (FDA) regulations (21 CFR 50, 21 CFR 56), as well as all other applicable federal, state, and local laws and regulations.

- The **Belmont Report** identifies and summarizes three main ethical principles that should govern human research:
  - *Respect for persons* (autonomy/voluntary participation/adequate information)
  - *Beneficence* (risks of research are reasonable in relation to the benefits the research may provide to subjects or science)
  - *Justice* (selection of subjects is equitable and is representative)

- The **Common Rule** (45 CFR 46) is the federal regulatory framework that governs federally funded research with human subjects and codifies the ethical principles of the Belmont Report. Under the Common Rule, research with human subjects is defined as follows:
  - *Research*: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
  - *Human Subject*: A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) information or biospecimens through interaction or intervention with the individual, and uses, studies or analyzes the information or biospecimens, or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.
• **21 CFR 50** and **21 CFR 56** serve as the regulatory framework for research regulated by the FDA (i.e., research involving drugs, devices, biologics). This set of regulations is derived from the Common Rule, but the FDA and HHS regulations have some notable differences in their content. Research that is sponsored by the Department of Defense (DOD), Environmental Protection Agency (EPA), Department of Energy (DOE), and Department of Education (ED) hold additional regulatory requirements.

• Other federal and state laws and regulations that apply to research include Family Educational Rights and Privacy Act [FERPA], Health Insurance Portability and Accountability Act [HIPAA], 21st Century Cures Act, General Data Protection Regulation [GDPR], and National Institutes of Health Policy on the Use of a Single Institutional Review Board for Multi-Site Research. (Guidance and clarification of regulations are provided by the Office for Human Research Protection [OHRP].)

### Possible Questions About the Ethical Conduct of Research and Federal Regulations

- What is ethical research?
- How do you communicate institutional values and ethical messages to your associates?
- What are the three fundamental ethical principles of the Belmont Report? When was the first time you heard of the Belmont Report?
- What is the Common Rule (45 CFR 46)? What are OHRP, FDA, and HIPAA?

### Section 4: Minimizing Risks and Protecting Participants’ Rights and Welfare

Minimizing risks to participants and ensuring participants’ rights and welfare are key components of human research protections. Below are some strategies through which these goals can be accomplished.

- Design and implement protocols that comply with applicable regulatory and institutional policies, as well as the principles of the Belmont Report.

- Verify procedures are consistent with sound research design by ensuring that the research is reasonably expected to answer the proposed question and that the resulting knowledge is expected to be sufficiently important to justify the research.

- Ensure that recruitment procedures foster the equitable selection of participants.

- Utilize procedures already being performed for diagnostic or treatment purposes, when possible.

- Ensure that appropriate resources are available to conduct the research (e.g., personnel, facilities, equipment, etc.).
• Establish adequate provisions for monitoring participants to identify adverse events and to review data collected to ensure participant safety, when appropriate.

• Keep in mind that “minimal risk” to subjects means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and that confidentiality is adequately protected.

• Develop plans for protecting participant privacy and the confidentiality of data. In human research, these terms are defined as follows:

  • **Privacy**—Relates to an individual having control over the extent, timing, and circumstances regarding the sharing of information about themselves with others

  • **Confidentiality**—Relates to the protection of a participant’s data that has been shared with the researcher with the expectation that it will be protected and not disclosed

• Ensure enhanced protection for participants vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or those economically or educationally disadvantaged)

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**Possible Questions about Minimizing Risks and Protecting Participants’ Rights and Welfare**

- What is the difference between privacy and confidentiality?
- What additional mechanisms can be put in place to protect research participants?
- What are the different possible levels of risk associated with a study? How is risk level assigned?
- Can sensitive information affect the risk level?
- What are your primary concerns when reviewing a protocol?

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**Section 5: Compliance with IRB and Other Review Unit Requirements**

Research at Einstein/MMC must be conducted in compliance with IRB policies and procedures, as well as other institutional and regulatory requirements. Below are some requirements that you should be aware of related to this responsibility.

• All research with human subjects must obtain IRB review and approval or a determination of exemption before work can begin.
• The requirements of the IRB (i.e., submission of initial review, continuing review, modifications, and reporting of adverse events and unanticipated problems) must be met and research must be conducted as specified in the IRB approved protocol.

• All proposed changes to the research, no matter how minor, must be approved by the IRB prior to implementation unless necessary to eliminate immediate hazard to participants - in which case, a report to the IRB must follow.

• Materials must be submitted to the IRB in a timely fashion (e.g., requests for changes, continuing review applications, etc.).

• Information regarding reportable events is available in on the OHRA Policies and Procedures page and includes SOPs on Unanticipated Problems involving risk to subjects or others, Noncompliance, and Other Reportable Events that must be reported to the IRB within 5 business days of becoming aware of the problem.

• Unanticipated Problem – Any information, including any incident, experience, or outcome that meets ALL of the following conditions:

  • unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied

  • related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research), and

  • suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized

• Potential non-compliance with laws, regulations, or IRB requirements by the research team or others must be reported, even if this non-compliance was unintentional or discovered during the course of quality assurance activities. Participants being exposed to unnecessary risk may also be reported as potential non-compliance.

• Reports of noncompliance or subject complaints can be forwarded to the OHRA.

Montefiore’s Research Compliance Office conducts for-cause and not-for cause audits in order to ensure research complies with the federal and applicable regulations, guidelines and institutional policies that govern research.
Possible Questions About Compliance with IRB and Other Review Unit Requirements

- What does the IRB do?
- In a dispute between IRB and a researcher, can an administrator overrule IRB’s decision?
- How do you handle complaints regarding the IRB system?
- To whom do you go to for help on issues, be they regulatory or ethical?

Section 6: Obtaining and Documenting Informed Consent / Waiver of Document of Informed Consent

Documenting of Informed Consent

Informed consent is the voluntary choice of an individual to participate in research based on a complete and accurate understanding of the study. Informed consent is not a single event or document but rather an ongoing process involving the investigator (or designees) and the research participant.

Informed consent requires full disclosure of the nature of the research, the participant’s role in that research, an understanding of that role by the potential participant, and the participant’s voluntary choice to join the study. For more information on obtaining and documenting informed consent, please visit the OHRA website and Einstein/MMC HRPP Policies and Procedures page - Conduct of Research, Informed Consent Guidelines.

- Investigators are responsible for ensuring proper informed consent is obtained and documenting before the research begins unless the IRB waives this requirement.

- Informed consent must be conveyed in language that is understandable to participants or their legally authorized representative.

- Consent must be sought under circumstances that minimize potential for coercion or undue influence.

- The participant will be given answers to questions and an adequate amount of time to consider participation in the study relative to the initiation of study procedures.

- It must be made clear to participants that their participation is voluntary and that they may withdraw at any time with no penalty.

- The recruitment and consent process will not promise participants a certainty of cure or benefit beyond what is outlined in the informed consent document/informed consent script.

- The recruitment and consent process will take place in an area in which it is possible to maintain privacy and confidentiality.

- Consent is documented by use of a consent form approved by the IRB unless a waiver of informed consent or a waiver of documentation of informed consent is granted.
• The Common Rule (45 CFR 46.116 (a)) outlines the required elements of informed consent.

• Investigators are responsible for retaining signed consent documents for at least three years after completion of the research (six years if protected health information will be used or disclosed in connection with the study) or longer if required by the institution or research sponsor.

Possible Questions About Informed Consent

- What is the process of consent?
- How can a participant obtain information about human research protections at Einstein/MMC?

Section 7: Conflict of Interest Disclosure

A Conflict of Interest (COI) is a situation in which financial or other personal considerations compromise, or have the appearance of compromising, an individual’s professional judgment in proposing, conducting, supervising or reporting research. Conflicts of interest include non-financial as well as financial conflicts, because non-financial interests can also come into conflict with a researcher’s primary commitment to maintain scientific objectivity.

The following relationships are examples of situations that may raise questions regarding an apparent or actual conflict of interest in research:

a) An investigator or study staff member has a consulting or other relationship with a company sponsoring a research project, or a company that manufactures or markets a product under evaluation in the research

b) An investigator, study staff member, and or the institution has intellectual property interests in a product or method under evaluation in the research

c) An investigator or study staff member is a founder and has equity interests in a start-up company that owns intellectual property under evaluation in the research

Potential COIs are identified through annual and continual disclosure requirements for investigators in Einstein’s COI Risk Manager System. Disclosures of investigators are reviewed by the Conflict of Interest Committee (COIC) in the context of each research project in which an investigator is engaged to determine whether or not a COI exists, and if so, how it will be reduced, managed, or eliminated in the interest of preserving research objectivity and protecting the rights and welfare of human research participants. For research involving human participants for which a COI determination is made, a management plan is
developed by the COIC and is provided to the IRB for assessment as to whether or not the management strategies adequately protect the rights and welfare of human research participants.

The following are examples of COI management strategies often instituted when an investigator is determined to have a COI related to a specific research project:

1. Disclosure of the related interest to research team members and collaborators
2. Disclosure of the related interest to human research participants in the informed consent document
3. Disclosure of the related interest in press releases, presentations, and publications arising from the research
4. Reduced role of investigator in the research project (e.g., cannot serve as PI, no involvement in enrollment or consent processes, etc.)
5. Independent review of data/independent data analysis

**Institutional Conflict of Interest (ICOI)** exists when the financial interests of the institution have the potential to cause bias in the conduct of research. Such conflicts occur most frequently in situations where a research project provides a direct benefit to an outside entity through evaluation, validation, trial or test of an invention, product, drug, service or technology, and the institution holds a financial interest in the outside entity. An institution-held financial interest in an outside entity includes, but is not limited to, receipt of royalties from the outside entity or an ownership interest in the outside entity.

Einstein/MMC has specific policies and processes governing conflict of interest in research, both on the individual and institutional level. Please take some time to review the Comprehensive Conflict of Interest Policy.

### Possible Questions About Conflict of Interest Disclosure

- Do you understand the Einstein/MMC COI policies and how COIs may influence the protection of human research participants?
- What is your role in managing conflicts of interest and institutional conflict of interest?

### Section 8: Accountability and Additional Administrative Requirements

Principal investigators must perform or delegate to qualified research staff all necessary tasks to carry out research, including specifically, obtaining IRB approval before research begins; securing informed consent of participants prior to study enrollment; conducting continuing review in a timely manner; informing the IRB of any disapprovals, suspensions or terminations by other review units; the creation and maintenance of accurate records; and that sufficient resources are available to meet the needs of study. The PI is ultimately responsible for proper conduct of the study and fulfillment of related obligations.

The negotiations of research contracts and management of grants takes place through the Office of Clinical Trials (OCT), the Office of Grant Support (OGS), and Research Finance.
Assistance with research development, services, and support can be obtained from the Institute for Clinical and Translational Research (ICTR).

Researchers may contact Melissa Epstein, Director of the Office of Human Research Affairs, to express concerns/share suggestions regarding the Einstein/MMC HRPP at irb@einsteinmed.org.

Possible Questions About Accountability and Additional Administrative Requirements

- Do you have access to adequate resources to perform your duties related to human research? Does the organization provide support for review and negotiation of contracts?

Section 9: Education

The Collaborative Institutional Training Initiative (CITI) Program provides research ethics education to the research community. The CITI program offers both initial and refresher courses covering human subjects protections. Information regarding research education requirements and training certification can be found at the OHRA website under Education and Training. In-person educational sessions for researchers, students, and staff are provided through the Office of Human Research Affairs. The iRIS system contains required certification(s) and status on each member of the study team, and also provides individuals with notification of impending expirations.

Possible Questions About Education

- What education must an investigator complete to be qualified to participate in human research? Were you trained in human research/ethics/carrying out research duties, etc.?
- How do you train your staff?
- How do you verify CITI certification status?
- How do organizational officials keep you informed of new developments in human research regulations?
Section 10: Additional Resources

- OHRA Website: AAHRPP Accreditation Visit
- OHRA Website
- Einstein OHRA Policies and Procedures
- AAHRPP

The OHRA staff are available to answer your questions and to help you have a successful interview.

If you have any questions, don’t hesitate to contact us at:

irb@einsteinmed.org.