**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.

**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?**