# DEPARTMENT OF PEDIATRIC'S INTERNAL GUIDE TO RESEARCH

## ESSENTIAL DEPARTMENT CONTACTS

*"Who should I let know about my research idea/project or submission plans?"*

**1) Mentor**- For all Jr. Staff research projects that utilize any institutional or department resource including principal investigator time, core facilities, animal studies and IRB protocol approval (external IRB's included) your mentor must be made aware of your plans. *This usually happens automatically during the planning process.*

**2) Division Chief**- You should inform your division chief of your research project either directly (depending on research level) or via your mentor if it will require any of the following resources or pathways:

1) IRB approval: Prior to initiating the IRB application.
2) If you are submitting an application - This is important as many opportunities require a letter of support that should either come from the division head, chair or both.
3) Project may require other divisional or departmental personnel effort or support.

**3) Research Administrator**- Each division is assigned a research administrator. They are housed on the Einstein campus and provide guidance and support for the administrative aspects of research projects and sponsored awards on both the Montefiore and Einstein side. These services include:

1. Specimen research- If an MTA is needed will assist you in completing and obtaining the correct institutional signatures
    a. SafeTPak training for shipment of samples: Your administrator will assist you in obtaining.
2. Data use agreements-same as above
3. Sponsored projects and funding: Assistance is given from start (submission) to finish (Project end) on all sponsored and internal funding opportunities.
    1) NIH Funding
    2) Foundational awards and opportunities
    3) Philanthropic donations toward research
    4) Individual scholar awards
    5) Internal awards
    6) Collaborations with other institutions
    7) Industry sponsors
    8) Investigator initiated projects
    9) NIH Tuition reimbursement
    10) Assistance in obtaining funding opportunities
    11) Purchasing research related items
    12) All contract executions
    13) Feasibility assessments
    14) Cost analysis (Clinical trials)
    15) VELOS and EPIC Research questions for clinical research projects
    16) Travel awards

4) **Divisional Clinical research assistant, CRA,** (IF APPLICABLE)- Include for any clinical research protocol that is sponsored and may require additional assistance with IRB submission and possible enrollment assistance on the study.

5) **The Pediatric Proposal Review Committee (PRC),** seeks to enhance the quality of research involving human subjects in the Department of Pediatrics. ***It is charged with review and approval of all proposals that require Institutional Review Board (IRB) review in which the Principal Investigator (PI) is in the Department of Pediatrics.*** (pg.15-17)

Alan Fleischman, MD, Chair afleisch@montefiore.org (917) 439-6364
Questions: May Thompson, Admin Asst. mathomps@montefiore.org (718) 741-2342

## FUNDING PATHWAYS & SUPPORT OFFICES

*"I have a project, how do I secure funding or apply to open opportunities"*

**GrantScoop:**
Grant Scoop is a Funding opportunity database and grant-search engine for biomedical, life science and health science research. Sign up via https://www.grantscoop.com/

- Create a User Account using "@einstein.yu.edu" email address
- At the bottom of the sign-up page, under "Plan," please choose "Institutional Access"
- Contact anindita.mukherjee@einstein.yu.edu for assistance

**Grant proposal advisory services:**
https://www.einstein.yu.edu/administration/grant-support/grant-advisory-service/ The College is now offering a grant proposal advisory service to Einstein investigators. The purpose of this service is to aid investigators in generating high quality, polished proposals in order to increase their chances of securing funding for their research. The specific aspects of the service are described below. The grant advisor is Dr. Tanya Dragic, **Contact information:** Please send all requests, application documents and supporting materials to tanya.dragic@einstein.yu.edu. Dr. Dragic can also be contacted directly every day between 9:30AM and 1:30PM at (914) 262-5441

**College Intranet funding listing:**
Please go to Einstein Intranet and sign in at https://www.einstein.yu.edu/auth/login/intranet/; Click on "Administrative Services"; Select "Grant Support" department; Click on the tab "Foundation Funding"; Click on "Grant Title" links for details of the funding mechanism

**eRA Commons:**
Necessary to have an account if applying for any federal funding. Please email your administrator for assistance in obtaining an institutional account

**Cayuse:**
Platform for applying for funding opportunities. Please email your administrator for assistance in obtaining an institutional account and to apply to funding opportunities. https://einstein.cayuse424.com

**Proposal Central:**
External funding site to apply for foundation and non-profit opportunities. Please contact your research administrator prior to applying to ensure all institutional contacts are added the correct pathway is taken.
To learn about potential funding please use the links above. Contact anindita.mukherjee@einstein.yu.edu for assistance.

**Internal Listing (EINSTEIN OGS):**
http://www.einstein.yu.edu/administration/grant-support/funding-opportunities.aspx

## INTERNAL RESEARCH OFFICES FOR SPONSORED PROJECTS AND FEDERAL AWARDS:

*"I found a funding opportunity that could work for me. I require assistance with submitting, writing the science and ensuring I have the resources I need"*

**The Office of Grant Support (OGS):**
Investigators intending to conduct federally funded research should contact their Administrator and The Office of Grant Support (OGS). OGS will work with your assigned Pediatric Research administrator to provide pre-award administrative assistance. All federally funded research including sub-awards granted to Albert Einstein College of Medicine will flow through this office. The office aims to enable faculty scholars to submit

competitive grant proposals and to successfully manage all subsequent non-financial responsibilities of the award, resubmission, and renewal processes. https://www.einstein.yu.edu/administration/grant-support/

**Fellowship awards and funding slideshow:**
http://www.einstein.yu.edu/uploadedFiles/administration/OGS/NIH%20Fellowships_Everything%20You%20Need%20to%20Know_Pre-doctoral%20Workshop_March2018%20(2).pdf

**Manuscript review:**
OGS also offers assistance/help with manuscript writing, editing, proof-reading, reviewing and critiquing to enhance publications. Contact: Dhanonjoy C. Saha, PhD Director, Office of Grant Support
Phone: 718-430-3642 Email: dhanonjoy.saha@einstein.yu.edu

**Funding Opportunity and Grant Development:**
Anindita Mukherjee, PhD
Assistant Director, Funding Opportunity and Grant Development
Belfer, Room 919A 718-430-3367
anindita.mukherjee@einstein.yu.edu

**Creative Services:** OGS is working with our creative services to offer high quality image or illustration for grant applications. Please contact Creative Services at (718) 430-2387.

**The Office of Research Sponsored Programs (ORSP):**
The Office of Research Sponsored Programs (ORSP) is the administrative body that manages federally funded research grants for Montefiore Medical Center (MMC). Only awards specific to Montefiore Medical Center should be routed through this office. All other federal opportunities should go through the Einstein OGS office unless the Animal Institution at Montefiore Medical Center is being utilized. ***Please contact your research administrator to ensure you are taking the correct pathway.***

**Office of Biotechnology and Business Development:**
The Office of Biotechnology serves as the technology transfer office of Albert Einstein College of Medicine, facilitating the licensing of college technology to industry and research collaborations between industry and faculty. The Office of Business Development serves to further enhance the value of the college's research, clinical and intellectual property assets by proactively collaborating with the commercial, governmental, financial and entrepreneurial communities in novel initiatives. Together, the offices work in partnership and build upon each other's strengths, in order to fulfill the mission of assisting the translation of basic research advances made at Einstein into clinical applications that can benefit the public. For Information about on the office's policies on patenting and working with industrial partners, as well as technologies available for licensing, please visit their website. (https://www.einstein.yu.edu/administration/biotechnology-business-development/) If the project incorporates a clinical trial component the office of biotechnology will work with both BRANY and OCT to execute the CDA, MTA and DUA depending on the research.

**The Office of Clinical Trials (OCT):**
OCT is responsible for clinical trials and other investigator initiated research projects. Please refer to the clinical research section on page 7 for more information.

**The Biomedical Research Alliance of New York (BRANY):**
BRANY is responsible for Industry support clinical research. It functions as both an external IRB and as a full service support organization for clinical research. Please refer to the clinical research section on page 7 for more information.

## ADDITIONAL INTERNAL RESOURCES AND PROJECT SUPPORT

*"I have a project, what resources can I use? What is required internally for me to proceed? How do I execute contracts, CDA's, MTA's, DUA's and feasibilities? Who can assist me?"*

**REMINDER: Your mentor and research administrator are two of your best departmental tools. Do not forget to include them for guidance.**

**Clinical Looking Glass (CLG):**
CLG is a patented software tool that can be used to access electronic data from the Montefiore health system for use in research and quality improvement. For more information:
CLG Website: http://exploreclg.montefiore.org/

- Instructions on how to get CLG access under the "Become a CLG User" tab

**CLG Office Hours with Diana S. Lee on Wednesday afternoons from 1-5 PM**

- Contact Beatrice Pitre (bpitre@montefiore.org) to arrange an appointment.
  * Please include a short description of the purpose of the appointment.*
- Contact Diana S. Lee (dialee@montefiore.org) if you need to schedule an appointment outside of Wednesday afternoon.

**Department of Pediatrics Biostatistics Services:**
Contact either Marissa Green (marissa.green@einstein.yu.edu) or Dr. Bauman to obtain the request form. All request forms should be sent to Dr. Laurie Bauman <Laurie.Bauman@einstein.yu.edu>

**Biostatistics, Epidemiology and Research Design Core (BERD)-** *(See ICTR information listed on page 6)*

**Walk-in Statistical Center Hours:**
Einstein Campus: Every Tuesday 3 – 5 pm, Belfer Building, Room 1303
Montefiore Campus: Every Monday 3 – 5 pm, Moses Research Tower, Room 8009

**The Institute of Animal Studies (IAS, EINSTEIN):**
The Einstein oversees all animal related activity and is home to the Institutional Animal Care and Use Committee (IACUC), The IAS ensures the highest quality animal biomedical research and teaching while ensuring the most humane care possible and compliance with all animal welfare and health and safety policies and regulations. To achieve this, health care for experimental animals at Albert Einstein College of Medicine (Einstein) is provided by the IAS veterinarians and veterinary technicians. Also, the IAS coordinates the purchase of experimental animals at Einstein and provides animal husbandry services.
https://www.einstein.yu.edu/administration/animal-studies/

*Clearance through Health and Safety is required prior to training.*

NOTE: All protocols involving animal studies must be reviewed and approved by the IACUC.
https://www.einstein.yu.edu/administration/animal-care-use-committee/

**Collaborative Institutional Training Initiative (CITI):**
***Required for all key and support personnel involved in both Human subject research and Animal research.***

1. Visit www.citiprogram.org.
2. Click on the "Register for the CITI Course" link.
3. Complete items 1-7 of the registration process and click "Submit".
4. You will then be directed to the "Select Curriculum" page. You will select curriculum based on your research needs. Specifics for both Human and animal requirements can be found on the IRB and IACUC webpages.

**iRIS:**
Internal protocol submission platform for clinical research. iRIS is now required for all new study submissions (Exempt, Expedited, and Full Board)! Learn more, visit the iRIS Info Page: https://www.einstein.yu.edu/administration/institutional-review-board/education/iris.aspx

**Electronic COI process:** PIs and Additional Investigators must have current electronic COI disclosures on file with the Einstein COI office. For more info see: http://www.einstein.yu.edu/administration/conflict-of-interest/disclosure-form

**VELOS:**
Clinical Research Management System to streamline, integrate and manage all clinical research and clinical trial activities. All contracts, including DUA's with Montefiore that are not federally backed will need to be added through VELOS prior to Legal review. See link: http://www.einstein.yu.edu/centers/office-clinical-trials/getting-started/ (Please refer to PI handout to obtain access) Questions. Email: veloshelp@montefiore.org

**EPIC Research:**
Necessary to have access if proposal is a clinical trial or utilizes an ancillary department service. Please email Marissa.Green@einstein.yu.edu

Research Training — EpicTrainingDept@montefiore.org
Epic Questions — call the help desk open a ticket 718-920-4554
Velos Questions — Veloshelp@montefiore.org
Research Billing Questions — Jo-Ann Oscar, manager of the new Revenue
Integrity Research Department- JOSCAR@montefiore.org

***Depending on the project it may be necessary to utilize a variety of resources. In order to proceed you may be required to obtain approval from multiple offices to ensure all internal and external requirements are fulfilled. Continued monitoring and oversight may be required.***

**Specimen Collection needs:**
Some projects may involve the collection of human specimens, cells, cell lines, or data obtained from live individuals for research purposes. Human specimens and samples can be collected as a necessary part of the current research protocol, or they can be stored for future research activities or projects.

1) Future Use of Specimens:
Investigators who plan to store specimens collected during the course and as part of an IRB approved research project for future use(s) should ensure the storage and possible future use(s) are described in the research protocol and consent forms. Investigators should adhere to Einstein IRB policy on the Collection and/or Study of Human Specimens. (Refer to the IRB handbook https://www.einstein.yu.edu/administration/institutional-review-board/policies.aspx)
2) Storage of Banked Samples:
The ICTR Biorepository Core provides secure archival sample storage as well as clinically-annotated specimen biobanks for defined research projects. The core serves the human research blood and tissue banking needs of clinical and translational researchers. Samples can be banked by an individual Principal Investigator or by a consortium of investigators. All samples are tracked and archived using a secure tracking database. The facility works under the best practices set out by NCI and ISBER (2006) for collection, storage, and retrieval of human biological materials for research. To access the core's services, please utilize the Analytical Core Lab & Biorepository Service Request Form. (See page for additional ICTR information)

Sharing Samples between Institutions:
Some clinical research involves sharing specimens and/or biological samples between investigators at different institutions. Investigators with protocols requiring the transfer of specimens or other biological across institutions require a Material Transfer Agreement (MTA). * *THIS SHOULD BE SENT TO YOUR RESEARCH ADMINISTRATOR TO GUIDE THE SIGNATURE PROCESS*

- Hazardous Goods Shipping

All investigators, clinicians and research personnel that are shipping biohazardous materials (i.e. blood and tissue specimens, radioactive materials, chemicals, etc.) must complete IATA

(International Air Transport Association) certification. Shipping these materials without certification can result in an institutional fine of up to $60,000 for each offense. **YOUR AMINISTRATOR WILL ASSIST YOU IN OBTAINING CERTIFICATION VIA WWW.SAFTPAK.COM**

**The Gruss Magnetic Resonance Research Center (MRRC)**:
Location on the main (Resnick) campus of the Albert Einstein College of Medicine.
More details: https://www.einstein.yu.edu/centers/gruss-magnetic-resonance-research/

**Rose F. Kennedy Intellectual and Developmental Disabilities Research Center - Human Clinical Phenotyping (HCP) Core** https://www.einstein.yu.edu/centers/iddrc/human-clinical-phenotyping-core/

**The Institute for Clinical and Translational Research (ICTR**)
The Institute for Clinical and Translational Research (ICTR) at Montefiore and Einstein is sponsored by the CTSA Consortium -a group of medical research institutions working together to improve the way biomedical research is conducted across the country, is funded by the National Institute of Health (NIH). The consortium shares a common vision to improve patient treatment by reducing the time it takes to develop laboratory discoveries and to engage communities in clinical research efforts.
Investigators looking to initiate their own clinical research protocols and/or in need of resources to execute a clinical research study can utilize the ITCR Core's: (Please work with both your mentor and administrator to ensure you are utilizing the best resources for your project). A detailed listing of the cores are outlined in separate handout and available online at http://www.einstein.yu.edu/centers/ictr/ .

- **Research Training, Education and Career Development Programs (RET) (Refer to additional handout for upcoming courses)**
- **Biostatistics, Epidemiology and Research Design Core (BERD)**
- **Research Informatics Core (RIC)**
    - **REDCap**
- **Clinical Investigation Services Core (CISC)/Clinical Research Center (CRC)**
- **Biorepository Core (BioR)**
- **Biomarker Analytic Research Core (BARC)**
- **Community Engagement Consultation Core (CECC)**
- **Project Acceleration Resource (PAR)**
- **Bronx CREED Document Translation Service**

# CLINICAL RESEARCH ADMINISTRATION OFFICES AND RESOURCES

Clinical research activity is managed and directed by a collection of institutional administrative offices across Montefiore Medical Center (MCC) and Albert Einstein College of Medicine (AECOM). Each office plays a particular role in the administration and supervision of clinical research. **Your research administrator should be included in all emails chains for potential projects with sponsors or Industry sources. They will guide you through the various offices and requirements mandatory for clinical research and ensure all department regulations/requirements are completed.**

## The Office of Clinical Trials (OCT):

The institutional Office of Clinical Trials (OCT) is the central administrative office for non-government funded consortiums sponsored research, subcontracts, collaborations between academic medical centers/institutions, Investigator-Initiated research and research sponsored by foreign companies or groups. The OCT specializes in contractual and budgetary start-up and on-going financial management of trials. Services include building and negotiating budgets, crafting and negotiating contracts, and engaging in business development. This is done in tandem with support from your research administrator.

## The Biomedical Research Alliance of New York (BRANY):

BRANY is a national organization providing support services to sponsors and investigators involved in research in a wide variety of therapeutic areas, medical devices, biologic and diagnostic trials. BRANY's services include:

- Site identification, initiation, and support
- Central IRB
- Quality assurance oversight
- Financial management
- Personnel training to advance the field of clinical research.

*All Industry – Sponsored clinical trials taking place at MMC and its affiliates should utilize BRANY for contractual and budgetary management.*

**NOTE: If contacted by an industrial sponsor and sent a confidential disclosure agreement (CDA) or feasibility assessment please email your administrator and forward the contract/assessment. The CDA will most likely be executed by BRANY instead of OCT. DO NOT SIGN WITHOUT CONTACTING YOUR ADMINISTRATOR**

## Research Billing Compliance:

The Research Billing Compliance Office ensures that Montefiore Medical Center is in compliance with all laws, regulations and contractual obligations pertaining to the billing of research-related charges for patients covered by Medicare, Medicaid and other third party payers. Laws and regulations include: Medicare, Medicaid and state insurance laws addressing coverage and payment for clinical services. Contractual obligations include: obligations under contracts with the sponsor of the clinical research and contracts with third party payers. Research billing is a critical compliance concern for Montefiore Medical Center. All clinical research activity conducted at Montefiore Medical Center and its affiliates must be compliant with the Research Billing Compliance Policy and Procedure to ensure that research and standard of care procedures are distinguishable and billed for accordingly. (Please refer to Appendix BLANK for more information)

## National Clinical Trial Numbers:

The Centers for Medicare and Medical Services (CMS) requires that National Clinical Trial Number (NCT Number) be reported on all billing claims for items/services related to a qualifying clinical trial. The NCT number is obtained when the trial is registered in the National Library of Medicine (NLM) via the ClinicalTrials.gov website (See Registration Requirements for Clinical Trial Protocols). The NCT Number is an 8-digit number preceded by the letters "NCT." The CMS uses the NCT number to identify and track all items and services provided to beneficiaries during participation in a clinical trial. Please refer to appendix B for more information.

## Institutional Review Boards (IRB):

An Institutional Review Board (IRB) is a committee, operating under federal regulations, state laws, and institutional policy, that reviews research involving human subjects to ensure the ethical and equitable treatment of those subjects. All research involving human subjects requires IRB review. An IRB is authorized to review and to approve, defer and/or require modifications to secure approval, table, or disapprove human subject research. Composed of scientists, doctors, lawyers, and lay persons, the IRB ensures that appropriate steps are taken to protect the rights and welfare of participants as subjects of research taking place at Montefiore Medical Center and/or its affiliates. Research matters reviewed by IRBs include:

- Subject safety and privacy via Degree of Risk
- Inclusion and Exclusion of participants
- Recruitment Plans
- Adequacy of the Informed Consent Form
- Quality and Integrity of Data (during an Audit)

Written IRB approval must be obtained before any human subject research activity begins. Per federal regulation, research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by other officials of the institution.
As a rule, any research taking place at Montefiore Medical Center, Einstein and/or its affiliates involving the use of human subjects or human tissues must be reviewed and approved by an IRB. ***Montefiore and Einstein have access to two separate IRBs, our own internal Einstein IRB, and an external central IRB managed by The Biomedical Research Alliance of New York (BRANY) IRB***. All investigator initiated protocols and those derived from federally sponsored studies are to be reviewed internally by the Einstein IRB. While industry sponsored protocols may be reviewed by either IRB, we are currently directing all industry sponsored trials to the BRANY IRB for review.

## The Biomedical Research Alliance of New York (BRANY) IRB:

Investigators conducting industry sponsored clinical trial research must utilize the BRANY IRB for review of their protocol and study materials. The BRANY IRB is a division of The Biomedical Research Alliance of New York (BRANY), an organization founded by the following institutions: Montefiore Medical Center, Mount Sinai School of Medicine, NYU School of Medicine, North Shore – Long Island Jewish Health System, and St. Vincent's Catholic Medical Centers. The BRANY IRB has been contracted by Montefiore Medical Center, to review human subject research taking place at the institution and its affiliates, to ensure that the rights and welfare of those research subjects are protected. Investigators should refer to BRANY's policies and procedures for obtaining review and approval of clinical research trials.
For information on federal regulations describing the mandate and operations of IRBs please review the Code of Federal Regulations 45 CFR 46.

## Pediatric Protocol Review Committee (PPRC)

Researchers who plan to involve children as research subjects must obtain the signature of the Chair of Pediatrics on the IRB application signature page, unless Investigators are submitting to the BRANY IRB, which does not require this signature. **All studies involving pediatric patients must submit their protocols to the Pediatric Protocol Review Committee (PPRC) for review and approval, prior to submitting to the either the Einstein or BRANY IRB for review and approval**. Please refer to additional handout for more details. (pg15-17)

## Magnetic Resonance Research Center (MRRC):

Investigators who intend to utilize the Gruss Magnetic Resonance Research Center facility must submit their research protocols to the MRRC for review and approval prior to initiating clinical research activity in the MRRC. Please note that MRRC review may lead to modifications of the research protocol. IRB review and approval may be given prior to MRRC submission. Investigators may visit the MRRC webpage for more information or contact Luda Slobodskaya at luda.slobodskaya@einstein.yu.edu or 718-430-3323.

**NBHN Research Protocol Working Group (RPWG) and Health and Hospitals Corporation (HHC):**

Investigators who intend to conduct any research involving the Health and Hospitals Corporation (HHC), New York Medical Association, North Bronx Health Network, Jacobi Medical Center, or North Central Bronx personnel, facilities, and/or resources must submit their research protocols to the North Bronx Health Network Research Protocol Working Group (RPWG) and Health and Hospitals Corporation (HHC) for review and approval prior to conducting research at any of the aforementioned sites. The IRB may review protocols in tandem to RPWG) and HHC submission.

Investigators should contact Howard Nadel at howard.nadel@nbhn.net or 718-918-7070 for guidance.

**Institutional Safety Committees:**

Some clinical research protocols require review and approval by institutional safety committees prior to obtaining Institutional Review Board (IRB) review and approval. This is the case regardless of whether a clinical research study is submitted to the Einstein IRB or BRANY IRB. Investigators are responsible for ensuring that all appropriate personnel are informed of his/her potential clinical research study, and obtain approvals where necessary. Below is a list of institutional safety committees, and the types of studies that require their review. Please refer to Table below for more details:

| COMMITTEE NAME | REQUIRED FOR | WHEN? | CONTACT |
|---|---|---|---|
| Einstein Institutional Biosafety Committee (IBC) | Any research involving the transfer of gene material, complementary DNA, full length genes, RNA, or oligonucleotides into humans | Before submitting to the IRB for review | Delia Vieira-Cruz (718-430-3560) |
| Cancer Center Protocol Review and Monitoring Committee (CCPRMC) | Any research involving a primarily cancer patient population. (Note: Studies receiving "expedited" review by the PRMC may be reviewed by the IRB prior to PRMC approval, but IRB approval will not be issued until after the PRMC approves.) | Before submitting to the IRB for review | Milagro Rodriguez (718-904-2783) |
| Pediatric Protocol Review Committee (PPRC) | Any research involving a pediatric patient population | Before submitting to the IRB for review | Alan Fleischman (718-741-2333) |
| Clinical Research Center Protocol Review Committee (CRC PRC) | Any research utilizing the CRC facilities | Before receiving IRB Approval; may submit to both offices in tandem | Elizabeth Castro (718-920-5126) or Vishwa Niranjan (718-430-2763) |
| Radiation Safety Committee (RSC) | Any research involving Radiation or Radioisotopes beyond standard clinical care at Einstein/Montefiore. | Before receiving IRB Approval; may submit to both offices in tandem | Manyu Chen (718-920-5012) |
| Magnetic Resonance Research Center (MRRC) | Any research involving the MRRC facility, prior to initiation the MRRC component of the study. Please note that MRRC review may lead to modifications of the research protocol. | Before beginning research activity in MRRC | Luda Slobodskaya (718-430-3323) |
| NBHN Research Protocol Working Group (RPWG) and HHC | Any research involving HHC/NYMA/NBHN/JMC/NCB personnel, facilities, and/or resources. | Before beginning research activity at these sites | Howard Nadel (718-918-7070) |

**Residents and Fellows:**

Residents and fellows may participate in research that is directed by a Montefiore/Einstein faculty member. As Principal Investigator, the faculty member directs the investigation and delegates study related tasks based on the resident's / fellow's prior experience, qualifications, and institutional policy. Residents and fellows generally are not Principal Investigators. Residents and fellows who engage in research must be included as Key Personnel on the IRB application or added by amendment prior to participating in the research.

**Medical Students:**
Medical Students may participate in research that is directed by a Montefiore/Einstein faculty member. As Principal Investigator, the faculty member directs the investigation and delegates study related tasks based on the student's prior experience, qualifications, and institutional policy. Medical Students who engage in research must be included as Key Personnel on the IRB application or added by amendment prior to participating in the research. Participation of medical students requires the written approval of the Einstein Dean of Students.

## CLINICAL RESEARCH

WHAT IS CLINICAL RESEARCH?

Clinical research is medical research that directly involves or that uses materials from humans, such as their behavior or samples of their tissue. The research may involve a specific individual or groups of people (also called subjects), and aims to uncover better ways to treat, prevent, diagnose, and understand human disease. Clinical research is conducted according a protocol, which is designed to safeguard the participants' health and answer specific research questions.

WHAT IS TRANSLATIONAL RESEARCH?

- T1 Translational Research is the conduct of laboratory-to-humans research, applying basic science research to human subjects and moving discoveries and knowledge into initial clinical testing. It is mechanism-oriented clinical research that may include laboratory-based research aimed at clarifying mechanisms of disease; developing measures or markers of disease presence, severity, or improvement; and developing drugs, devices, or interventions to treat disease or to improve health.

- Clinical Research includes studies in human subjects such as surveys, cross-sectional studies, case series, case-control studies, cohort studies, first-in-human, proof of principle, health services research and all phases of clinical trials.

- T2 Translational Research performs evidence to practice research concentrating on the dissemination and implementation of best practices in prevention and treatment in the community. T2 research includes identifying community, patient, physician, and organizational factors that serve as barriers and facilitators to translation; developing novel intervention and implementation strategies to increase translation, such as quality improvement programs or policies; and evaluating the impact of strategies to increase translation of relevant healthy behaviors and processes of care.

## TYPES OF CLINICAL RESEARCH

- **Patient-oriented research:**
  This type of research is conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects.
    - Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual, tissue banking, and studies that do not require patient consent.

- **Epidemiological & behavioral studies:**
    - Epidemiological studies seek to identify the patterns, causes, control of disorders and effects of health and disease in groups of people. e.g. surveillance, risk assessment, outcome, environmental, and behavioral studies.
    - Behavioral studies, seek to improve the understanding of human behavior and how it relates to health and disease.

  A behavioral epidemiology framework is proposed to specify a systematic sequence of studies on health-related behaviors, leading to evidence-based interventions directed at populations.

    - The phase are:
        - 1--establish links between behaviors and health;

- 2--develop measures of the behavior
- 3--identify influences on the behavior
- 4--evaluate interventions to change the behavior
- 5--translate research into practice.

Mature research areas are expected to have more studies in the latter phases

- **Health services research:** looks at how people access health care providers and health care services, how much care costs, and what happens to patients as a result of this care. Protocols designed to evaluate delivery, processes, management or financing of health care.

- **Treatment Research:** generally involves an intervention such as medication, psychotherapy, new devices, or new approaches to surgery or radiation therapy.

- **Prevention Research:** looks for better ways to prevent disorders from developing or returning. Different kinds of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes.

- **Diagnostic Research:** refers to the practice of looking for better ways to identify a particular disorder or condition.

- **Screening Research:** aims to find the best ways to detect certain disorders or health conditions.

- **Quality of Life Research:** explores ways to improve comfort and the quality of life for individuals with a chronic illness.

- **Genetic studies:** aim to improve the prediction of disorders by identifying and understanding how genes and illnesses may be related. Research in this area may explore ways in which a person's genes make him or her more or less likely to develop a disorder. This may lead to development of tailor-made treatments based on a patient's genetic make-up.

## CLINICAL RESEARCH CATEGORIES

**Interventional:** Individuals are assigned prospectively by an investigator based on a protocol to receive specific interventions. The participants may receive diagnostic, treatment, behavioral, or other types of interventions. The assignment of the intervention may or may not be random. The participants are followed and biomedical and/or health outcomes are assessed.

**Observational:** Studies that focus on cancer patients and healthy populations and involve no prospective intervention or alteration in the status of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator of the observational study is not responsible for assigning specific interventions to the patients of the study.

**Ancillary:** Studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Only studies that can be linked to individual patient or participant data should be reported.

**Correlative:** Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported

**Clinical Trials: Evaluate the effects of an intervention on health outcomes**

**NIH Definition of a Clinical Trial:**

A research study in which one or more human subjects are *prospectively* assigned to one or more *interventions* (which may include placebo or other control) to evaluate the effects of those interventions on *health-related biomedical* or *behavioral outcomes*.

1) The term "prospectively assigned" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

2) An "intervention" is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

3) A "health-related biomedical or behavioral outcome" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

***Answer a few simple questions below to help determine if your study is a clinical trial***

***1. Does the study involve human participants?***

***2. Are the participants prospectively assigned to an intervention?***

***3. Is the study designed to evaluate the effect of the intervention on the participants?***

***4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?***

**Note that If the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, *even if*…**

•You are studying healthy participants

•*Your study does not have a comparison group (e.g., placebo or control)*

•Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug

•Your study is utilizing a behavioral intervention

Not Clinical Trial:

1) Studies intended solely to refine measures are not considered clinical trials.

2) Studies that involve secondary research with biological specimens or health information are not clinical trials.

Note for ancillary studies:
When answering the prior questions, take into account only the work being proposed in the ancillary study, not the work being done in the parent project.

**Phases of clinical trials: when clinical research is used to evaluate medications and devices:**

**•Phase I trials**
Researchers test an experimental drug or treatment in a small group of people for the first time. The researchers evaluate the treatment's safety, determine a safe dosage range, and identify side effects.

**•Phase II trials**
The experimental drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.

**•Phase III trials**
The experimental study drug or treatment is given to large groups of people. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

**•Phase IV trials**
Post-marketing studies, which are conducted after a treatment is approved for use by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use.

## CLINICAL RESEARCH CONSIDERATIONS

Typically, an Investigator is contacted by an external Sponsor and is solicited to participate in a clinical research study. Very little is revealed to the investigator about the study protocol at this stage, until a Confidentiality Disclosure Agreement (CDA) is executed. A fully executed (signed by all parties) CDA enables an investigator to access to the sponsor's final protocol. Executing a CDA is very typical for Industry-Sponsored clinical research trials. All CDAs **MUST** be negotiated and signed by the institution on behalf of the Investigator. Investigators are not permitted to negotiate or sign CDAs individually. Investigators who receive a CDA should contact their divisional research administrator for guidance.

**Feasibility:**

Once a CDA has been fully executed, a sponsor will release the protocol to investigator. At this stage, potential investigators are expected to scrutinize the protocol and determine his/her interest, and capacity to conduct the activities expected of him/her as dictated by the protocol. This is called the *Feasibility* stage.
Some key questions for Investigators to consider during the Feasibility stage are listed here:

- *Am I interested in the science being conducted via this protocol?*
- *Do I have access to the appropriate patient population for this study?*
- *Can dedicate the necessary time out of my professional and/or academic schedule to conduct these research activities?*
- *(Do I have access to the necessary additional personnel to execute these activities? (study nurse, CRA, technologists, Co-Investigators, etc.)*
- *Which ancillary departments do I need to partner with?*

**Feasibility Questionnaire:**

Once an investigator has determined that he/she would like to participate in the study, he/she may be expected to complete a *Feasibility Questionnaire*. Industry-sponsors may send this questionnaire to investigators in tandem with the final protocol, or the protocol may be sent shortly afterwards. At this point, an investigator will answer several questions pertaining to his or her ability to conduct the study at this site/institution. The sponsor, who may be selecting from various institutions for partnership on the study, utilizes the responses to this questionnaire, among other factors, to help determine which institutions or sites will be participating in this study. Investigators are expected to be realistic in their answers on these questionnaires. It is recommended that investigators use the above referenced questions as a guide to complete the questionnaire.

**Clinical Looking Glass (CLG):**
Investigators are encouraged to utilize the Clinical Looking Glass to help determine whether he/she has the adequate patient population as required by the protocol.
(See page 3 for additional information)

**Study Budgeting**:
Clinical research studies should include a budget that meets the financial needs of executing the protocol activities. Clinical research budgets are often negotiable. Research budgets are usually drafted by the study sponsor. Your research administrator will assist you and the ancillary department processing your agreement to ensure all needs are meet. You will be consulted to ensure that appropriate fees are considered during this process.

## NEW PROCEDURES:

- IRB will not provide approval until the contract is signed, if applicable
- The Research Billing Committee needs to review all budgets and billing grids prior to contract execution.
    - Investigators need to ensure the determinations are made prior to budget and contract submission.
    - The Investigator has the option of providing the determination with justification or submitting it to BRANY for a full Medicare Coverage Analysis. BRANY charges $1,575.00 for the analysis.
- Protocol needs to be initiated in iRIS up until question 8 to ensure the file if generated in VELOS
- Contract needs to be marked and added in VELOS to initiate contract execution
- Please refer to the VELOS handout for more information regarding SOP for clinical research studies

**Acuvia eRegulatory Binder:**
•Mandatory for all Industry Sponsored Trials
•Ensure your coordinators are trained and utilizing them!
Work with the Acuvia Administrator to identify and address compliance issues
Acuvia Administrator: Lissy Wassaff (lwassaff@montefiore.org)

**Greenphire Clincard Training:** (Contact your administrator for more details)
•Institutional system for research subject reimbursement
•Ensure that Study Teams complete eLearning module
•Amounts dispensed to participants must reflect the Informed Consent Form

Department of Pediatrics

Pediatric Proposal Review Committee

**Purpose**:

The Pediatric Proposal Review Committee (PRC) seeks to enhance the quality of research involving human subjects in the Department of Pediatrics. It is charged with review and approval of all proposals that require Institutional Review Board (IRB) review in which the Principal Investigator (PI) is in the Department of Pediatrics. Proposals subject to review include quality improvement projects, clinical trials, funded and unfunded research, retrospective chart reviews, and all proposals subject to exempt, expedited or full IRB review. The PRC reviews each proposal to assure that the quality of the proposal, including clarity, plan for analysis, data management, and protection of the research subjects is adequate for submission to the peer review process of an IRB.

**Process**:

It is expected that before submission to the Committee, proposals will have been reviewed by a senior member of the PI's Division. Questions about this process may be addressed to the Chair, Admin Asst, or to any member of the Committee.

1-The PRC meets monthly (see attached meeting dates for 2018). The deadline for submission of a proposal for committee review is the Friday prior to the meeting date.

2-Previously funded studies, multi-center trials including those that will be reviewed by the BRANY IRB, and proposals already reviewed and approved by another IRB will be expedited by the PRC Chair.

3-Simple and straight forward proposals that reach the Committee between meeting dates, in some circumstances, will be reviewed through an expedited process to facilitate review and approval prior to the date of the next Committee meeting.

4-Proposals may reach the Committee in two ways:

a) Submission of a proposal to the Einstein/Montefiore IRB through the Einstein Integrated Research Information System (IRIS) will automatically refer the proposal for the signature of the Chair of the Department of Pediatrics or her Designee if the Department of Pediatrics is designated as the primary department of the PI. The Chair of the PRC (Alan Fleischman, MD) is the Departmental Designee expected to sign off on proposals. His name should be designated as a signatory in the IRIS section on Signature Instructions. This approval must occur before the formal IRB review process can begin.

b) Submission of a proposal directly via email to the Chair of the PRC or the Administrative Assistant to the Committee (May Thompson) will result in review of the proposal by the PRC, whether or not it has been submitted to the IRIS system.

5-The PRC will review each proposal and inform the investigators, the Department Chair, and the Division Director whether the proposal is:

a) Approved;

b) Approved with suggestions for enhancement; or

c) Not Approved and required to be resubmitted to the Committee after revisions.

If the proposal is approved, or approved with suggestions, the investigator may proceed with the IRB review process and the Chair of the PRC will approve the proposal when it is submitted through the IRIS system. If the proposal is not approved, it is expected if the investigator wishes to proceed with the proposal that he/she will revise the proposal and submit a revised proposal to the committee along with a memo describing how the investigator has dealt with each of the Committee's suggestions for enhancement.

Department of Pediatrics

Pediatric Proposal Review Committee

**Committee Members**


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| Alan Fleischman, MD, Chair | afleisch@montefiore.org | 917 439-6364 |
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Peter Belamarich, MD
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Ellen Silver, PhD
Gitit Tomer, MD


| **Meeting Dates—2018** | **Submission Deadline** |
|---|---|
| August 10 | August 3 |
| September 14 | September 7 |
| October 19 | October 12 |
| November 16 | November 9 |
| December 14 | December 7 |