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| **RELIANCE AGREEMENT REQUEST FORM**  **MetroHealth IRB to serve as IRB of Record/Single IRB**  **(V. 07-01-24)** |
| **INSTRUCTIONS AND INFORMATION for INITIAL SUBMISSION:**  Relying Sites should only complete this request form **AFTER** the MetroHealth IRB has approved the study locally.  One form is to be completed for **EACH** institution that agrees to rely on the MetroHealth IRB.  **Submit the following documents to the Relying site for completion:**   1. Reliance Agreement Request Form MetroHealth IRB to serve as IRB of Record/Single IRB (***complete Metro study information 1st)-*includes** Relying Site Local Context Template **(Appendix A) -**used to add local context to the MetroHealth IRB approved consent/assent documents (TRACK CHANGES MUST BE TURNED ON) 2. Current approved IRB protocol, consent(s)/assent(s) (if applicable)   **Submit the following documents to the METROHEALTH IRB to add a relying site via eIRB:**   1. Completed Reliance Agreement Request Form METROHEALTH IRB to serve as IRB of Record/Single IRB 2. Tracked copy of the consent/assent which includes the relying site LOCAL CONTEXT information included. 3. If applicable, copy of the relying site’s Stand-Alone HIPAA authorization if Relying site chooses to serve as their own HIPAA Privacy Board/grant applicable waivers. |

**SUBMISSION VERSION DATE**:

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| **Study Information** | |
| **MetroHealth STUDY #:** |  |
| **MetroHealth Principal Investigator:** |  |
| **Complete Full Protocol Title:** |  |

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| **METROHEALTH IRB Contact Information** | | |
| **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/Telephone** | John Chae, MD / [jchae@metrohealth.org](mailto:jchae@metrohealth.org)/216-778-7086 |

*\*\*\*\*\*RELYING SITE START HERE\*\*\*\**

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| **Relying Institution Information**  A representative from the Relying Institution should complete the remaining sections of this document for EACH new protocol. | |
| **Relying Institution Name** |  |
| **Relying Institution FWA#** |  |

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| **Institutional Official Name** |  |
| **Institutional Official Phone #/Email** |  |

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| **Name, credentials, training, and contact information of the person responsible for the research conducted at this relying site.**  **Include copy of PI CV** | Local PI Name       Credentials (e.g., MD, PhD)  Training (e.g., NIH, CITI)  Contact Info (e-mail/phone) |
| Do you confirm the relying site is a member of [SMART IRB](https://smartirb.org/participating-institutions/) and will conform to their [SOP’s](https://www.google.com/url?client=internal-element-cse&cx=000741335895712361513:s7gfmll2gx8&q=https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf&sa=U&ved=2ahUKEwj0uNak3KzqAhVSmXIEHTA7DgcQFjAAegQIAxAB&usg=AOvVaw2yOrQ4DhmcG_iEuaJL2bBU)? | YES  NO  **If NO**, the METROHEALTH IRB will provide a Reliance Agreement prepared for signatures AFTER completion and review of this request form. |
| The relying institution verifies that all personnel engaged in this research have completed the organization’s required human subject protection training, including Good Clinical Practice training, if applicable. | YES |
| Does the relying institution apply its FWA to all research? | YES  NO  If no, describe what research is not covered by their FWA:  **Note:** Oversight provided by the METROHEALTH IRB serving as the sIRB must satisfy the terms of the relying institution’s FWA. One of the eligibility criteria for participation in SMART IRB is that the institution requires IRB review and institutional oversight for their human subject’s research regardless of funding source. |
| Will the Relying Institution enroll subjects? | YES  NO IF yes, N= |
| Indicate the roles & responsibilities of the Relying Institution’s researchers. | **S*elect all that apply)*:**  Recruitment  Obtain consent  Data collection  Implement/administer research interventions  Identifiable data/sample analysis  Other – specify: |
| Populations requiring additional protections enrolled at Relying Site | **N/A**  ***(Select all that apply):***  Children  Neonates  Pregnant women  Prisoners  Adults with impaired decision-making capacity  Employees  Students  Active military personnel  Other – specify: |
| Do you confirm that METROHEALTH IRB will 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 ***If YES, this means:***   1. METROHEALTH will grant all HIPAA Waivers 2. The Relying Institution agrees to use METROHEALTH’s HIPAA Authorization language in the consent. 3. Does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects (e.g., the institution does NOT consider this "Preparatory to Research" activities)?   Yes  No  NO **If NO, this means:**   1. The Relying Institution HIPAA Privacy Board will grant all HIPAA waivers/partial HIPAA Waivers. 2. The Relying Institution will use their own institutional HIPAA Privacy Authorization Form. Your institutions language will not be included in the IRB approved consent form. |
| Describe how the relying site study team will protect the privacy of participants: | **Describe:** |
| Describe the local recruitment procedures at the relying site. | Not applicable to this study or site  **Describe:** |
| Describe any differences in research procedures (from the METROHEALTH IRB approved protocol) that will be done at the relying site: | Not applicable to this study or site  **Describe:** |
| Describe how study data and/or specimens will be stored and protected from unauthorized access at the relying site. | **Describe:** |
| Do you confirm that the relying site has the adequate resources (including space, equipment, and personnel) for conducting the study? | YES |
| Are there any other names by which the relying site is known, or does business and any corporate affiliations it has with other organizations, such as a university or hospital network? | YES  NO  If yes describe: |
| If any of the sites identified above are within a network or system, do they have a separate FWA? | YES  NO  N/A  If yes, identify the sites with the separate FWAs: |
| Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subject’s research proposed at the site? | YES  NO  If yes, “yes”, please explain the outcome of any investigations, audits or findings that may be relevant. |
| Does the relying institution have a post- approval monitoring program, quality assurance/audit group or other regulatory oversight for ongoing research? If yes, provide contact information for person in charge of Post-Monitoring Program.  Name  Email  Phone | YES  NO  If yes, does the post-approval monitoring program or other regulatory oversight monitor studies that have been deferred, to an external IRB?  Provide a link (URL) to the post approval monitoring program/regulatory oversight information or paste information here. | |
| Does the organization have other oversight mechanisms?  YES  NO  If yes, provide contact information for person in charge of quality assurance/audit or other oversight mechanism | If YES, please describe mechanisms:  Name  Email  Phone | |

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| **Local Context Issues**   **NA – subjects not enrolled at relying site** |
| 1. Are there any state or local laws that the Reviewing IRB will need to consider that would impact a research protocol or informed consent document (wards of state, emancipated minors, results of pregnancy testing)?   YES  NO If YES, describe:   1. Are there any local, community or cultural issues that may be different for your population of subjects that require consideration?   YES  NO If YES, describe:   1. Is 18 the Age of Majority for the state in which your site is located?   YES  NO If No, identify the age:  4. Is there anything described in the protocol that would not fall within the policies and practices of your institution that the  IRB needs to be aware of?  YES  NO If yes, describe:  **NOTE**: *It is the responsibility of the Relying Institution, to inform the Reviewing IRB of any changes to the state or local laws that could affect a research protocol or informed consent document.*  **Site Policies**  **NA – subjects not enrolled at relying site**  Does the site have a posted policy for any of the following?  YES  NO If YES, complete details below  **NOTE: Please only select those for which there is a posted institution policy; (generally accepted practice and guidance are not policy)**  **Age of Assent Policy or** NA no Minors  If selected, please provide a link (URL) to the policy, or paste the policy below   |  | | --- | |  |   **Consent Process for those with Impaired Decision-Making Capacity or**  NA No cognitively impaired adult subjects  If selected, please provide a link (URL) to the policy, or paste the policy below   |  | | --- | |  |   **Use of short forms for non-English speaking individuals or**  NA No non-English speaking subjects  If selected, please provide a link (URL) to the policy, or paste the policy below   |  | | --- | |  |   **Translation of consent forms for non-English speaking individuals or**  NA No non-English-speaking subjects  If selected, please provide a link (URL) to the policy, or paste the policy below   |  | | --- | |  |   **Local Consent Requirements: (no URL; paste language directly into document)**  **NA – subjects not enrolled at relying site.**   1. Provide institutionally required language regarding compensation in the event of a research related injury:      1. Provide any institutionally required language for pregnancy testing in minors:      1. Provide any institutionally required language for genetic testing:      1. Provide any other language required by site policy or state law:      1. Is there a Conflict of Interest in this study?  YES  NO   Note: Each Institution is responsible for reviewing the protocol and determining if a conflict of interest exists in accordance with the Institution’s policies. The Conflict-of-Interest Management Plan must be disclosed to the IRB.  If YES, provide the language the institution requires in the consent form regarding the conflict.   1. Any additional local language to be included in Header/footer of document (e.g., relying institution study tracking #)   NO YES: |

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| **Indicate which of the following site-specific documents are being submitted to the METROHEALTH IRB:**  \*Required for all studies - Relying site PI’s curriculum vitae or Bio sketch  Site-specific Consent/Assent documents: List:  Site-specific recruitment materials: List:  Site-specific HIPAA Authorization form (separate from consent form)  Site-specific measure(s) (e.g., surveys, observation forms, interview guides etc.) List:  Relying site Conflict of Interest management plan List:  Other – specify: |

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| **APPENDIX A: RELYING SITE LOCAL CONTEXT TEMPLATE** |
| **INSTRUCTIONS AND INFORMATION**  This Appendix provides guidance on how to convert the METROHEALTH IRB approved consent/assent form(s) into a consent form(s) that is specific to a relying site when the METROHEALTH IRB is serving as the IRB of Record for a multisite study. Revise the model Metro Consent accordingly with TRACK CHANGES ON.    If any changes are necessary beyond filling in the placeholders with site-specific information, it is recommended, that you include comment bubbles in the tracked consent/assent form or a cover letter to provide clear rationale for why the METROHEALTH IRB approved language in that specific section is being changed for the local relying site.  **Version Tracking:** All site versions should have the same content in the footer, which should include the consent form site-specific version date. For example: Version: 02-28-23 should be converted to placeholder [Site Name] Version dated [MM-DD-YY] |

**FRONT PAGE CONSENT**

*INSTRUCTIONS: Replace with Relying site Contact Information*

**Principal Investigator-** ADD LOCAL SITE NAME].**:** name and phone # (required)

**Study Coordinator-** ADD LOCAL SITE NAME].**:** name and phone # (optional)

**Section 1.3 # Of subjects enrolled at Relying Site:**

*INSTRUCTIONS: Include the # of subjects to be enrolled at the relying site.*

Approximately [\_\_\_] people will take part in this study at [ADD LOCAL SITE NAME].

**Section 5.2 -What happens if I am injured while taking part in this study?**

*INSTRUCTIONS: Relying site’s compensation in case of injury local context language added here*

**Section 5.5-Could MetroHealth or the researchers at [ADD LOCAL SITE NAME] profit or financially benefit from the study results?**

*INSTRUCTIONS: Identify any researcher conflicts of interest. If any of the investigators on the study have an owndership, consulting. Or similar financial relationship with the sponsor, they should disclose it here in accordance with an approved COI management plan. Also identify any institutional conflict, if applicable. Suggested language is provided below.*

[Insert name of PI; if [ADD LOCAL SITE NAME] has an institutional conflict, it should be listed here too] has a financial or other interest in this study. In some situations, the results of this study may lead to a financial gain for the researcher and/or [ADD LOCAL SITE NAME] This financial interest has been reviewed in keeping with MetroHealth policies. It has been approved with certain conditions that are intended to prevent bias and protect study participants. If you have any questions about this conflict of interest, please ask your study doctor or call the MetroHealth Ethics and Compliance Department at (216) 778‑4997.

[If there are no researcher conflicts of interest, then add the following]:

Neither [ADD LOCAL SITE NAME] nor the researchers involved with this study have a conflict of interest that would allow them to profit or financially benefit from the study results.

**Section 6,1- Authorization to Use and Disclose Your Protected Health Information**

*INSTRUCTIONS: Review the relying site’s determination as to whether or not to have the MetroHealth IRB serve as the HIPAA privacy board. If they choose to have the MetroIRB serve as the HIPAA Privacy Board (and grant applicable waivers), see sections below that require the local site name replace MetroHealth.*

*If MetroHealth is not serving as the HIPAA Privacy Board, the Relying institution is required to use their own Stand Alone HIPAA authorization document.*

Your medical information and billing records are protected health information (“PHI”). By signing this form, you allow the researchers for this study to obtain, use, and share your PHI as described more below. Your permission to allow the use and disclosure of your PHI is required if you want to take part in this study. [ADD LOCAL SITE NAME] has rules and procedures to protect information about you. Federal and state laws also protect your privacy. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at [ADD LOCAL SITE NAME] or any benefits to which you are already entitled. You will receive a copy of this form for your records.

* **Who may use or disclose my PHI?**

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at [ADD LOCAL SITE NAME] may see or give out your information. These include people who review research studies such as the MetroHealth Institutional Review Board (IRB) and other [ADD LOCAL SITE NAME] staff here and at MetroHealth authorized to access your information.

* **Who may receive or use my PHI?**

The parties listed in the last paragraph may disclose your PHI to the following parties for their use in connection with this research study:

* The Office for Human Research Protections in the U.S. Department of Health and Human Services
* Include list of sponsors, funding agencies, and collaborators who may need to view the PHI.
* List every other class of persons or organizations not affiliated with [ADD LOCAL SITE NAME] such as a sponsor, data safety monitoring board, collaborators at other institutions, outside data analysts, the National Institutes of Health, insurance companies, auditors, etc. to whom the participant’s information might be disclosed. If the study is a clinical investigation involving a test article (drug, device, biologic) that is subject to FDA regulations, include the FDA.

***Section 6.3 What will happen to my information that is collected for this study?***

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. [ADD LOCAL SITE NAME] has no control over the use of your information once it is released. This information may be used for purposes unrelated to this research and could potentially be used to identify you.

Sharing data is part of research and may increase what we can learn from this study to help scientific purposes. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your samples and/or data may be stored and shared for future research projects without further consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples and/or data, no one will know that it is related to you specifically, and we will no longer be able to identify and destroy them. Your data, after being stripped of all identifiers, may be shared with other researchers at [ADD LOCAL SITE NAME] , the MetroHealth System, other academic institutions, for-profit companies, sponsors, government agencies, and other research partners.

***Section 6.5 Use of your identifiable information or samples for future research***

It is possible that the identifiable [data/samples] collected during this research project may be helpful for other project(s) as well. We would like to ask your permission to use your identifiable information in these project(s). [Specify PHI elements that will be retained.] This data may be shared with other researchers at [ADD LOCAL SITE NAME], and The MetroHealth System, and other academic institutions, sponsors, government agencies, and other research partners. Please check the box that correctly indicates your choice.

My identifiable [data/samples] may be used for this project only.

My identifiable [data/samples] may be used for future research.

***Section 7.2 What happens if I stop participating in the study?***

You are free to leave the study at any time. Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care at [ADD LOCAL SITE NAME] If you withdraw from the study, with your written permission, clinical data will continue to be collected from your medical records. [Add the following for studies regulated by the FDA:] Data collected on you up to the time of your withdrawal must remain in the study database and cannot be removed.

**Section 6.4 Certificate of Confidentiality**

*INSTRUCTIONS: The statement regarding protection by a Certificate of Confidentiality should only be included if the main locally approved MetroHealth consent contains the statement.*

To further protect your identifiable data and/or identifiable biospecimens (for example, blood or tissue) collected and used under this research, a Certificate of Confidentiality from the United States Department of Health and Human Services (DHHS) and the National Institutes of Health (NIH) has been obtained.

This added protection to your privacy limits the redisclosure of your private identifiable data by the researchers without your permission in any federal, state, or administrative proceedings.

The Certificate will not prevent the researchers from notifying the appropriate authorities when there is a federal, state, or local law that requires reporting, such as reporting communicable diseases or child/elderly abuse.  The Certificate cannot be used during required auditing or evaluation of federally funded projects or when required by the Federal Food and Drug Administration (FDA).

This Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.  If an insurer or employer learns about your participation, and obtains your consent to receive research information, we may not use the Certificate of Confidentiality to withhold this information.  This means you must actively protect your own privacy.

If you have any questions about what this notice means and would like to speak to someone, you may call the study doctor, [ADD LOCAL PI NAME] Study Coordinator, [ADD LOCAL SC NAME] or the MetroHealth Institutional Review Board, at (216) 778-2021.  If you would like to read more about Certificate of Confidentiality, the NIH has a website you can visit online at:  <https://grants.nih.gov/policy/humansubjects/coc.htm>.