Obesity and Asthma: Unveiling Metabolic and Behavioral Pathways
Protocol
PI: Juan P. Wisnivesky, MD, DrPH
NCT04113746
Document Date: June 29, 2022

Mount Sinai	Protocol Name:	Obesity and Asthma: Unveiling Metabolic and Behavioural Pathways
	Principal Investigator:	Juan Wisnivesky, MD, DrPH
	Primary Contact Name/Contact Info:	Elisa McBratney / elisa.mcbratney@mountsinai.org / 212-824-7460
	Date Revised:	1/25/21
	Study Number:	STUDY-16-00079

HRP-503 Application (Protocol)

- *This application can only be used in conjunction with a protocol. If this project does not have a protocol from the sponsor or is already included in a grant application then a comprehensive protocol should be developed. A comprehensive template and online wizard is located at: NIH Wizard.*
- *Note that, depending on the nature of your research, certain questions, directions, or entire sections below may not be applicable, or may have been fully covered in the protocol. Provide information if and when applicable. If the answer is found in the protocol please provide a page reference. If the question is not applicable to the study, mark the section "N/A". Do not delete any sections.*
- *Be sure to complete any supplement questions from one or another ancillary office that you receive during the RUTH application process. Please make certain that the protocol, this 503 application and responses to ancillary offices do not contradict each other and the information is incorporated in all documents where appropriate. Be sure to save the Ancillary office responses you provided within RedCap and upload them to Ruth.*
- *Throughout this application are references to checklists. These tools are used by the IRB to make specific regulatory findings. To allow us to do that it is the applicant's responsibility to ensure that your protocol has sufficiently addressed these additional regulatory criteria for approval, and that the applicant identifies those protocol specific findings required by the checklist. how will they do that, here or a separate form?*
- *Keep an electronic copy of this version of the document. You will need to modify this copy when making changes.*

1. Setting of the Human Research:

- *Where within the Mount Sinai health system or its affiliates will research activities take place including subject recruitment?*
  The study sites will include New York City (the Mount Sinai Hospital System [MSHS]), Denver (University of Colorado), and Toronto (The Hospital of Sick Children).

  The research at Mount Sinai will take place in the Center for Advanced Medicine Building at 17 East 102nd St., New York, NY 10029. Follow-up interviews may take place at a location other than the hospital campus if the subject requests that. Subjects can be recruited from outpatient clinics and practices that treat asthma and other pulmonary conditions at Mount Sinai Hospital.

- *If there are any differences in the recruitment or study procedures between the sites please highlight them here.*

The Hospital for Sick Children will not be recruiting subjects.

- *For research conducted outside MSSM and its affiliates under the supervision of the Sinai investigator:*
  N/A – each site has its own PI.

  (a) Site-specific regulations, laws or customs affecting research.
  (b) Local scientific and ethical review structure.

2. Resources Available to Conduct the Human Research: (the aim here is to assess if the research is likely to be successful and thus justify the efforts and risks taken by the subjects):

- *Explain the feasibility of meeting the recruitment goals of this project, and demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period. (For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? If this has been reviewed by a committee for recruitment feasibility [e.g. PR&MC], please indicate so.)*

  It will be feasible to meet our recruitment goals of 400 participants. During 2014, there were ~2,500 unique adult asthmatics that had outpatient visits to the primary care and pulmonary practices. In our prior MSH-based cohort studies, approximately 30% were overweight and 30% obese.

- *For research involving considerable data extraction or mining describe who will be providing those services.*

  Mount Sinai Data Warehouse (MSDW) will provide lists of potential eligible participants as well as daily report for any participants enrolled in our study hospitalized with asthma exacerbation.

- *For research conducted outside MSSM and its research affiliates, describe the facilities used for conducting the research.*

  At the University of Colorado, The Asthma Clinical Research Center is located on the 6th Floor of the UCH, Anschutz Outpatient Pavilion Building, it has Approximately 5000 sq. ft. of clinical areas with eight patient exam rooms, which are equipped with exam tables, BP cuffs, otoscopes, spirometers, 2-Niox VEROs, and a negative pressure filter ventilated room for methacholine challenges. The Clinical Center sees over 2,000 patients with obesity and asthma per year. The Asthma Center counts with a full time Asthma Nurse Educator who is involved

with patient recruitment and consent. Administrative support staff are available to support research activities. Standard office supplies and capabilities, including confidential fax machine, mail, and photocopying are available. In addition, the research coordinators have dedicated 200 square feet of locked, shared office space immediately adjacent to the MICU at the University of Colorado Hospital. These office spaces constitute sufficient resources for the research coordinators and ancillary staff to conduct these research studies.

Dr. Grasemann's lab is located on the 9th floor of SickKids new research facility, the Peter Gilgan Centre for Research and Learning (PGCRL). Completed in 2013, the PGCRL is the largest high-rise research facility in Canada and houses more than 2,000 research staff; consolidating scientists and core facilities under one roof. The state-of-the-art laboratory and learning space allow for interaction and interconnectivity among the various disciplines, enhancing the opportunities for long-term collaboration and hence promoting and fostering SickKids' strengths in multidisciplinary inquiry. For the purpose of this project Dr. Grasemann will extensively use the services of the Analytical Facility for Bioactive Molecules: this fee-for-service core facility (2000 sq. ft) is fully equipped for metabolomic and lipidomic analyses using state-of-art mass spectrometry (MS/MS, MALDI-TOF, IRMS, GC/MS), liquid chromatography (HPLC), and ELISA-based multiplexing assays

- *Describe your process to ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions. If research is being carried out in a clinical setting explain how the clinical staff will be informed of the trial and their involvement, e.g. medication administration. If nursing or other services have reviewed and approved this project please upload the documentation.*

  All study staff will be required to undergo all institutional-specific regulatory trainings prior to beginning the project and will also be required to update this training annually. During data collection and the pilot phase, the PIs and research teams will meet biweekly to discuss all aspects of study administration and data collection.

3. Study Design:

a) Recruitment Methods (see PPHS policy):

- *Describe the source of potential subjects.*

  Potential subjects will be identified through queries of the registration systems at outpatient practices each site.

- *Describe the methods that will be used to identify potential subjects (e.g. ResearchMatch.org, social media, texting, etc.).*

  We will request a list of potentially eligible participants from MSDW of patients from the outpatient primary care and pulmonary clinics at MSHS.

- *Describe how potential subjects will be approached, the involvement of the treating clinicians, use of letter, emails, calls, or similar, opt-out provisions, etc. Describe materials that will be used to recruit subjects. Include copies of these documents with the application. For advertisements, submit the final copy of printed advertisements. When advertisements are taped for broadcast, provide the final audio/video file. You may submit the wording of the advertisement prior to taping for pre-approval but final audio/video recording has to receive IRB approval before use.*

  There will be no "cold-contact" of patients. The RAs will obtain permission from physicians to contact their patients. The RAs will contact the patient and they will be scheduled for an in-person interview. At time of scheduling, RAs will mail or email the consent document to the scheduled patient. The RA will then follow up with the scheduled individual to review the consent over the phone and ask questions about asthma history. The patient should have an interview scheduled within four weeks of the phone consent. Data will be recorded in the patient record. If the patient does not come in for the study visit or for rescheduled visits, the data collected over the phone will be destroyed. RAs will try to reschedule patient interviews up to 5 times, depending on the patient, before destroying the data collected during the phone consent process.

  RAs will obtain consent and administer the interview in a space that safeguards confidentiality. Based on preliminary data, we expect a distribution of participants well-balanced by obesity status and by age of asthma onset (early vs. late). We will recruit both obese and non-obese subjects. Obesity is defined as having a body mass index greater than or equal to 30 kg/m2. However, we will monitor these parameters during recruitment and conduct purposeful sampling if unbalances are identified.

  Acute Care Episodes: We will also interview participants (<30 minutes) and collect blood samples within 24 hours of admission when they have asthma exacerbations resulting in hospitalization at participating sites. There is a limit of one hospitalization interview within a 12 month period. The purpose is to determine whether L-arginine/ADMA ratios and arginase levels fall disproportionately among obese patients with late onset asthma during exacerbations. We will determine when hospitalizations occur by daily electronic queries of the hospitals' registration systems.

For all interviews, acute and non-acute subjects will not sign the consent form unless they are comfortable with the research. Subjects can take as much time as they deem necessary to review the consent form and ask questions.

- *For social media, in addition to providing the content please explain how people will be selected or targeted to receive the ads. For websites used for screening or recruitment, provide details and access. Complete the INFO Sec screening questions and follow up as needed.*

  N/A

b) Inclusion and Exclusion Criteria:

- *Indicate any local changes not specified or differing from the protocol.*
  Inclusion criteria: participants that are > 64 years of age are eligible.
  Exclusion criteria: participants that have a >15 pack-year smoking history are exluced.

- *Describe how you will screen for eligibility and if you will need a waiver of Informed Consent or HIPAA. If you are using an outside firm to screen or data mine for subjects please provide details here.*
  We will request reports from MSDW for patients that fill our eligibility criteria detailed in the protocol. The potential subjects will also be screened through a chart review.

  A HIPAA waiver has been requested and approved.

- *Any exclusions based on race, sex/gender, preferred language must be explained.*
  We are unable to recruit participants that do not speak English or Spanish as the study team is not equipped administer the study measures in languages other than Spanish or English.

  (NOTE: You may not include members of vulnerable populations as subjects in your research unless you indicate this in your inclusion criteria).

c) Number of Subjects:

- *Specify local recruitment numbers if not in the protocol*
  Please refer to the protocol.

- *Indicate the total number of subjects to be accrued locally. This will be the maximum number of subjects that can sign the consent form without additional IRB approval. Please be sure to account for screen failures, drop-outs, etc. If applicable, distinguish between the number of subjects who are expected to be pre-screened, enrolled (consent obtained),*

randomized, and complete the research procedures (i.e., numbers of subjects excluding screen failures) and between subgroups of subjects (e.g. healthy volunteer, disease cohort).
We will recruit 200 participants at Mount Sinai.

- *If this is a multicenter study, indicate the total number of subjects to be accrued across all sites.*
  We will recruit 400 participants between Mount Sinai and University of Colorado.

d) Study Timelines:

- *If not in the protocol, please clarify the how long an individual subject may be in the protocol, and for how long the protocol will be active at Mount Sinai.*

  Describe:

- *The duration of an individual subject's participation in the study (including follow-up).*
  Subjects will participate in the study for 18 months. If they are eligible to enroll in the pilot, subjects will participate for an additional 8 weeks.

- *The duration anticipated to enroll all study subjects.*
  We will enroll all subjects in 2.5 years.

- *The estimated date for the investigators to complete this study (complete primary analyses)*
  5 years

  The study will take place from April1, 2016 to August 28, 2021. The end date is 120 calendar days after the end of the period of performance, as per the NIH Final Progress Report Guidelines.

e) Specimen Banking for Future Uses Not Part of This Project:

- *If storage will be occur at Sinai and elsewhere (e.g. the sponsor) be sure to answer these questions for both sets of samples as, at the very least, governance of future uses will differ.*

  See below answers.

- *If specimens will be banked for future use, describe:*

  Specimens will be banked for future ADMA and L-arginine analyses.

- *Where the specimens will be stored, what access controls and security systems will be in place?*

  The specimens with be stored in Dr. Paula Busse's laboratory in the Icahn Medical Institute at 1425 Madison Avenue [redacted]. The specimens will

be stored in -80 degree freezer and locked securely to minimize the risk of a breach of confidentiality. Specimens will then be shipped to Dr. Grasemann's lab at the Hospital for Sick Children on the 9th floor of SickKids new research facility, the Peter Gilgan Centre for Research and Learning (PGCRL). The specimens will be stored in freezer and locked securely to minimize the risk of a breach of confidentiality

- *How long they will be stored?*

  Samples will be stored indefinitely.

- *How will researchers gain access to the specimens? If there is a resource utilization committee please provide a description.*

  These specimens will not be released to any additional requestors at any institution until a formal request has been submitted to the IRB and Dr. Wisnivesky.

- *List the information to be stored or associated with each specimen (including how the specimens are labeled/coded).*

  Data specimens will be stored in an identifiable manner using indirect identifiers. The patient study identifiers will be linked to the blood sample. The file that links the study identifiers with the patient is stored on a secure server that is encrypted and password-protected and encrypted.

- *If the specimens are part of bank where frequently sharing among several or more users is contemplated then a complete set of Standard Operating Procedures for the repository should be submitted.*

  N/A

f) Data Storage, Transmission and Confidentiality:

Describe the data and specimens to be sent out or received. If storage will occur at Sinai and elsewhere (e.g. the sponsor) be sure to answer these questions for both sets of samples as, at the very least, governance of future uses will differ.

As applicable, describe:

- *How will data be collected?*

All data will be collected in a deidentified manner. Data will be collected through REDCap, Mount Sinai's electronic research data capture platform. Additional data will be collected through spirometry tests, FeNO tests, and asthma dosers.

- *How will data be transmitted? If clinical trials software or similar is being used provide the names as well as the security/regulatory specifications it complies with (e.g. FDA)*

Data will be transmitted from other sites to Mount Sinai via the secure Mount Sinai-hosted OneDrive, a secure, HIPAA-compliant shared drive. This will be used to transmit de-identified accelerometer and spirometry data. University of Colorado research staff will also have access to Mount Sinai's REDCap, where they will input deidentified survey data.

- *How will data be stored? Provide data standards where known.*

To preserve patient confidentiality, study subjects will be assigned code numbers. Using these codes, none of the collection forms will contain the names or medical record number of the patients or other personal identifiers. There will be a master list at each institution matching the names of the patients to the code numbers. The list will be safely stored in secure network drives. Paper-based consent and HIPAA documents will be stored in locked cabinets within locked offices, separate from the master lists. All electronic data will be stored on mainframe servers, and terminals and Tablet PCs will be password protected and maintained in locked offices.

Database protection: Patient information will only be accessible to the PI, project manager, and research coordinators associated with the research. Data collected on Tablet personal computers (PC) will be uploaded on a daily basis to mainframe servers supported by the local institutions and encrypted using encryption software. These data will lack personal identifiers other than a study identification code. Following the upload, the data on the Tablet PCs will be deleted. Encrypted data from the other sites will be transferred electronically to Mount Sinai on a weekly basis. The transferred data will be free of personal data that qualifies as PHI. All data received at the data coordinating center (Mount Sinai) will be entered into a computerized database and stored in encrypted files on a mainframe server that is backed up nightly by the Mount Sinai Hospital IT Department.

- *How long will data be stored?*

Data will be stored for 7 years following the completion of data analysis.

- *What are the SOPs that govern data sharing?*

No data will be shared outside of the investigators and study team named on this protocol.

- *If this project is not funded by NIH will a Certificate of Confidentiality be obtained? If not, why not?*

N/A – this study is funded by the NIH.

g) Data and Safety Monitoring Plan:

- **For projects with a Data Safety Monitoring Board/Data Safety Committee (DMSB/DMC):**
- *If not included in the protocol, attach a description of the DMC/DSMB, including the number, names (if available} and area of professional expertise of the members. The responsibilities of the DSMB/DMC must be clear as well as their powers and their degree of independence. The DSMB charter must be provided to the PPHS before the study may begin. Reports of the DMC/DSMB must be made available to the local PI and the MSSM PPHS. The report need not contain specifics of the study or data, but there should be clear statement if the study can continue as is, or requires changes or termination.*

Please refer to the protocol for a description of the DSMB (pg. 126-127). The DSMB members and their roles are detailed below:

Name	Role	Title	Institution	Email
Joel Erblich	Biostatistician	Associate Professor; Psychology	City University of New York	jerblich@hunter.cuny.edu
Katie Krauskopf	Primary Care Physician	Medical Director, Outpatient Addiction Services	Providence Behavioral Health, Trinity Health Of New England	Katherine.krauskopf@sphs.com
Anne Dixon	Chair/Pulmonologist	Professor; Pulmonary Disease and Critical Care Medicine	University of Vermont	Anne.dixon@uvmhealth.org
Sharmilee Nyenhuis	Behavioral Health Research Scientist	Assistant Professor; Medicine	University of Illinois at Chicago	snyenhui@uic.edu

h) Withdrawal of Subjects:

- *Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.*

The PI, the sponsor or the institution may stop the participant's involvement in this research study at any time without consent. This may be because the research study is

being stopped, the instructions of the study team have not been followed, the investigator believes it is in the participant's best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without the participant's consent.

- *Describe any procedures for orderly termination.*

  Study participants have the option withdraw from further participation at any time. Voluntary withdrawal will in no way affect the quality of patient care that is provided to them within the Mount Sinai Health System. However, any data and/or biological samples that have already been collected will be retained unless the participant requesting in writing that his/her data and/or biological samples be destroyed. If a subject asks for complete withdrawal from the study, he/she must do so by notifying the site PI in writing.

- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

  If participant withdraws from the study, they must do so in writing as specified in the consent. The research team will not contact the participant further for study interviews. The participant will be asked if he/she will allow the study team to keep data and specimens that have already been collected. If the participant refuses, the data recorded in REDCap will be destroyed and the samples collected will be destroyed.

4. Provisions for Research Related Harm/Injury:

- *Explain how clinically important incidental results will be handled. Examples include an abnormal lab finding or a survey answer indicating possible danger to self or others.*
  This study does not collect blood or spirometry results that are clinically important.

  If a patient indicates a possible danger to themselves or others, the PI or other qualified clinician will be immediately summoned to evaluate the participant.

- *Describe the availability of medical or psychological resources that subjects might need as a result of any anticipated adverse events that may be known to be associated with the Human Research.*

  In order to further safeguard the mental health of the study participants: (1) Any participant who becomes discomforted or distressed will be given the opportunity to speak with a clinical psychologist, social worker or qualified medical professional immediately; (2) we will track the occurrence of these events and after two incident reports are filed for a participant, they will be flagged for a consultation with a counselor (clinical psychologist, social worker or qualified medical professional)

- *If the research involves more than minimal risk to subjects, explain any medical treatments that are available if research-related injury occurs, who will provide it, what will be provided, and who will pay for it.*

  The expected risks include those related to performing a pulmonary function test. These may include dizziness related to performing a full inspiratory maneuver. Those who report dizziness will be promptly instructed to discontinue the test, and a qualified medical professional will be sought if symptoms persist. See answer to question above regarding procedure to patients that express a danger to themselves or others.

  The pilot intervention does not involve any procedures that would result in research-related injuries.

5. Recordings: N/A

6. Provisions to Protect the Privacy Interests of Subjects:

[Note: This section is soliciting <u>different information</u> than the confidentiality information solicited in section #5f. Answers will vary widely based on the complexity of the research design, the sensitivity of the subject matter and the populations being recruited.]

- *Describe the steps that will be taken to protect subjects' privacy interests, particularly a person's desire to control how, where and with whom, they interact and communicate, especially on issues that prospective research participants may deem sensitive or private. Consider privacy interests that may arise from the time participants are identified for recruitment until they complete study participation. Consider privacy interests that may arise in communications with the study subjects (e.g. phone messages, mail, etc), including through long-term follow-up.*

  To protect the privacy interests of subjects, all communications with study subjects will be via face-to-face visit, telephone or email. Phone messages left will not refer to the study in which they are enrolled but only the site where they were enrolled. For example, the study team would leave a message such as, "This is XXXX calling from Mount Sinai." Patients will be asked whether they prefer phone contact or email contact for their follow-up.

- *Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.*

During the consent process and prior to every study visit, participants will be informed that some of the questions asked during the study visit may make them feel uncomfortable. The study team will emphasize that each part of the study is voluntary and they are free to skip any part that causes them discomfort.

- *Describe why it is acceptable and appropriate for members of the research team to approach the prospective participant about the research.*

  This project has been deemed of important scientific merit. Members of the research team have all completed ethical research training as well as extensive training in the protocols of this project. Measures are put into place to take the utmost care in contacting and interacting with prospective participants.

7. Economic Impact on Subjects:

- *Describe any foreseeable costs that subjects may incur through participation in the research (exclude billing for procedures that are part of clinical care e.g. copayments for studies that involve an overlap of clinical care & research).*
  The study will have no foreseeable economic impact on participants.

- *In answering this question, the Financial Administration of Clinical Trials Services (FACTS) must be consulted in determining the appropriate responsible party for subject care costs incurred as part of the clinical research study. Additional information can be found at (FACTS Office)*

8. Payments/Reimbursements to Subjects:

Describe the amount and timing of any payments/reimbursements to subjects. Payments must be pro-rated. Completion bonuses may be permitted but may not represent undue inducement. Review ISMMS Finance webpage for restrictions on payments, requirements for tracking cash, gift card, etc. payments.

Subjects will be reimbursed for their time and effort. Subjects may receive up to $380 for participating in the observational study. Subjects will receive $50 in cash after the completion of the baseline interview. Up to an additional $20 will be given to the subjects once they return the electronic monitoring device for the medication ($10) and accelerometer ($10). Subjects will receive $50 in cash after the completion of each follow-up interview (6 months, and 12 months and 18 months). Up to an additional $20 will be given to the subjects once they return the electronic monitoring device for the medication ($10) and accelerometer ($10) after each follow up interview. Subjects will receive $50 in cash after the completion of each post-hospitalization interview (limit of one interview within 12 months). Payment for each interview and device return is not contingent upon the completion of the entire study.

Patients participating in the pilot phase of the study will be paid $20 for each visit of the pilot that they complete, including the 30-day follow-up visit. Subjects will be paid in cash for returning their devices at the next visit unless otherwise requested. If devices are returned after the final in-person interview or if subject should choose to withdraw from the study, payment for device return will be made by money order. This payment will be sent within a 6 week period by mail.

Interview Period	Payment Amount	Medication Device Return	Accelerometer Return	Possible Total Payment
Baseline	*$50*	*$10*	*$10*	*$70*
6-month interview	*$50*	*$10*	*$10*	*$70*
12-month interview	*$50*	*$10*	*$10*	*$70*
18-month interview	*$50*	*$10*	*$10*	*$70*
Hospital interview	*$50*	-	-	*$100*
Each pilot visit	*$20*			*$100*
30-day follow-up pilot visit	*$20*			*$20*

9. Consent Process:

*This section always applies, please indicate whether consent will be obtained from subjects. (If not, proceed to the **Waiver or Alteration of the Consent Process** section below).* *If you will be obtaining consent, describe:*

- *The setting of the consent process.*

  Informed consent will take place either in person or over the phone in a space that safeguards confidentiality.

- *Describe any waiting period available between informing the prospective subject and obtaining the consent.*

  The participant will have as much time as needed to review the consent.

- *If you will be following "SOP HRP-090 Informed Consent Process for Research", after addressing the points above, indicate this. Otherwise, also describe:*
  - *The role of the individuals listed in the application as being involved in the consent process.*
  - *The time that will be devoted to the consent discussion.*
  - *Steps that will be taken to minimize the possibility of coercion or undue influence.*
  - *Steps that will be taken to ensure the subjects' understanding.*
  - *Describe any tools that will be utilized during the consent process*

The team will adhere to "SOP-HRP-090 Informed Consent Process".

-

***Non-English Speaking Subjects* (See PPHS policy)**

Indicate what language(s) other than English are understood by prospective subjects or representatives. If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. *If you intend to exclude potential participants who do not speak English, provide a justification for doing so.*

Spanish-speaking participants will be enrolled. All study materials have been translated into Spanish and back-translated by study team members who are fluent in Spanish. The study team contains a Research Coordinator who is fluent in Spanish and will administer the study visits in Spanish to Spanish-speaking participants.

This study will exclude participants who do not speak English or Spanish as the study team is not equipped to administer the study visits in languages other than English or Spanish.

Waiver or Alteration of the Consent Process

If the Human Research involves a request for a waiver or alteration of the consent process, review the "CHECKLIST HRP-410 Criteria for Waiver or Alteration of the Consent Process" and make sure your submission provides adequate information for the IRB to assess the criteria for approval. It is highly recommended that you provide additional information here to address each of the criteria for approval (e.g. impracticability).

N/A

Examples of when a waiver or alteration of the consent process may be applicable:

- *Research that does not obtain consent from subjects*
- *Research that omits some information that is required in the consent template*
- *Research that involves deception*
- *Research that involves obtaining private information about third parties who have not provided consent*

- *Research that requests a waiver of the consent process for planned emergency research. Please review the "CHECKLIST HRP-506 Criteria for Waiver of the Consent Process for Planned Emergency Research" to ensure you have provided sufficient information for the IRB to make these determinations.*

10. Process to Document Consent in Writing:

a) If consent will be obtained at a distance using the written consent form as the official version, please provide details of how the subjects will receive a copy of the consent form, how the consent form will be reviewed with the subject, and how signature will be obtained and documented.

In addition to consenting participants in person, we will also consent participants over the phone. For any subject being consented via phone we will follow the following procedure:

1. Send the approved phone consent authorization to the prospective research subject for review.
2. Arrange for a conversation between the participant and an authorized member of the research team to allow for full discussion of the combined consent/authorization. If verbal consent is obtained, collect identifiable data as applicable.
3. If there is an adult witness on the phone at the time of the initial verbal consent, the documents will not be returned.

4. If there is no adult witness to the phone consent/authorization, the written document will be requested to be returned via regular mail, fax, or email. If after two weeks, the signed document is not returned the data will be stripped of all identifiers and links such that the de-identified data are permanently anonymized.

b) If using any sort of e-Consent on any device, including iOPEN, provide access to the PPHS to allow us to review the built consent. e-Consent is defined as consent designed to be obtained with minimal human interaction, generally using specialized software.

- *If not iOPEN please provide details and complete the InfoSec "screening questions" for further instructions.*

N/A

c) If you want a waiver of written documentation, please review the "CHECKLIST HRP-411" to ensure that your protocol has sufficiently addressed these additional regulatory criteria for approval, including protocol specific information to support the determinations. You will also need to request a waiver of HIPAA authorization. Unless you are eligible for a complete waiver of consent, your consent form or script should still contain the needed elements of consent as laid out in our consent template.

N/A

11. Vulnerable Populations:

a) Unless already detailed in the protocol, please indicate which of the following populations are either included or excluded in this project: Indicate specifically whether you will include (target) or exclude each of the following populations:

Include	*Exclude*	*Vulnerable Population Type*
	x	*Adults unable to consent*
	x	*Individuals who are not yet adults (e.g. infants, children, teenagers)*
	x	*Wards of the State (e.g. foster children)*
	x	*Pregnant women*
	x	*Prisoners*

b) Describe other aspects of the subject population that may increase their vulnerability (marginalized populations, poverty, illiteracy and under-education, legal status, home/institution-bound individuals; students participating in their professor's research, cognitively-impaired

minors, etc.). For those subjects at an increased risk of not understanding the aims, procedures, risks and benefits of this project, OR whom may be at increased vulnerability to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.
There are no aspects of the research population that are anticipated to increase their vulnerability.

c) *What steps are being taken to assure that a diverse group of research subjects are approached to participate in this study? What are the projected demographics of the enrolled subjects at study completion.*

We are recruiting participants from a wide range of medical settings within the Mount Sinai Hospital System. The Mount Sinai Health System has locations throughout the New York metropolitan area and the demographic composition of its patients reflects the diversity of the surrounding communities.

12. Multi-Site Human Research:

a) Besides research sites within the Mount Sinai System please detail the PI's responsibilities for other sites, or overall responsibility for the project?

Drs. Wisnivesky, Federman, and Holguin will be responsible for the oversight and coordination of the entire study. More specifically, Drs. Wisnivesky and Federman will oversee subject recruitment and data collection at the Mount Sinai site. They will supervise a project manager, a data analyst, and the research assistants. Dr. Wisnivesky will be the contact PI and responsible for all communication with NIH. Dr. Holguin will oversee the research assistants and study activities at University of Colorado.

Mount Sinai will serve as the data coordinating center. The study teams at ISMMS and University of Colorado will work together on recruitment. University of Colorado will recruit participants from its site only and will only have access to data from its site.

b) If coordinating center functions are taking place at Sinai, whether or not it is also a clinical site, please answer the following with appropriate justification and documentation, if needed:

(i) Are the management, data analysis, and Data Safety and Monitoring (DSM) systems adequate, given the nature of the research involved? Yes

(ii) Is the sample protocols and informed consent documents developed and distributed to each

collaborating institution?; Yes

(iii) Does each collaborating institution hold an applicable OHRP-approved Assurance?; Yes

(iv)Will each protocol be reviewed and approved by the IRB at the collaborating institution prior to the enrollment of subjects?; Yes

(v) Have all substantive modifications by the collaborating institution to the sample consent, especially related to risks or alternative procedures, been appropriately justified?; Yes

(vi) Will informed consent be obtained from each subject in compliance with HHS regulations? Yes

If this is a multi-site study where you are the lead investigator, describe the management of information (e.g., results, new information, unanticipated problems involving risk to subjects or others, or protocol modifications) among sites to protect subjects.

The PIs will participant in biweekly study meetings to discuss all aspects of study administration and data collection. The PIs will communicate as needed to discuss new information, unanticipated problems or protocol amendments.

13. Community-Based Participatory Research

a) *Describe involvement of the community in the design and conduct of the research.*
N/A

(Note: "Community-based Participatory Research" is a collaborative approach to research that involves the community in all aspects of research process. Community-based Participatory Research begins with a research topic of importance to the community and has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities. Simply recruiting participants from the community is not CBPR. If your research does not involve the community in all aspects of the research process, mark N/A)

b) *Composition and involvement of any community advisory board for research conducted outside of MSSM.*
N/A

14. Sharing of individual and study Results with Subjects:

a) *If not in the protocol, or in response to other questions (e.g. Radiation Safety) add here. Be sure to remain compliant with NYS laws around genetic testing and the use of research tests, as only FDA or NYS DOH a approved tests from CLIA labs can be used to guide clinical decision making. If results are not being returned, explain the rationale.*
See below.

b) *Specify which results will be returned to subjects and/or their clinical care team. If results are not being returned, explain the rationale.*
Results are not being returned to subjects and/or their clinical care teams. Results of spirometry will not be shared with the participants as they were not administered by a respiratory technician or physician and they are not clinically relevant. The blood tests collected for this study are for research purposes only and are not clinically relevant.

c) *How and when will subjects be informed of the study results? The PPHS expects proactive outreach by the study team.*
Study results will not be communicated with study participants as part of the study so as not to influence decision making.

15. External IRB Review History

If you have previously submitted this protocol for review by an external IRB (non-Mount Sinai IRB), provide the name of the reviewing IRB and the associated project identification number. Please include the details of the review with appropriate documentation including the date of review and the IRB contact information.
N/A

16. Control of Drugs, Biologics, or Devices:

a) *If not included in the protocol, the supplemental questions of the Investigational Drug service or included in other uploaded documents please add here:*
N/A

- *If the Human Research involves drugs, biologics, or devices, describe the plans to store, handle, and control those drugs, biologics or devices so that they will be used only on subjects and be used only by authorized investigators. This very well may involve OR personnel, nursing, central sterilization and supplies etc. The plan should be comprehensive and robust.*

- *Note: If there are required departmental policies that regulate the control of drugs, biologics, or devices, provide that information here.*

- *Note: For studies involving research drugs or biologics, you will need to obtain the approval of Investigational Drug Service (IDS) of the Mount Sinai Pharmacy, regardless of whether you will be utilizing the IDS to manage the control of research drugs and biologics.*