DEPARTMENT OF MEDICINE
NEW CLINICAL RESEARCH PERSONNEL TRAINING/USER ACCESS CHECKLIST

✓	N/A	ACTIVITY	DATE COMPLETED
☐	--	Human Subjects Research (CITI)*	
☐	--	Good Clinical Practice (CITI)*	
☐	--	Comprehensive Velos and EPIC Research Training*	
☐	☐	HIPAA Training	
☐	☐	iRIS Training (Einstein IRB)	
☐	☐	BRANY SMART/IRB Manager Access (Biomedical Research Alliance of NY)	
☐	☐	REDCap Introductory Training	
☐	☐	Clinicaltrials.gov Registration Requirements/User Access	
☐	☐	Blood-Borne Pathogens Training	
☐	☐	Hazardous Communication and Lab Safety Training	
☐	☐	Shipping and Transport of Regulated Biological Materials (IATA)	
☐	☐	Participant Reimbursement Training (Greenphire ClinCard)	
☐	☐	ResearchMatch User Training	
☐	☐	EPRO Access	

See Additional Resources on Page 7

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Instructions for Accessing Clinical Research Training

1. **Human Subjects Research (HSR) - CITI*** - Human Subjects Research (HSR) education is required of all Key Personnel who conduct research involving human participants. Key Personnel is defined as individuals who contribute in a substantive way to the scientific development or execution of the project, or the consent process. Training is satisfied by completing the Collaborative Institutional Training Initiative's (CITI) Basic Course in Human Subjects Research (estimated to take 4-6 hours). **HSR certification must be renewed every 5 years**.

   CITI Basic HSR Course Registration:

   For Individuals taking CITI course for the first time:

   1. Visit http://www.citiprogram.org
   2. Click on "Register" (upper right corner)
   3. Enter "Albert Einstein College of Medicine, Inc." under *Select Your Organization Affiliation*.
   4. Complete CITI "Steps 1 through 7"
      a) You can register for the Good Clinical Practice (GCP) module by selecting "Yes" in Question #3. GCP is required for drug/device studies.
   5. Under "Step 7" in *Select Curriculum Question 1*, select appropriate Biomedical enrollment option* based on your research type:
      a) Biomedical Research (includes Epidemiology)
      b) Biomedical Research with Drug/Devices – recommended for drug/device studies
   6. Click "Complete Registration"

   **Either Biomedical Research enrollment option (5a/5b) satisfies the Human Subjects Research education requirement and does not affect your ability to do drug/device research. If you want to do drug/device research, you must also complete the Good Clinical Practice (GCP) requirement (#2 below).*

   For Individuals taking the CITI Refresher Course (every 5 years):

   1. Login at www.citiprogram.org (upper right corner)
   2. Under *Institutional Courses* click "View Courses" next to *Albert Einstein College of Medicine*
   3. Under *Courses Ready to Begin,* click "Start Now" next to the appropriate Human Subjects refresher module [Biomedical Research (Epi) or Biomedical Research (Drug/Device)]

   Please refer to the Human Subjects Research Education page under the Office of Human Research Affairs (OHRA) for additional details on requirements.

2. **Good Clinical Practice (GCP) - CITI***- Training in Good Clinical Practice (GCP) is required for all Key Personnel involved in investigational drug and/or device studies, including FDA-registered studies and investigator-initiated protocols. This requirement applies to studies reviewed by the Einstein IRB and approved external IRBs (e.g., BRANY, NCI CIRB, etc.). Training is satisfied by completing the CITI Good Clinical Practice course. **GCP certification must be renewed every 3 years.**

CITI GCP Course Registration:

For Individuals completing CITI GCP Course for the first time:

1. Visit http://www.citiprogram.org
2. Click on "Register" (upper right corner)
3. Enter "Albert Einstein College of Medicine, Inc." under *Select Your Organization Affiliation*.
4. Complete CITI "Steps 1 through 7"
    a) Select "Yes" in Question #3 to register for the "Initial GCP Course"
5. Click "Complete Registration"

For Individuals taking the CITI GCP Refresher Course (every 3 years):

1. Login at www.citiprogram.org (upper right corner)
2. Under *Institutional Courses* click "View Courses" next to *Albert Einstein College of Medicine*
3. Under *Courses Ready to Begin,* click "Start Now" next to the GCP Refresher module.

Please refer to the Human Subjects Research Education page under the Office of Human Research Affairs (OHRA) for additional details on requirements.

3. **Comprehensive Velos and EPIC Research Training*** – Velos is our clinical research management system which captures and manages clinical research activity. EPIC is our Electronic Health Record (EHR/EMR) system. You may need to enter data for research participants into both systems. This training is designed to walk you through data entry requirements and how to manage clinical research activity in both systems.

Registration:

Montefiore Associates: Visit Montefiore IT Self-Service Portal (**network access required**) -> Request for Access-> Other Request. Under *Description* enter "Comprehensive Velos-EPIC Research Training" and specify your preferred training date. See training schedule for dates (**network access required**). Complete all other fields and submit. Forward the ticket number to epictrainingdept@montefiore.org and await further instructions.

Einstein Associates: Please contact Cevita Webb (cevita.webb@einsteinmed.edu) with a scheduled training date.

User Access Request (after training is completed):

Montefiore AND Einstein Associates:

Epic User Access: After completing training, visit Montefiore IT Self-Service Portal (**network access required**) -> Request for Access -> Other Request. Under *Description* indicate you are requesting access to EPIC and the date you completed Velos-EPIC Research training. Complete all other fields and submit.

Velos User Access: After completing training, email Veloshelp@montefiore.org with training completion date. You will be provided with User Access and Confidentiality forms to complete.

Velos-Only Training for Principal Investigators only - PIs who have completed Epic Training and require access to Velos may self-certify by following these instructions to access the online training video. Email veloshelp@montefiore.org and indicate you completed the training video.

4. **HIPAA Training:** Research personnel who will have access to Montefiore patient medical records and private health information should undergo HIPAA training at Montefiore Medical Center. The Health Insurance Portability Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge.

   Montefiore Associates undergo HIPAA Training during New Hire Orientation. Einstein Associates can access the HIPAA training via Montefiore's eLearning System. The training covers the requirements and importance of maintaining patient privacy, and the security mechanisms implemented in order to do so.

   Registration:

   Montefiore Associates undergo HIPAA Training during New Hire Orientation.

   Einstein Associates:

   1. Log into Montefiore's eLearning System (access from network computer).
      a) Your Username will be your Active Directory account (network ID).
      b) The first time you log in, your Password will be **"welcome1".** You will then be prompted to change your password. Upon logging in, you will be on the Learning Homepage.
   2. Locate *Find Learning*, enter **"HIPAA Refresher Training"**, click *Go*.
   3. Select *HIPAA Refresher Training*. You can select *Assign to Me* (adds the course to your Learning Plan for later access) or click *Start Course* to begin the course.

      The course is estimated to take 25 minutes to complete.

   4. Once you complete the course, file the certificate of completion in your regulatory binder and/or personnel file.

   Contact 718-920-8787 if you encounter any difficulties accessing the Montefiore eLearning Network.

5. **iRIS Online Application System** – iRIS is the online system for submitting clinical research protocols and related materials to the Einstein Institutional Review Board (IRB). The Einstein IRB reviews all investigator-initiated protocols and those derived from federally sponsored studies; it also reviews industry-sponsored projects that are NOT clinical trials.

   Registration/Access: Log into https://iris.einsteinmed.edu/ using your Montefiore/Einstein user ID and Password. After logging in the first time, email the following information to IRB@einsteinmed.eduto have your iRIS account activated:

   - Your full name
   - MMCAD username
   - Institution (e.g., Einstein, Montefiore or NBHN)
   - Academic department (and for the Department of Medicine, Division name)
   - Status (e.g., faculty, staff, or student)

   Requesting system user training: If you would like training on how to use the iRIS system, please submit the Training and Consultation Request Form on the Office of Human Research Affairs website. Select "Training or Consultation" then "Individual." Under *Topic of Discussion* select "iRIS Technical Questions" and indicate that you are requesting system user training in the comment boxes.

Single IRB – Studies that require the use of a Single or Central IRB must review the Office of Human Research Affairs' Single IRB Review/Request page for guidance.

NOTE: Investigators doing Industry-sponsored clinical research must submit a Request to Initiate Industry Sponsored-Projects in Human Subjects form for departmental approval prior to submitting to the Einstein IRB.

6. **Biomedical Research Alliance of New York (BRANY) SMART & IRB Manager -** BRANY reviews protocols and manages contract/budget negotiations for industry-sponsored clinical trials ONLY. BRANY uses SMART and IRB Manager for regulatory and contract management.

   Confidentiality/Non-Disclosure Agreements (CDA/NDA) for industry-sponsored trials should be emailed to Eileen Summers at esummers@brany.com.

   After CDA execution, Investigators will be able to review the protocol and request departmental approval to initiate the industry study via the Request to Initiate Industry-Sponsored Research Projects in Human Subjects form. After approval, coordinators can request access to the BRANY IRB Manager and SMART systems.

   NOTE: Investigators doing Industry-sponsored clinical research must submit a Request to Initiate Industry Sponsored-Projects in Human Subjects form prior to submitting to the BRANY IRB

   Register/User access request: Contact Eileen Summers at esummers@brany.com with the approved *Request to Initiate Industry-Sponsored Clinical Research Projects in Human Subjects* form, research protocol, and draft clinical trial agreement (CTA).

7. **REDCap Introductory Training** – REDCap is a secure web-based application for building and managing online surveys and databases. It can be used to collect various types of data (including 21 CFR Part 11, FISMA, and HIPAA- compliant environments), and is specifically designed to support online or offline data capture for research studies and operations.

   Registration: Complete this registration form (**network access required**) to sign up for one of the monthly training sessions.

   User Access to existing Research Projects: Use your Montefiore/Einstein username and password to access REDCap via https://redcap.einsteinmed.org/. Contact REDCap-Help@einsteinmed.eduif you cannot access an existing research project.

8. **Clinicaltrials.gov Registration Requirements -** ClinicalTrials.gov is a public registry established by federal mandate as a means to provide public access to information on clinical trials for a wide range of diseases and conditions. Registration and, for certain studies, results reporting are required by regulatory and funding agencies including FDA, NIH, ICMJE, and CMS.

   User Access: Data entry for ClinicalTrials.gov is done through the Protocol Registration and Results Reporting System (PRS) at register.clinicaltrials.gov. To obtain a PRS account, email ClinicalTrials.gov@einsteinmed.edu

9. **Blood-Borne Pathogens Training** – Required if your role involves direct or indirect contact with human blood or bodily fluids.

   Registration:

   Einstein Associates: Complete the electronic registration form on the Environmental Health and Safety webpage and select a training date.

Montefiore Associates: Complete the "Biosafety" module in your Talent Management eLearning@Montefiore Account. To assign yourself the course, log into your eLearning account using your user ID (EZ ID number) and password (Date of Birth), click *Catalog,* and enter "Biosafety" in the *Browse for a Course* search box. Click *Enroll in this Course*. For trouble shooting, email LearningNetwork@montefiore.org or call 718-920-8787.

10. **Hazardous Communication and Laboratory Safety Training –** Working in research laboratories and some clinical settings requires knowledge of chemical, biological, fire, and radiation safety and industrial hygiene. Lab safety training is required for personnel whose role involves potential exposure to and handling of biological specimens and chemical hazards encountered in the laboratory setting.

    Registration:

    Einstein Associates: Contact Laboratory Safety Officer, Delia Vieira–Cruz (delia.vieira-cruz@einsteinmed.edu) to request training.

    Montefiore Associates: Montefiore covers this topic in two separate trainings:

    Hazardous Communication: Complete the *Hazard Communication Online Montefiore 2013* module in your Talent Management eLearning@Montefiore account. Assign yourself the course by logging into your eLearning account using your user ID (EZ ID number) and password (Date of Birth), click *Catalog* and enter "Hazard Communication Online Montefiore 2013" in the *Browse for a Course* search box. Click *Enroll in this Course*. For troubleshooting email LearningNetwork@montefiore.org or call 718- 920-8787.

    Laboratory Safety: Contact Alexander Lochner (alochner@montefiore.org) to request training

11. **Shipping and Transport of Regulated Biological Materials** - This training course provided via the Collaborative Institutional Training Initiative (CITI) is available to research personnel who will be packaging and shipping diagnostic and clinical human or animal specimens, human or animal pathogens, and other regulated biohazards. Personnel performing these tasks must be trained in International Air Transport Association (IATA) and the U.S. Department of Transportation (DOT) standards.

    The CITI *Shipping and Transport of Regulated Biological Materials* course is designed to meet the requirements of the International Air Transport Association (IATA) and the U.S. Department of Transportation (DOT).

    Register for the course via your CITI Account. Select *Add a Course* under *Learner Tools Albert Einstein College of Medicine*. Select *Biosafety/Biosecurity (BSS)*, and then select *Shipping and Transport of Regulated Biological Materials*.

12. **Greenphire ClinCard Participant Reimbursement System -** Greenphire-ClinCard is a web-based payment system that enables research participants to be compensated for their time, travel and expenses. Investigators and study coordinators are able to process reimbursements included in a study budget on the day of a participant's visit.

    For Research Managed by Einstein (Grant-funded studies): Contact your Division Administrator for instructions on setting up a Greenphire account for your grant funded study at Einstein.

    For Research Managed by Montefiore: New Associates (Montefiore and Einstein) must complete the Greenphire e-Learning Module (**network access required**) and email the certificate of completion to the Greenphire Administrator, Carmen Rodriguez at carmrod@montefiore.org. For new studies you should request a "Greenphire New Study Application" from Carmen. For user access to existing studies in Greenphire, you must provide Carmen with the IRB number for each study.

13. **ResearchMatch User Training -** ResearchMatch is a national registry of patients interested in volunteering for medical research. It is a free participant recruitment and feasibility analysis tool for researchers at participating institutions who are conducting research which is health related.

    User Access: Contact Zoe Tsagaris at zoe.tsagaris@einsteinmed.edu

    User Training: Users have access to video tutorials on the ResearchMatch Dashboard

14. **EPRO Access (for Einstein Associates) -** EPRO is Einstein's marketplace with preferred pricing catalogs from many vendors including Amazon, Apple, Fisher Scientific, HiTouch, and Staples. Users can order office and lab supplies to be used for research-related activity here.

    User Access/Account Set-up: contact your Division Administrator.

    Access via EPRO Shoppers: https://solutions.sciquest.com/apps/Router/Login?OrgName=Einstein

Additional Resources

Clinical Research Core Support services through the Institute for Clinical and Translational Research (ICTR): The ICTR is a member of the nationwide Clinical and Translational Science Awards (CTSA) consortium, funded by the National Institutes of Health (NIH). The CTSA is designed to break down barriers that inhibit cross-disciplinary, bidirectional research from the laboratory to the clinic and back again. Core services are listed below. Visit the Clinical and Translational Research Services page for more information including how to access services.

- Biomarker analytic Research Core (BARC)
- Biorepository Core (BioR)
- Biostatistics, Epidemiology & Research Design Core (BERD)
- Research Informatics Core (RIC)
- Clinical Research Center (CRC)
- And more…

Sign up to receive the ICTR Newsletter and receive program updates

We also encourage you to take advantage of the following resources to help you navigate clinical research at the institution:

- **The Human Subject Research Project Navigation Tool** is designed to guide your research activities throughout the project lifecycle and is organized into 5 key sections: Education & Training, Planning & Development, Project Setup or Initiation, Project Management, and Close Out. Within each section you will find all relevant topics, and a summary of the topic's importance, requirements (ex: federal regulations, institutional policies, etc.), best practice tips, "how to get started", and related tools and resources.

- **Join the ICTR Research Coordinator Forum:** The ICTR has created a Research Coordinator Forum for research staff in study/regulatory coordinator roles. This forum is hosted in Microsoft Teams and gives members the opportunity to ask questions, share best practice tips, helpful resources and more. This communication channel will also be used to share news about upcoming events, training opportunities, and other important updates! Please e-mail HSRProjectNavigation@einsteinmed.edu to be added to the forum.

- **Join the Research Coordinator and Clinical Investigator Distribution List:** The Research Coordinator and Clinical Investigators distribution list helps rapidly inform the clinical research community about educational opportunities, meetings and other matters of interest. To register contact Carmen Rodriguez at carmrod@montefiore.org.

- **Office of Grant Support's (OGS) Listserv:** The OGS listserv provides process updates from the Office of Grant Support and upcoming funding opportunities. Contact Regina Janicki at regina.janicki@einsteinmed.edu to register.

- **Visit the Office of Human Research Affairs' (OHRA) Research Education Page:** The OHRA provides access to a number of different trainings and educational resources to educate investigators on the protection of human subjects in research. Investigators have access to online training courses, training presentations, training workshops, and external training resources**.** Please visit the Human Subjects Research Education page for information on upcoming education/training opportunities.