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| --- |
| **RELIANCE AGREEMENT REQUEST FORM**  **Non-MetroHealth IRB to serve as IRB of Record**  **(Version: 02-12-2024)** |
| **INSTRUCTIONS AND INFORMATION for INITIAL SUBMISSION**   * This form should be completed to implement an agreement for METROHEALTH to rely on a Non-METROHEALTH IRB to serve as the IRB of Record (Reviewing IRB) for a single study or a group of studies. * The following documents are to be submitted to the METROHEALTH IRB **via eIRB:**   **[Note: Please use** **the eIRB Reliance Request submission checklist-Appendix C]**   * Reliance Agreement Request Form: Non-METROHEALTH IRB to serve as IRB of Record/Reviewing IRB * Requirements for any ancillary approvals (e.g., Scientific Review Committee, PRMC, Radiation Safety, Risk Assessment). * Current version of the approved protocol document * Original approval notice from the Reviewing IRB * If applicable, most recent continuation approval notice from the Reviewing IRB * If applicable, FDA correspondence for IND/IDE determination * If applicable, Waiver of MetroHealth Pharmacy Investigational Drug Services (MPIDS): only required when the MetroHealth Research Pharmacy will NOT be used. * If applicable, Metro Site Specific consent (see Appendix A or B) * ***Appendix A: MetroHealth IRB Consent/Assent Local Wording Template*** * ***Appendix B: NCI CIRB Boilerplate Template*** |

**SUBMISSION VERSION DATE**:

|  |  |
| --- | --- |
| **METROHEALTH IRB Contact Information** | |
| **Institution Name/FWA#/IRB Registration#** | MetroHealth System /00003938/ IORG0004136 |
| **METROHEALTH IRB Contact Information** | Joanne Fraifogl [jfraifogl@metrohealth.org](mailto:jfraifogl@metrohealth.org) / (216) 778-8559  Eileen Sembrowich [esembrowich@metrohealth.org](mailto:esembrowich@metrohealth.org) /216-778-7237 |
| **Institutional Official** | Richard J. Blinkhorn Jr., MD/216-778-8305 |
| **METROHEALTH Study Contact Information** | |
| METROHEALTH Principal Investigator | Name: |
| Is the METROHEALTH study team [engaged](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html#:~:text=In%20general%2C%20an%20institution%20is,2)%20identifiable%20private%20information%20about) in non-exempt human subject research? | YES: If yes, indicate:  Expedited  Full Board  **Note**: METROHEALTH will not rely on a Non-METROHEALTH IRB for exempt research. |
| **Reviewing IRB Contact Information** | |
| **Reviewing IRB Name/FWA#** | **Name:**       **FWA#**: |
| **IRB Contact Name/Email** | Name:       Email: |
| Is the Reviewing IRB a member of SMART IRB and will the SMART IRB Reliance Agreement and SOP’s be used?  See SMART Participating Institutions [HERE](https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&cad=rja&uact=8&ved=2ahUKEwiImPit6tvdAhVHqlkKHV48CkEQjBAwAXoECAYQCQ&url=https%3A%2F%2Fsmartirb.org%2Fparticipating-institutions%2F&usg=AOvVaw00In5OPEiqw2B3hTR3jbph) | YES  NO--METROHEALTH IRB will need to initiate a NEW Reliance Agreement |
| Is the Reviewing IRB using [IRB Exchange](https://www.irbexchange.org/p/) (IRex) as the platform to collect regulatory documents? Please verify with the Reviewing IRB if you are not sure. | NO  YES **If yes**, include with your submission, the protocol specific “STUDY INFORMATION” document from IRB Exchange (*IREx)* at the time of your submission. If unsure, contact the Reviewing IRB. |
| **Study Specific Information** | |
| **MetroHealth STUDYID#**  Study Title: |  |
| Sponsor Name or Overall PI |  |
| Will subjects be enrolled at METROHEALTH? | YES If yes, **N=**  NO |
| Indicate the roles & responsibilities of METROHEALTH researchers. | **S*elect all that apply)*:**  Recruitment  Obtain consent  Data collection  Implement/administer research interventions  Identifiable data/sample analysis  De-identified data/sample analysis  Anonymous data/sample analysis  Other – specify: |
| Will the Reviewing IRB serve as the HIPAA Privacy Board or act upon requests for a waiver or an alteration of the HIPAA Authorization requirement under the Privacy Rule for uses and disclosures of PHI for this study? | YES  NO  **If yes, this means:**   1. The Reviewing IRB’s HIPAA Privacy Board will grant all HIPAA waivers/partial HIPAA Waivers.   *Note: MetroHealth requires approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects (e.g., this institution does NOT consider this "Preparatory to Research" activities)?*   1. The Reviewing IRB will use their own institutional HIPAA Privacy language in the IRB approved consent form.   **If no, this means:**   1. MetroHealth IRB will grant all HIPAA Waivers 2. The Reviewing IRB agrees to use MetroHealth’s IRB HIPAA Authorization language in the consent. |
| Is the study federally funded **or** regulated by FDA? | YES  NO (**Note: If YES, do not answer remaining questions in this box**)  ***If NO,*** *does the Reviewing IRB apply the federal regulations to all research regardless of funding source (have unchecked the FWA box)*  **Yes  No**  ***If YES,*** *will the Reviewing IRB report UPs, serious or continuing non-compliance to federal agencies, regardless of funding source?*  **Yes  No**  *If No****,*** METROHEALTH will report UP’s et al to Federal agencies)  Note: METROHEALTH study team will need to verify responses with the  Reviewing IRB. |
| Do you confirm that the METROHEALTH study team will take responsibility for ensuring that all local consent language, provided by the METROHEALTH, is included in all versions of the consent/assent documents? | YES |
| Do you confirm that the METROHEALTH site has adequate resources (including space, equipment, funding, and personnel) for conducting the study? | YES |
| Does this study use or involve the research of a drug, biologic, supplement, food additive or chemical NOT APPROVED by the FDA for the indication, dose, and route used in this protocol? | No  YES: **If yes,**  **Drug Name:**  **IND#**  **Holder of IND:** |
| Does this study use a medical device that is NOT APPROVED/CLEARED for MARKETING by the FDA for the indication used in this protocol?  Note: If you are evaluating the safety and/or effectiveness of a medical device, must be answered yes | No  YES: **If yes,**  **Device Name:**  **IDE#**  **Holder of IDE:** |
| Does this study involve gene therapy? | No  YES, **if yes explain**: |
| Do you plan to deviate from the Sponsor’s protocol in any way? (e.g., not doing certain substudies at MetroHealth) | No  YES, **if yes explain**: |
| Is there a Certificate of Confidentiality (CoC) for this study?   * *If the study is federally funded answer this question YES.* | No  YES |
| **Data Management and Confidentiality** | |
| Describe the steps that will be taken to secure the data during storage, use or transmission *(e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality [if study federally funded, C of C should be noted], and separation of identifiers and data)* |  |
| Where and how will data and/or specimens be stored? |  |
| How long will the data and/or specimens be stored? | Note: *Data* must be kept for a minimum retention period of 4 years following study completion as this is the minimum retention period per MetroHealth policy, 6 years for studies accessing protected health information [PHI] but not obtaining written HIPAA Authorization as required per HIPAA, and 22 years for studies enrolling pregnant women and children per MetroHealth policy. |

**CONSENTING PROCESS**  **N/A-no subjects enrolled at MetroHealth**

1. **From whom will consent/assent be obtained-choose all that apply?**

Adults

Parents of Minors

Minors

Adults who Lack Capacity to Provide Informed Consent

Legally Authorized Representative

Pregnant Women

Non-English Speakers (MUST include either fully translated consent or short forms with submission)

1. **Who will be introducing the consent, conduct the discussion and obtain consent/assent from the potential subject(s)?**

|  |
| --- |
| The principal investigator is ultimately responsible for the conduct of the study and must ensure that informed consent from each potential research subject is:  1. Obtained by an IRB approved consent designee, and  2. Documented using the **method approved by the IRB of Record.**  Informed consent must be obtained before the subject takes part in any aspect of the research study unless the IRB has approved a waiver of the requirement to obtain consent. |

*Check all applicable options:*

Principal Investigator

Qualified member(s) of the study team

1. **When will potential subjects be asked to provide consent/assent?**

|  |
| --- |
| **IMPORTANT:** Consent should NOT be solicited immediately before beginning an elective procedure or scheduled therapy because the subject will not have time to consider whether to participate or not. When using DocuSign for electronic consent the subject must has access to their own computer, tablet, or smart phone.  For security reasons, subjects should not use public or shared devices for signing e-informed consents. |

**►**IF consent must be obtained the same day that study procedures commence, explain why the subject cannot be given more time to decide to consent and what will be done to ensure the potential subject has enough time to make an informed decision.  N/A

1. **Where will informed consent/assent be obtained?**

*Check all applicable options:*

**IN PERSON WRITTEN** Informed Consent (**on-site** wet ink signature)

**IN PERSON ELECTRONIC** Informed Consent using an electronic device such as a tablet or a computer when subjects are **on-site** with study personnel present.

**(If checked, must complete 1-vi below)**

**REMOTE ELECTRONIC** Informed Consent where **subject is not in the same location as the investigator**.

**If either In Person E-Consent and/or Remote E-consent are checked, complete below:**

* + - **What ELECTRONIC platform will be used and how will the signature be proven legitimate?**

* + - **How will the subject be provided with a copy of the signed consent document to satisfy** [**HIPAA regulatory requirements**](https://www.hipaajournal.com/can-e-signatures-be-used-under-hipaa-rules-2345/#:~:text=%E2%80%9CNo%20standards%20exist%20under%20HIPAA,applicable%20State%20or%20other%20law.%E2%80%9D)**?**

*For example, can participants download a PDF of the signed consent? Will the study team download the PDF, print it, and send a paper copy to each participant? Will the study team send an emailed version to each subject?*

* + - **How will assent and parental permissions be obtained for minors when using e-Consent? What if two-parent signatures are needed. How will this be managed by the MetroHealth study team?**

N/A-no minors are enrolled.

* + - **How will the translation be addressed for non-English speaking subjects when using e-Consent? How will e-Consent be witnessed in this scenario?**

N/A-English speaking subjects only

* + - **What if a subject does not have the right technology or ability to use e-Consent. How will the MetroHealth study team manage this scenario?**

**IMPORTANT INFORMATION FOR IN PERSON e-CONSENTING or REMOTE e-CONSENTING:**

The study team must AGREE to comply with the following requirements:  **YES**

* Provide subjects with a way to access a copy of the consent document.
* Confirm the subject or LAR identity using 2 forms of identification.
* Include instructions on how to print the consent form or provide a mechanism to email a copy of the signed consent form to the subject.
* Document e-Consent using a verifiable electronic signature AND use an application that meets the required MetroHealth Data Security standards. (DocuSign, RedCap, Qualtrics).
* Document the subject’s agreement to provide electronic consent AND consent to participate in the study: (TWO separate consent fields).

1. **If recruiting minors or adults with impaired decision-making capacity, specify how parental guardian/LAR consent will be obtained prior to approaching the minor or the decisionally-impaired adult subject.**

N/A-no minors are enrolled

N/A -no adults with impaired decision-making capacity enrolled

1. **What protections are in place to protect the rights and welfare of subjects so that any possible coercion or undue influence is eliminated?**

*Check all applicable options:*

Consent will be obtained by the research coordinator rather than the Investigator.

Employees will be reassured that their decision will not affect their job or benefits.

Students will be reassured that their decision will not affect their status as a student or their grades.

If minors are enrolled, parental permission will be obtained prior to explaining the study to a minor and the minor’s assent will be obtained prior to initiation of study procedures.

All subjects, especially those who are educationally disadvantaged will be asked open ended questions to confirm that they understand the study.

Other Explain:

**AND CONFIRM the following:**

1. Subjects will be assured that their relationship with their MetroHealth care provider(s) will not be affected if they decide not to participate  **YES**
2. Subjects will be given all the time needed to make their decision and will not be pressured for a quick decision.  **YES**
3. Subjects will be encouraged to seek advice from friends and family before signing consent.

**YES**

1. **How will the person obtaining consent/assent assess subject understanding and how will questions be answered?**

1. **Are there any cultural considerations (e.g., tribal or group permission requirements) or technological limitations that must be considered?**

Investigator Responsibilities for Studies Overseen by a NON METROHEALTH IRB

* No member of the study team is currently debarred by the US FDA from involvement in clinical research studies.
* No member of the study team is involved in any regulatory or misconduct litigation or investigation by the FDA.
* The proposed research project will be conducted by me or under my close supervision. It will be conducted in accordance with the protocol submitted to and approved by the Reviewing IRB including any modifications, amendments or addendums submitted and approved by the Reviewing IRB.
* No personnel will have access to subjects or their information until they have completed the human subject research protection on-line training through CITI/CREC/GCP if applicable, and the Reviewing IRB has been notified.
* All personnel working on this protocol will follow all Policies and Procedures of:
* the IRB of Record
* the METROHEALTH Human Research Protection Program (HRPP SOPS)
* Provide the Reviewing IRB with:
  1. The list of research personnel engaged in the conduct of research.
  2. Evidence of training for all engaged research personnel, including the investigator; and
  3. Any other information required for IRB review.
* Assure that all research activities at METROHEALTH are not initiated until all IRB and funding-related requirements are complete.
* Assure that any additional METROHEALTH requirements for ancillary human research protection reviews (pharmacy, radiation safety, Scientific Review Committee, Risk assessment, PRMC etc.) are obtained and followed.
* Conduct protocols and obtain informed consent as approved by the IRB and in compliance with IRB of Record’s policies and procedures and all relevant federal, state, and local regulations for human subjects’ research.
* Report to the Reviewing IRB, all post-approval events such as proposed modifications and protocol violations.
* Provide any information requested by the Reviewing IRB that may be necessary for the continuing review process. This may include information regarding subject recruitment, summary of all enrolled subjects, screen failures, violations, and all other information needed for continuing review.
* Notify the Reviewing IRB within five days of becoming aware of potential unanticipated problems involving risk to subjects or others or of serious or continuing non-compliance.
* If at any time IRB approval lapses, cease all human subjects research work related to the expired protocol. Notify the Reviewing IRB of any subjects who are already enrolled who may be harmed if research ceases.
* Promptly cooperate with any investigations of serious or continuing non-compliance or unanticipated problems.
* Promptly cooperate with any post approval monitoring conducted by METROHEALTH. Such cooperation will include, but is not limited to, providing research records and related information and meeting with institutional research representatives upon request.
* Signed consent forms and other research records will be retained in a confidential manner.
* Cooperate with the Reviewing IRB in reporting and resolving any conflicts of interest reported by METROHEALTH investigators, including but not limited to entering into management plans, as required by the Reviewing IRB.
* If written consent is being obtained insert the approved METROHEALTH local consent language into all consent forms used to enroll METROHEALTH subjects.

**APPENDIX A:**

**MetroHealth Consent/Assent Local Context Wording Template**

**Version: 02-12-24**

**(For all Single IRBs except NCI CIRB)**

Note: MetroHealth local context wording noted below, must be applied to the model consent/assent provided by the IRB of Record and submitted to the MetroHealth IRB for administrative review.

1. **In footer or header include: (**METROHEALTH Study ID#**)**

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# **Local Study Team Contact(s) for Questions About the Study**

**Whom do I call if I have questions or problems?**

If you have questions about any part of the study now or in the future, or if you wish to communicate concerns or a complaint, you should contact [Principal Investigator name], who may be reached at (216) 778 XXXX. If you experience any side effects or injuries while participating in this study, please contact [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_], who may be reached at (216) 778 XXXX. For after hours, weekends and/or holidays, call [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_], at (216) 778-XXXX. Any written communications with the study team may be sent to [address].

If you have any questions about your rights as a research participant, or if you wish to express any concerns or complaints, please contact The MetroHealth System’s Institutional Review Board—a group of people who review the research to protect your rights—at (216) 778 2021.

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1. *If METROHEALTH Subjects will be compensated:*

# **Compensation for Participation**

[To be included any time subjects are being paid:] The Accounting Department at MetroHealth will be given your name, address, and Social Security number to process payment for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

[If applicable] The research done with your sample(s) may lead to the development of new products in the future. You will never receive any compensation, royalty, or other financial benefits resulting from any product, procedure, or other items developed from studying your sample(s). Storage and future testing of your sample(s) will involve no cost to you. Your sample(s) will be used only for research and will not be sold.

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1. **Compensation in Case of Injury/Availability of Treatment for Injury**

It is important that you tell your study doctor, [investigator's name(s)], if you think that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at [telephone number].

|  |
| --- |
| **CHOOSE ONE OF THE OPTIONS BELOW**   * **If this study is being conducted with a COMMERCIAL SPONSOR, you must choose OPTION#1.** The option you choose may not conflict with the language in the contract. * Any changes made to an option below or any additional language added by the sponsor may require review by the METROHEALTH General Counsel’s office and the IRB. Please track any changes to this section made by the sponsor. |

Option # 1**: Commercial sponsor pays for injuries regardless of insurance type**.

The study sponsor has agreed to pay for the costs to treat injuries that are related to your participation in the Study as long as you meet certain conditions. The study sponsor will pay for your treatment only if the need for treatment was caused by the study drug, device, or procedure. The study sponsor and the study doctor are responsible for determining whether your injury was caused by your participation in the study. The injury also cannot be the result of: (i) a medical condition that you had before you started the study; (ii) the natural progression of your disease or condition; or (iii) your failure to follow the study plan or the study personnel’s instructions.

If the study doctor determines that your injury is a result of your participation in this study, your insurance company will not be billed. You or your health plan must pay for any treatment that is part of your usual medical care or that is related to a medical condition you had before participating in the study.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and, if you have health insurance coverage through Medicare, your Medicare Beneficiary Identifier (MBI). If you receive Medicare benefits and the sponsor pays for any study-related injuries, the sponsor may also be required by law to report these payments to Medicare.

MetroHealth has not committed to pay you or to pay for your treatment if you suffer an injury because of being in the study. There are no plans for MetroHealth to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research-related injuries. However, you are not waiving any legal rights by signing this form, including the right to seek compensation for an injury.

Option # 2- **There is no sponsor, or the sponsor is a government agency such as the NIH or there is a commercial sponsor who has not agreed to pay for injuries.**

If you are injured as a result of being in this study, the costs for medical treatment may be billed to you or your health insurance plan. Health insurance plans may or may not cover costs for treatment of research-related injuries. If you have insurance, you should check with your health insurance plan before deciding to participate in this research study. If your health insurance plan covers some or all of the treatment costs, you may still be responsible for any co-pays or deductibles required by your plan.

MetroHealth has not committed to pay you or to pay for your treatment if you suffer an injury as a result of being in the study. There are no plans for MetroHealth to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research-related injuries. However, you are not waiving any legal rights by signing this form, including the right to seek compensation for an injury.

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1. **Genome Wide Association**

[For NIH Studies] Your data may also be put in government or other databases/repositories if required by law.

[For genetics studies, if samples will be submitted to the National GWAS Repository for Genome Wide Association Studies, or to any of the NIH-designated genomics data repositories]

Data from the study may be sent to a national database of information. The information and specimens that scientists are going to collect include your DNA and information on your medical history. Before your information is sent to a central database, your name and other identifiers will be removed and replaced with a study code. Although we will try to keep your identity and sample confidential, there is a risk that someone will be able to identify you from the information in the database. The sample will be sent to a repository at the NIH (National Institutes of Health). The NIH repository stores and distributes blood samples and associated data from people with many conditions. The purpose of sending your blood samples to the repository is to make samples available for future research by investigators not involved in this study. Researchers who use samples from the NIH repository must request and receive approval to do so from scientific reviewers at the NIH and from research oversight boards at their institutions.

You can withdraw your sample at any time by writing to [insert name of PI]. If you withdraw from the database, the NIH will no longer release your information to new investigators. However, if your information has already been released to an investigator, it cannot be returned.

1. **If your study is required to** [**register at ClinicalTrials.gov**](https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/informed-consent-posting-guidance/index.html)

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

1. **Risks of Genetic Research**

*If study involves genetic research and similar language is not already in the consent, the METROHEALTH site is permitted to enter additional info regarding genetic risks as noted below in the* ***consent form****:*

A Federal law, called the Genetic Information Non-discrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

* Health insurance companies and group health plans may not request your genetic information that we get from this research.
* Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
* Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Ohio also has state laws that prohibit employers and health insurers from discriminating on the basis of genetic test results and other genetic information.  Like GINA, these state laws would not protect you from genetic discrimination by other types of insurance providers, such as life insurance or long-term disability insurance.

**APPENDIX B:**

**MetroHealth Consent/Assent Local Context Wording Template for NCI CIRB studies**

**Version: 02-12-24**

Note: MetroHealth local context wording noted below, must be applied to the model consent/assent provided by the NCI CIRB and submitted to the MetroHealth IRB for administrative review.

1. *If METROHEALTH Subjects will be compensated:*

# **Compensation for Participation**

[To be included any time subjects are being paid:] The Accounting Department at MetroHealth will be given your name, address, and Social Security number to process payment for your study participation. Study payments are considered taxable income and reportable to the IRS. Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

[If applicable] The research done with your sample(s) may lead to the development of new products in the future. You will never receive any compensation, royalty, or other financial benefits resulting from any product, procedure, or other items developed from studying your sample(s). Storage and future testing of your sample(s) will involve no cost to you. Your sample(s) will be used only for research and will not be sold.

# **Local Study Team Contact(s) for Questions About the Study**

**Whom do I call if I have questions or problems?**

If you have questions about any part of the study now or in the future, or if you wish to communicate concerns or a complaint, you should contact [Principal Investigator name], who may be reached at (216) 778 XXXX. If you experience any side effects or injuries while participating in this study, please contact [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_], who may be reached at (216) 778 XXXX. For after hours, weekends and/or holidays, call [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_], at (216) 778-XXXX. Any written communications with the study team may be sent to [address].

If you have any questions about your rights as a research participant, or if you wish to express any concerns or complaints, please contact The MetroHealth System’s Institutional Review Board—a group of people who review the research to protect your rights—at (216) 778 2021.

**APPENDIX C:**

**eIRB Reliance Request Submission Checklist**

**Version: 02-12-24**

**Effective 2-12-24**, the Reliance Consultation Request form and MetroHealth site specific protocol have been discontinued.

|  |
| --- |
| **NEW:** **Reliance Agreement Request form: Non-Metro IRB to serve as the IRB of Record**  *This form should be completed and uploaded into the eIRB system along with the required documents for METROHEALTH to rely on a Non-METROHEALTH IRB.* |

**NOTE: The MetroHealth study team is only required to complete those sections noted with an \*** **in eIRB.**

**BASIC STUDY INFORMATION:**

Question 1: Title of Study

Full title of study listed.

Question 2: Short Title

Short title contains the words “SHELL STUDY” before the title.

Question 3: Brief Description

Brief description

Question 4: What kind of study is this?

Multi-Site selected.

Question 5: Will an external IRB act as the IRB of record for this study?

“yes” selected.

Question 7: Local Principal Investigator

MH Principal Investigator’s name

Question 8: **Attach the approved PROTOCOL provided by the IRB of Record**

**BASIC LOCAL SITE INFORMATION:**

Only one of the following will apply:

Enter 'ALL' if MetroHealth will perform all study related procedures.

If not performing all study related procedures, describe what procedures will be performed at MetroHealth

**EXTERNAL IRB:**

Question 1: External IRB

Add name of External IRB

If the IRB of record is not populating, then please contact IRB staff to create an institutional profile for the IRB of record. Note: If the study is federally funded, then for question 3, enter “This study is federally funded. Single IRB is mandatory.”

**STUDY FUNDING SOURCES:**

Fill in as applicable to your study.

**LOCAL STUDY TEAM MEMBERS:**

Question 1: Identify each additional person involved in the design, conduct, or reporting of the research:

Add all study staff.

Make sure [RIC and CREC](https://irb.metrohealth.org/eIRB/sd/Doc/0/DENQ32Q5N08USU4H0K1A4LIG00/Getting%20Started%20with%20the%20MetroHealth%20IRB_8.22.2023.pdf) are up to date. Note: RICs will not populate until after the PI submits the study

Question 3: What department review is required?

Fill in as applicable to your study.

**STUDY SCOPE:**

Fill in as applicable to your study.

**LOCAL RESEARCH LOCATIONS (the sites where the MetroHealth PI will oversee the research):**

Fill in as applicable to your study. This answer will typically be “The MetroHealth System”.

**DRUGS OR DEVICE**

Questions 1 and 2

Fill in as applicable to your study.

**LOCAL SITE DOCUMENTS:**

**Question 1: Consent forms**

MH Specific consent/assent form(s) [approved model consent from the IRB of Record] **tracked** with the MH local context information (See Appendix A or B. The ICF will need to be reviewed by the IRB PRIOR to sending to the sponsor for approval to ensure required language is present.

**Question 3: Other attachments**

Documentation of Approval for MetroHealth as a relying site--generally in the form of a modification approval from the reviewing IRB.

NOTE: This approval notice generally is not sent to the relying sites initially until the RELYING IRB has provided documentation of agreement to cede review to the Reviewing IRB. Continue with your submission to the MetroHealth IRB with this as a pending requirement.

Reliance Agreement Request Form: Non-METROHEALTH IRB to serve as IRB of Record/Reviewing IRB

Requirements for any ancillary approvals (e.g., Scientific Review Committee, PRMC, Radiation Safety, Risk Assessment).

Original approval notice from the Reviewing IRB

If applicable, most recent continuation approval notice from the Reviewing IRB

If applicable, FDA correspondence for IND/IDE determination

If applicable, Waiver of MetroHealth Pharmacy Investigational Drug Services (MPIDS): only required when the MetroHealth Research Pharmacy will NOT be used.

**Questions:**

Joanne Fraifogl

IRB Specialist for Reliance Reviews

**E:** [**jfraifogl@metrohealth.org**](mailto:jfraifogl@metrohealth.org)

**P: 216-778-8559**

or

Eileen Sembrowich CCRP, CIP

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Manager, Institutional Review Board

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