AAHRPP Site Visit 2021:
Interview Guide for IRB Members and Staff

Accreditation
AAHRPP, or the Association for the Accreditation of Human Research Protection Programs, will conduct an accreditation site visit at Albert Einstein College of Medicine and 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 and Montefiore are applying for initial AAHRPP accreditation.

AAHRPP has been provided with a written description of the Office of Human Research Affairs (OHRA) 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 those policies and procedures have been implemented effectively and are being adhered to throughout the organization.

As an IRB member or staff person, you are an integral part of the Einstein/MMC Human Research Protection Program (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 IRB members and staff 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 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 IRB. 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. 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: OHRA Policies and Procedures**
- **Section 3: Ethical Conduct of Research and Federal Regulations**
- **Section 4: IRB Review**
- **Section 5: Minimizing Risks to Subjects and Protecting Subjects’ Rights and Welfare**
- **Section 6: Compliance with IRB and Other Review Unit Requirements**
- **Section 7: Obtaining and Documenting Informed Consent**
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 structure
- Clearly describe your role in supporting the protection of research participants
- Be familiar with OHRA’s 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 where to obtain answers to ethical/regulatory questions
- Know the process for non-compliance reporting at Einstein/MMC
- Know the human research training requirements and resources at Einstein/MMC
- Describe the training you have received as an IRB reviewer/staff
- 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
- Know the ethics of recruitment and inclusion/exclusion criteria

Possible General Questions

- What does the IRB do? What are your responsibilities as an IRB member?
- What is the IRB’s reputation on campus?
- Is the IRB workload fair?
- Why does Einstein value AAHRPP accreditation? What do you think of it?

Section 2: OHRA Policies and Procedures

The following sections are taken from the OHRA Policies and Procedures available on the OHRA website.

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, Dr. Burns has assumed responsibility as the organizational official for the overall Human Research Protection Program. The IOs have the authority, but is 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 IOs may delegate duties to representatives including the Office of Human Research Affairs and IRB Chairs, as appropriate.

Melissa Epstein is the Director of the OHRA, 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 HRPP is supported by:

• The OHRA and Einstein IRB, Conflict of Interest Committee, Research Compliance, Office of Grant Support, Office of Research Sponsored Programs, Office of Clinical Trials, Institutional Biosafety Committee, Protocol Review and Monitoring Committee, Institute for Clinical and Translational Research, Research Pharmacy, and 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 OHRA Policies and Procedures

• Who is the organizational official responsible for Einstein’s HRPP? What are the components of the HRPP?
• What is the mission of the HRPP at Einstein?
• What is your role in the HRPP?
Section 3: Ethical Conduct of Research and Federal Regulations

Einstein and MMC foster 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 the organization. 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 institutional and IRB policies governing human research.

The review and conduct of human 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 there are 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 the 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).)

• Institutional policies and procedures that ensure enhanced protection for participants vulnerable to coercion or undue influence (e.g., children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons).
**Possible Questions About the Ethical Conduct of Research and Federal Regulations**

- 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 is the Office for Human Research Protections (OHRP)?
- What types of research are regulated by the FDA?
- What is HIPAA and what is its relevance to human research?

### Section 4: IRB Review

IRBs must obtain sufficient information prior to review of applications for initial or continuing review so that it can apply and satisfy the requirements for approval of research.

The IRB considers the following with respect to each application for initial, continuing, or modification review:

1. Does the activity described in the IRB iRIS application meet the definition of human subjects research as defined in the Common Rule?
2. Is the activity human subjects research as defined in FDA regulations?
3. Is Einstein/MMC engaged in the research?
4. Is the research exempt from IRB oversight?

These determinations are made consistent with the guidance provided by the US Department of Health and Human Services Human Subject Regulations Decision Charts and in consultation with IRB administrators or chairs, as appropriate. If the research:

- Involves activities or data subject to other rules or regulations such as the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, the Health Information Technology for Economic and Clinical Health Act (HITECH) Security Rule, the Family Educational Rights and Privacy Act (FERPA) or rules of other federal agencies, the review ensures compliance with these other regulations or rules

- Is exempt or not human subjects research, a designated IRB staff member may issue an exemption or “not human subjects research” determination. There is no regulatory requirement for IRB review of research that is not regulated under the Common Rule.

IRB’s ensure research is approved only when all of the requirements in 45 CFR 46.111 or 21 CFR 56.111 (for FDA-regulated research) are met. The criteria for IRB approval includes: (a) scientific merit and feasibility; (b) minimizing risk; (c) risk-benefit analysis; (d) equitable subject selection; (e) informed consent and parental permission; (f) data monitoring; (g) privacy and confidentiality; (h) attention to vulnerable populations; (i) test article accountability procedures; and (j) resources.

Because the Einstein IRB reviews FDA-regulated clinical trials, they have additional requirements including: determining whether an IND or IDE is required; for device studies, making significant/non-significant risk determinations; emergency use notification and reporting procedures; procedures for reviewing protocols for anticipated additional use in emergency situations; waiver of informed consent for certain emergency research, if permitted by the IRB; guidelines and procedures for reportable new information; communications, if any, with sponsors and IND and IDE holders; and test article accountability procedures.
**Possible Questions About the IRB Review**

- What is your process for reviewing a study? Do you utilize guidance or written checklists?
- What is the process for scientific review of research at Einstein?
- Do you consider the scientific validity of studies that you review?
- What are the expedited and exempt review categories? When are they used?
- What is the difference between human research that is exempt from IRB oversight and research determined to be not human subjects research?
- What is continuing review?
- Do you know what is not part of an IRB review? Can you give examples?
- Are IRB community members recognized as contributing board members?

**Section 5: Minimizing Risk to Participants and Protecting Rights and Welfare**

Minimizing risks to participants and ensuring participants’ rights and welfare are key components of human subjects 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.)

- 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

- Establish adequate provisions for monitoring participants to identify adverse events and to review data collected to ensure participant safety, when appropriate

- 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
Possible Questions About Minimizing Risks & 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?

Section 6: Compliance with IRB and Other Review Unit Requirements

Research at Einstein must be conducted in compliance with the IRB, 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 OHRA Policies and Procedures – Compliance and Reporting, and includes Unanticipated Problems Involving Risks to Subjects or Others (UP) which must be reported to the IRB as soon as possible, but no later than 10 working days after the investigator becomes aware of the event.

  - **UP** – 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 noncompliance 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

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AAHRPP Accreditation, 2021
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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 the 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**

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<tr>
<th>Question</th>
<th>Answer</th>
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<tr>
<td>What is the process for continuing review?</td>
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<td>What is the difference between an adverse event and a UP?</td>
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<tr>
<td>What is non-compliance? When is it considered serious and/or continuing non-compliance? What is the difference between non-compliance and an adverse event?</td>
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<td>To whom do you go for help on issues, be they regulatory or ethical?</td>
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**Section 7: Obtaining and Documenting Informed Consent / Waiver of Document of Informed Consent**

**Documentation 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 [Informed Consent](#), on the OHRA website, and [OHRA Policies and Procedures – Conduct of Research Informed Consent Guidelines](#).

- Investigators are responsible for ensuring proper informed consent is obtained and documented 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:

- A statement that the study involves research
- Information on the purpose of the research
- The expected duration of participation
- A description of the procedures (identification of experimental procedures)
- A description of reasonably foreseeable risks or harms
- A description of any benefits to participants or other
- Disclosure of appropriate alternative treatments/procedures, if the research involves clinical treatment
- A description of how the confidentiality of records will be maintained
- A description of procedures related to compensation for injury, if the research is more than minimal risk
- Contact information for the PI and the IRB
- A statement that participation is voluntary and that the participant may withdraw at any time with no penalty or loss of benefits

One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

1. A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

2. A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

The participant (or their legally authorized representative) should be provided with a copy of the consent document at the time of consent.

Investigators are responsible for retaining signed consent documents for at least three years after completion of the research (seven 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.

**Waiver of Consent**

In order to waive or alter consent, the IRB must find and document:

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. 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;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
5. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
Waiver of Documentation of Informed Consent (e.g. Oral Consent)
The IRB may waive the requirement for the Investigator to obtain signed (documented) informed consent for some or all participants [45 CFR 46.117(c)] if it finds that:

- The only record linking the participant to the research would be the consent form, and the principal risk to the participant is the potential harm resulting from a breach of confidentiality. In that event, each participant (or legally authorized representative) should be asked if he/she wishes to have documentation linking the participant with the research. The participant’s wishes will govern.

- The research presents no more than a minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context (e.g., drawing a blood sample, or asking shoppers in a mall about the ambient lighting or temperature).

- If the participant (or legally authorized representative) is a member of a distinct cultural group in which signing forms is not the norm, that the research presents no more than minimal risk of harm, and there is an appropriate alternative for documenting that informed consent was obtained.

Where documentation of informed consent has been waived, the IRB may require investigators to provide participants with a written statement regarding the research.

Possible Questions About Informed Consent
- What are the requirements of informed consent?
- How can a participant obtain information about human protections at Einstein/MMC?
- When reviewing a consent form, what do you look for?
- What does the consent process entail?
- What is the difference between a waiver of consent and a waiver of documentation of consent?

Section 8: Conflict of Interest Disclosure
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 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 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 full policies below:

**Disclosing Financial Conflicts of Interest to the Einstein IRB**

**Comprehensive Conflict of Interest Policy**

**IRB Member and Consultant Conflicts of Interest**

**Possible Questions About Conflict of Interest Disclosure**

- What is a conflict of interest?
- How does Einstein assess and manage conflicts of interest?
- What should be disclosed to subjects regarding a financial conflict of interest?
- Does the IRB view and approve COI management plans for human research?
- What do you do if you have a conflict of interest related to a protocol you are reviewing?
**Section 9: 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; and 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 Harold and Muriel Block Institute For Clinical and Translational Research at Einstein and Montefiore (ICTR).

Researchers may contact Edward R. Burns, Executive Dean, or Melissa Epstein, Director of the Office of Human Research Affairs to obtain answers to questions, express concerns, or share suggestions regarding Einstein’s OHRA. Email: irb@einsteinmed.org

### Possible Questions Accountability and Additional Administrative Requirements

- Do you think you have access to adequate resources to perform your duties related to the protection of humans in research?
- What sort of support do you receive from OHRA administration?
- How is communication facilitated throughout the OHRA? Is this an effective system? Is the IRB workload reasonable?
- Describe your annual evaluation process.

**Section 10: 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.

IRB chairs, members, and staff are trained and oriented to provide them with the knowledge and skills to effectively discharge their duties and uphold the federal and local laws, institutional policies, and ethical standards related to human research. Continuing education for new and existing IRB staff and members is also required and is provided in the form of workshops, presentations, national webinars, and printed and electronic materials that are shared on an ongoing basis. IRB members and staff are also kept informed of opportunities for continuing education and encouraged to attend. In-person educational sessions for researchers, students, and staff are provided through the OHRA, ICTR, OCT, OGS, and the administrators of the iRIS Online IRB submission system. The iRIS system contains required certification(s) and status of each member on the study team, and also provides individuals with notification of impending expirations.
Possible Questions About Education

- Describe the training you’ve had to be qualified to review human research projects.
- What sort of continuing education do you receive related to research ethics and human research?
- What ongoing professional meetings/trainings are offered, or have you attended?
- How do organizational officials keep you informed of new developments in human research regulations?

Section 11: Additional Resources

- OHRA website: AAHRPP Reaccreditation Visit
- Einstein OHRA Webpage
- Einstein OHRA Policies and Procedures
- AAHRPP

OHRA and IRB Office 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