**DATA and/or SPECIMEN ONLY PROTOCOL**

**GENERAL INSTRUCTIONS:**

* Use this template to prepare a protocol for a study that will only involve use of data or specimens, and does not include any direct interaction or intervention with human research participants.
* This template **should not be used** for prospective studies where samples are collected solely for research purposes (for example: collection of research specimen by biopsy).
* There is a streamlined application process for research accessing retrospectively collected data via the [CTSI Best Practices Integrated Informatics Core (BPIC) service](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic). Follow the instructions on this template to determine if your research is eligible. If eligible, you will only complete a small portion of this protocol template.
* As you are creating your protocol, remove all instructions and guidance text (including these) so that they are not contained in the final version.
* Pg. 2-3 includes guidance regarding retrospective and prospective review and consent requirements. Additional guidance can be found in the [Investigator Manual (HRP-103)](https://drive.google.com/open?id=0B7644h9N2vLcOWtzU2FmSU5oS0U) regarding the use of information and/or specimens for research purposes (see Appendix B-2).
* Complete Appendix A, to indicate the types of materials/specimens that will be collected, used, or studied in this research study.
* Complete Appendix B to indicate whether any, some, or all identifiable information will be collected, used, or studied in this research study.

**Data Review Guidance:**

***What is the difference between a retrospective and prospective review?***

* A Retrospective Review evaluates participant data that exists at the time the study is submitted to the IRB for initial review.
* A Prospective Review evaluates participant data that does not yet exist at the time the project is submitted to the IRB for initial review.

***What type of consent should I request?***

* *Waiver of Consent:* Waiver of consent is often appropriate for both retrospective and prospective reviews. In order for the IRB to approve a waiver of consent, the IRB must be satisfied that the following criteria in “[CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)](https://research.umn.edu/units/irb/toolkit-library/checklists)” are met:
* The research involves no more than minimal risk to the participants;
* The waiver or alteration will not adversely affect the rights and welfare of the participants;
* The research could not practicably be carried out without the waiver or alteration; and
* Whenever appropriate, the participants will be provided with additional pertinent information after participation.
* If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

*Waiver of Documentation of Consent:* This type of consent is not usually requested for a data review. Under a waiver of documentation of consent, an investigator must still obtain consent from the participant. However, the investigator does not need to obtain a signed consent form from participants if the IRB agrees that the criteria in “[CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)](https://research.umn.edu/units/irb/toolkit-library/checklists)” are met:

* The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether she or he wants documentation linking her or him with the research, and the participant's wishes will govern; or
* The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.
* *Written Consent:* The IRB may determine that written consent is required if the investigator is unable to justify why it is impracticable to conduct the research without a waiver. This is often the case for prospective review studies, but may occur in retrospective review studies. For example, if an investigator wishes to review the data of all of the patients he refers onward for a colonoscopy to collect outcome measures, the IRB may determine that the investigator should obtain written consent because he will have the chance to obtain consent from the patients during their clinic visit with him.

**ANCILLARY REVIEWS**

**DO NOT DELETE. Submit the completed checklist below with your protocol.**

|  |  |  |  |
| --- | --- | --- | --- |
| **Which ancillary reviews do I need and when do I need them?**  Refer to [HRP-309](https://drive.google.com/file/d/0B7644h9N2vLcMTl0ZE9yQkhLd3c/view) for more information about these ancillary reviews. | | | |
| **Select yes or no** | **Does your study…** | *If yes…* |  |
| **Yes**  **No** | Include Gillette resources, staff or locations | *Gillette Scientific review and Gillette Research Administration approval is required. Contact:*  [*research@gillettechildrens.com*](mailto:research@gillettechildrens.com) | **Required prior to IRB submission** |
| **Yes**  **No** | Involve Epic, or Fairview patients, staff, locations, or resources | *The Fairview ancillary review will be assigned to your study by IRB staff*  *Contact:* [ancillaryreview@Fairview.org](mailto:ancillaryreview@Fairview.org) | **Approval must be received prior to IRB committee/ designated review.**  **Consider seeking approval prior to IRB submission.** |
| **Yes**  **No** | Include evaluation of drugs, devices, biologics, tobacco, or dietary supplements or data subject to FDA inspection | *The regulatory ancillary review will be assigned to your study by IRB staff*  *Contact:* [*medreg@umn.edu*](mailto:medreg@umn.edu) |
| **Yes**  **No** | Require Scientific Review? Not sure? See guidance in the [Investigator Manual (HRP-103)](https://drive.google.com/uc?export=download&id=0B7644h9N2vLcOWtzU2FmSU5oS0U). | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **Yes**  **No** | Relate to cancer patients, cancer treatments, cancer screening/prevention, or tobacco  NOTE: CPRC review is not required for Retrospective Chart Review, Retrospective Sample Review, or Prospective Specimen Repository studies | *Complete the* [*CPRC application process*](https://www.cancer.umn.edu/for-researchers/investigator-resources/cancer-protocol-review-committee)*.*  *Contact:* [*ccprc@umn.edu*](mailto:ccprc@umn.edu) |
| **Yes**  **No** | Include the use of radiation  (x-ray imaging, radiopharmaceuticals, external beam or brachytherapy) | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) | **Approval from these committees must be received prior to IRB approval;**  **These groups each have their own application process.** |
| **Yes**  **No** | Use the Center for Magnetic Resonance Research (CMRR) as a study location | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **Yes**  **No** | Include the use of recombinant or synthetic nucleic acids, toxins, or infectious agents | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **Yes**  **No** | Include the use of human fetal tissue, human embryos, or embryonic stem cells | *STOP – Complete* [*the Medical Template Protocol (HRP-590)*](https://drive.google.com/open?id=0Bw3yHuGQzD8CaExVUkZEWjBVSU0) |
| **Yes**  **No** | Use data from [CTSI Best Practices Integrated Informatics Core](https://ctsi.umn.edu/services/data-informatics/biomedical-informatics-and-data-access)  (Formerly the Information Exchange) | *See instruction within this template.*  *Contact:*  [bpic@umn.edu](mailto:bpic@umn.edu) | **Approval must be received prior to IRB approval.**  **These groups do not have a separate application process but additional information from the study team may be required.** |
| **Yes**  **No** | Include PHI or are you requesting a HIPAA waiver | *If yes, HIPCO may conduct a review of this protocol.*  *Contact:* [*privacy@umn.edu*](mailto:privacy@umn.edu) |
| **Yes**  **No** | Use the Biorepository and Laboratory Services to collect tissue for research | *The BLS ancillary review will be assigned to your study by IRB staff.*  *Contact: Jenny Pham*  *Pham0435@umn.edu* |
| **Yes**  **No** | Have a PI or study team member with a conflict of interest | *The CoI ancillary review will be assigned to your study by IRB staff*  *Contact:* [*becca002@umn.edu*](mailto:becca002@umn.edu) |
| **Yes**  **No** | Need to be registered on clinicaltrials.gov | *If you select “No” in ETHOS, the clinicaltrials.gov ancillary review will be assigned to your study by IRB staff*  *Contact:* [*kmmccorm@umn.edu*](mailto:kmmccorm@umn.edu) |
| **Yes**  **No** | Require registration in OnCore | *If you select “No” or “I Don’t Know” in ETHOS, the OnCore ancillary review will be assigned to your study by IRB staff*  *Contact:* [*oncore@umn.edu*](mailto:oncore@umn.edu) | **Does not affect IRB approval.** |

**PROTOCOL COVER PAGE**

|  |  |
| --- | --- |
| **Protocol Title** | CPET Data Analysis |
| **Principal Investigator/Faculty Advisor** | Name: Christopher Lundstrom |
| Department: Kinesiology |
| Telephone Number: |
| Email Address: lund0982@umn.edu |
| **Student Investigator** | Name: Anton Hesse |
| Current Academic Status (Student, Fellow, Resident): Student |
| Department: Kinesiology |
| Telephone Number: (612) 616-0944 |
| Institutional Email Address: hesse151@umn.edu |
| **Biospecimens and/or Data** | Medical record number  Patient ID (generated by CTSI)  Gas exchange data files from exercise tests  Age at each test  Test date / test ID  Sex |
| **Number of Records and/or Specimens** | N# of Records: Approximately 250 patients,  N# of Specimens: Most patients will have between 1-3 exercise test files. We estimate there will be approximately 350 exercise test files. |
| **Version Number/Date:** | 1  5/4/2022 |

**REVISION HISTORY**

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| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

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**ABBREVIATIONS/DEFINITIONS**

Include any abbreviations or definitions for key or technical terms you use in your protocol.

* VT1 and VT2: the first and second ventilatory threshold, respectively
* LOA: limits of agreement
* VO2 and VO2max: volume of oxygen and maximal aerobic power, respectively
* HRmax: maximal heart rate

# **Objectives**

* 1. Purpose: Describe the purpose, specific aims, hypothesis, or objectives.

The purpose of this study is to quantify the effects of different data processing methods on algorithm-selected values for VT1 and VT2.

Aim 1: Calculate the LOA for the absolute VO2, %VO2max, and time at VT1 and VT2 while modifying combinations of prior data processing and analysis steps including outlier selection, interpolation, data averaging, threshold graph, and threshold algorithm choice.

We hypothesize that some combinations of data processing and analysis steps will result in LOA that are wider than the expected error in the measurement device.

# **Background**

* 1. Significance of Research Question/Purpose: Describe the relevant prior research and gaps in current knowledge for your research question.

Exercise intensity is likely the most challenging exercise prescription variable to individualize. Without information from an exercise test, the next best alternative to prescribe cardiovascular exercise is to use percentages of maximal anchors or percentages of reserve anchors, such as %HRmax or % heart rate reserve, respectively. These methods typically incorporate different zones such as 50-59%, 60-69%, 70-79%, etc. of %HRmax. Unfortunately, what may be a moderate or challenging zone or a given %HRmax for one individual may be easy for another. Previous research shows that prescribing cardiovascular exercise from physiological thresholds, such as VT1 and VT2 typically yields better and more predictable improvements to fitness. If one can determine these thresholds, they must be calculated correctly for accurate exercise prescription.

One source of data used to find these thresholds is ventilatory data from an exercise test. The gases released at the mouth reflect whole-body metabolism and therefore exercise intensity, but there is considerable variability breath to breath. Most of this variability originates from rapidly oscillating ventilation, rather than slower metabolism. Therefore, some data processing, such as removing outliers, interpolating data, and averaging the data, is required to uncover the underlying metabolic demand.

Our lab recently analyzed pilot data where we averaged ventilatory in five different ways and then used a common algorithm to locate VT1. The results of our pilot data show that on average, the VO2, %VO2max, and time at VT1 are similar between averaging methods. However, calculating the LOA between any two method shows this LOA is var wider than the error expected in the measurement. This suggests that the choice of averaging method likely plays a practically significant role in the ultimate exercise prescription from the values at VT1.

Therefore, the purpose of this study is to extend our analysis to a larger data set and incorporate more data analysis choices including outlier boundaries, data interpolation, and other steps that may influence the final values at VT1 and VT2. We will quantify the effect of these choices by calculating the LOA between different data processing and analysis sequences.

* 1. Preliminary Data: Describe any relevant preliminary data (if applicable).

We have pilot data from the marathon training class at the University of Minnesota (PE 1262). At the beginning of the semester, they underwent pre-testing, including a VO2max treadmill test. With this data we quantified the LOA for the VO2, %VO2max, and time at VT1 between different averaging methods. The results indicate that the LOAs for all comparisons are wider than the expected error in the device measurement.

* 1. Existing Literature: Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Previous research on exercise intensity finds that using submaximal thresholds such as VT1 and VT2 to individualize prescription produce superior changes to fitness compared to using standardized methods such as %HRR (Weatherwax et al., 2019; Wolpern et al., 2015). Specifically, these studies find that using these thresholds results in 100% of participants improving their VO2max, while only about half of participants using standardized methods improved VO2max. VO2max does not capture all aspects of cardiovascular fitness, but every 3.5 point increase in relative VO2max translates to a 13 and a 15% decrease in annual all-cause and coronary heart or cardiovascular disease event mortality, respectively (Kodama, 2009). Therefore, this prognostic value and the benefits of using submaximal thresholds to improve VO2max supports the value in reliably detecting and using thresholds to prescribe exercise when possible.

Using ventilatory data is a non-invasive and common method to determine these thresholds. Collecting exhaled gases at the mouth reflects whole-body metabolism, but oxygen consumption from breath to breath is highly variable and differs by up to 86% (Robergs et al., 2010). Whole-body metabolism changes much more slowly, so some data processing is required to parse the signal from the noise. To date, there are no universally agreed upon data processing steps and research on this topic is limited the effect of different averaging methods on the attainment and value of VO2max. (Astorino, 2009; Astorino et al., 2000).

This research will extend previous analyses by considering not only the averaging method, but also the effects of different outlier thresholds, data interpolation, and combinations of those choices on the values at VT1 and VT2. Previous research estimates the measurement error in VO2 to be approximately 0.091 L/min (Robergs & Burnejtt, 2003). The average LOA (Altman & Bland, 1983) between averaging methods at VT1 from out pilot study are about 0.31 L/min, or about 3.5 as wide as the expected error. This suggests that data processing choices meaningfully contribute to the intensity at submaximal thresholds and the resultant exercise prescription.

**References**

Altman, D. G., & Bland, J. M. (1983). Measurement in Medicine: The Analysis of Method Comparison Studies. *The Statistician*, *32*(3), 307. https://doi.org/10.2307/2987937

Astorino, T. A. (2009). Alterations in VO2 max and the VO2 plateau with manipulation of sampling interval. *Clinical Physiology and Functional Imaging*, *29*(1), 60–67. https://doi.org/10.1111/j.1475-097X.2008.00835.x

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Robergs, R. A., & Burnejtt, A. F. (2003). METHODS USED TO PROCESS DATA FROM INDIRECT CALORIMETRY AND THEIR APPLICATION TO VO2MAX. *Journal of Exercise Physiology Online*, *6*(2), 44–57. https://www.asep.org/asep/asep/Robergs3.pdf

Robergs, R. A., Dwyer, D., & Astorino, T. (2010). Recommendations for improved data processing from expired gas analysis indirect calorimetry. *Sports Medicine*, *40*(2), 95–111. https://doi.org/10.2165/11319670-000000000-00000

Weatherwax, R. M., Harris, N. K., Kilding, A. E., & Dalleck, L. C. (2019). Incidence of VO2max Responders to Personalized versus Standardized Exercise Prescription. *Medicine and Science in Sports and Exercise*, *51*(4), 681–691. https://doi.org/10.1249/MSS.0000000000001842

Wolpern, A. E., Burgos, D. J., Janot, J. M., & Dalleck, L. C. (2015). Is a threshold-based model a superior method to the relative percent concept for establishing individual exercise intensity? a randomized controlled trial. *BMC Sports Science, Medicine and Rehabilitation*, *7*(1), 1–9. https://doi.org/10.1186/s13102-015-0011-z

# **Procedures Involved**

* 1. Study Type (check all that apply):

Retrospective Review

Prospective Review

Both: Retrospective and Prospective Review

* 1. Identify the Source of the individually identifiable information (Check all that apply)

Information Exchange (IE) Services through CTSI Best Practices Informatics Consulting (BPIC)

* Include a copy of the [BPIC](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic) Consultation form with the IRB Submission
* Limited access to [EPIC](https://www.epic.com/) through the AHC-IE Security Gateway for validation/supplemental purposes only.

NOTE: HealthEast EPIC data is not included in the IE. If accessing HealthEast EPIC data, complete all sections below.

EPIC records accessed outside of the Information Exchange. Please provide the information requested below:

-Describe what you will access

- Indicate how many patients’ records you plan to access

- Describe how you will access the data

- Describe the authority you have to access the data

- Explain how you will exclude the records of those who have opted out of research

Information will be collected directly from research participants

I will retrieve records directly from axiUm / MiPACS

I will receive data from the Center for Medicare/Medicaid Services

I will receive a limited data set from another institution

If the limited data set used will contain information from somewhere other than the University of Minnesota or MHealth, then you must enter into a [Data Use Agreement](https://research.umn.edu/units/spa/unfunded-agreements/overview) with the data source. You may use the University’s standard Data Use Agreement or another form approved by the health information Privacy & Compliance Office. Please upload the Data Use Agreement you will use for this transfer of information in the supporting documents section of ETHOS.

If you do not have a Data Use Agreement in place, you may continue with application, however, you must complete a Data Use Agreement before you can receive the Limited Data Set. More information about Limited Data Sets can be found [HERE](http://www.healthprivacy.umn.edu/policies-procedures/creating-limited-data-set) or by contacting the privacy office at 612-624-7447, or by email at [privacy@umn.edu](mailto:privacy@umn.edu)

Other sources of individually identifiable information: Describe in detail the source of the information, including justification regarding the investigator’s authority to collect the information from the source or if approval (and from whom) was received to collect the information.

If this project requires only **RETROSPECTIVE REVIEW** and **ALL DATA** will be made available to you by CTSI Best Practices Integrated Informatics Core through the information Exchange you do not need to complete the remainder of this protocol (3.3 – 10, Appendices).

* Upload a copy of your BPIC consultation form with this protocol in ETHOS if you are using the abbreviated process.
* HIPCO and Fairview ancillary reviews are waived for these projects
  1. Date Range: Describe the date range of data / specimens to be obtained for this study. If this is a retrospective review, the end date must be before the IRB submission date. The beginning date is the start of the Executive Health Program at the University of Minnesota Physicians Clinics and Surgery Center. The end date is the day before the IRB submission in Ethos.

* 1. Approximate number of records required for review:

~600

* 1. Research conducted with populations with additional protections:

We are unaware if any records will be associated with populations that require additional protections. The typical age range of patients in the Executive Health program is at least 40 years old, but it is possible that a small number of the women in the program were pregnant at some point.

* 1. Informed Consent: Clarify whether informed consent for research use of records was ever obtained for the records you intend to utilize for research purposes or whether records where patients “opted out” will be excluded from the record set. Describe whether informed consent should be obtained for the purposes of this research (for information on whether consent is required, see the Appendix B-2 of the Investigator Manual (HRP-103)).

Upon enrollment in the executive health program, patients were asked if they consented to allow their data to be used for research purposes. The information from the CTSI will only return those patients who opted to allow their data to be used for research purposes.

* 1. Study Design: Describe and explain the study design.
  2. Study Procedures: Provide a description of all research procedures being performed and when they are performed. For research involving data, describe how the data will be selected and who will define the data selection.
  3. Individually Identifiable Health Information: Identify whether the research study involves the use of individually identifiable health information. Also complete Appendix B. If this research will involve the use of individually identifiable health information, either collecting or having access to, complete Section 4 below. See [UMN Privacy Office Policies](https://policy.umn.edu/operations/phi) and/or [Fairview Health Services Privacy Policies](https://www.fairview.org/Research/Forresearchers/Researchcompliance/Researchpolicies/index.htm), and [UMN HIPAA Agreement Templates](https://policy.umn.edu/contracts/categories/OT/240/253)*.* For research conducted at Gillette Children’s Specialty Healthcare refer to [Gillette Research Administration](https://www.gillettechildrens.org/for-medical-professionals/research/research-administration) for guidance.

# **Health Information and Privacy Compliance**

Under the HIPAA Privacy Rule, research studies at the University are permitted to use and disclose protected health information with the authorization of the research participants, or without individual authorization in limited circumstances.

* 1. Select which of the following is applicable to your research:

My research does not require access to individual health information and therefore HIPAA does not apply.

I am requesting the IRB to approve a Waiver or an alteration of research participant authorization to participate in the research.

I will be obtaining HIPAA Authorization from participants.

* 1. Appropriate Use for Research: Explain how you will ensure that only records of patients/participants who have agreed to have their information used for research will be reviewed.

We are using the CTSI to obtain medical record numbers for only those patients who were in the Executive Health program who underwent VO2max testing.

* 1. Location(s) of storage, sharing and analysis of research data, including any links to research data (check all that apply). In the case of research involving sensitive data (including data that is sensitive but not covered by HIPAA), the protocol must include a robust security plan in compliance with the University’s [Data Security Policies.](https://policy.umn.edu/operations/phi) Review additional policies that may apply including the [University’s Data Security Classification](https://policy.umn.edu/it/dataclassification) and [Information Security policies](https://policy.umn.edu/it/securedata).

In the [BPIC](about:blank) data shelter of the [Information Exchange (IE)](https://www.ctsi.umn.edu/consultations-and-services/data-access-and-informatics-consulting/bpic)

Store  Analyze  Share

In the Bone Marrow Transplant (BMT) database, also known as the HSCT (Hematopoietic Stem Cell Transplant) Database

Store  Analyze  Share

In REDCap (recap.ahc.umn.edu)

Store  Analyze  Share

In Qualtrics (qualtrics.umn.edu)

Store  Analyze  Share

In OnCore (oncore.umn.edu)

Store  Analyze  Share

In the University’s Box Secure Storage (box.umn.edu)

Store  Analyze  Share

In an AHC-IS supported server. Provide folder path, location of server and IT Support Contact:

The path should be in the form of “\\vp.ahc.umn.edu\vp\Research\Study0004” If accessing PHI, HIPCO requires this information to verify the data are in a properly encrypted server.

In an AHC-IS supported desktop or laptop.

Provide UMN device numbers of all devices:

If accessing PHI, HIPCO requires and will confirm that devices used in this manner are properly encrypted.

Store  Analyze  Share

Other. Describe in detail the location and whether the data / specimens will be stored, analyzed, or shared, and in what ways.

Indicate if data will be collected, downloaded, accessed, shared or stored using a server, desktop, laptop, external drive or mobile device (including a tablet computer such as an iPad or a SmartForm (iPhone or Android devices) that you have not already identified in the preceding questions

I will use a server not previously listed to collect/download research data

I will use a desktop or laptop not previously listed

I will use an external hard drive or USB drive (“flash” or “thumb” drives) not previously listed

I will use a mobile device such as a tablet or smartphone not previously listed

* 1. Consultants. Vendors. Third Parties. Describe whether you will collect, store, analyze or share any information using a consultant, vendor, or third-party software application, system, device or technology (other than REDCap or OnCore).
  2. Links to identifiable data: indicate how you will generate the links, how you will store these links, and how and when you will destroy these links
  3. Storage of Documents: Describe how you will store any paper or electronic documents generated as a result of this research project.
  4. Disposal of Documents: Describe if, when, and how you will dispose of research documents. Reminder: research regulations and policies require each investigator to retain research data not only while the research is being conducted but also after the research is completed. Retention requirements vary depending on whether federal funding was provided for the project, whether there is funding from industry with contractual provisions governing data retention, or whether the study was conducted under FDA regulations. It is recommended that researchers comply with the longest applicable standard.

# **Data/Specimen Management & Analysis**

* 1. Data Analysis Plan: Describe the data analysis plan, including any statistical procedures and who will conduct the analysis. Indicate the minimum number of records and/or specimens necessary to carry out the objectives of your study.
  2. Power Analysis: Provide a power analysis, if applicable.
  3. Data Integrity: Describe any procedures that will be used for quality control of collected data.
  4. Existing Specimens (if applicable): Describe the type(s) of specimens that will be used. Complete Appendix A. Indicate whether you will use specimens under the control of BioNet. If you are not using [BioNet](https://www.ctsi.umn.edu/consultations-and-services/specimen-procurement/tissue-procurement-facility), identify the biobank that you will utilize for this study. In addition, explain where the specimens will physically reside during the study.
  5. Specimen Storage and Access:

Describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the data/specimens. Indicate if[BioNet](https://www.ctsi.umn.edu/consultations-and-services/specimen-procurement/tissue-procurement-facility)will be used for specimens. State the person or group that will be the custodian of the specimens. Explain the purpose of storing specimens and define how they will be used. Clearly indicate where the specimens will be stored and clearly state for how long. If you are using BioNet for these purposes, you can include the following statement, “BioNet will maintain and store the specimens for this study. [BioNet](https://www.ctsi.umn.edu/consultations-and-services/specimen-procurement/tissue-procurement-facility)retention procedures will be followed.

* 1. Data associated with specimens: Specify which data will be associated with specimens.
  2. Plans for Identifiers on Specimens (if applicable):

Explain whether anyone, including the investigator, can identify the participant based on any information on the specimen.Explain whether there will be a unique code on the specimen that can be used to identify the participant but that will not, by itself, reveal who the participant is. If there will be a unique code, explain whether the researchers on this study will have a link to who the participant is. Explain how all specimens will be labelled.

* 1. Release/Sharing:

Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain specimens, and the data elements to be provided. Describe any plans for sending specimens outside the University of Minnesota including to whom, where, and for what purpose. Indicate whether a[Data Use Agreement](https://policy.umn.edu/contracts/categories/OT/240/253)is in place.

* 1. Destruction of Specimens*:* Describe how data/specimens will be destroyed when no longer needed.

# **Study Population**

* 1. Inclusion Criteria: Describe the criteria that define who will be included in your final study sample.

Research involving pregnant women, prisoners, or children must be reviewed by the IRB in accordance with Subparts B, C or D of the federal regulations. If it can be presumed that the participants are not pregnant, incarcerated, or under the age of 18 during the conduct of the study, the subparts do not apply. If, however, during the course of the study, the investigator becomes aware that the participant(s) meet one or more of these conditions, the PI must either exclude the participant(s) from the dataset or the IRB must promptly re-review the study in accordance with the requirements of Subparts B, C or D.

* 1. Exclusion Criteria: Describe the criteria that define who will be excluded in your final study sample.
  2. Age Range: Describe the specific age range that will define who will be included in the study population.

# **Consent Process**

* 1. Consent Process (when consent will be obtained written or orally): Describe the consent process, including:
     + Where the consent process will take place.
     + Any waiting period available between informing the prospective participants and obtaining the consent.
     + Who and how will it be determined that a potential participant understands the information.
     + Any process to ensure ongoing consent.
     + If you will document consent in writing, submit a consent document in ETHOS.
  2. Waiver or Alteration of Consent Process (when consent will not be obtainedIf you are not requesting a consent alteration or waiver, type “N/A” and delete the bullets below. Otherwise, complete all items below:
     + Review “[CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)](https://research.umn.edu/units/irb/toolkit-library/checklists) to ensure that you have provided sufficient information in this protocol for the IRB to make these determinations. Do not fill out the checklist. Describe how your protocol meets the requirements noted in HRP-410.
     + If the research involves a waiver of the consent process for planned emergency research, please review “[CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)](https://research.umn.edu/units/irb/toolkit-library/checklists)” to ensure that you have provided sufficient information for the IRB to make these determinations.
  3. Waiver of Written/Signed Documentation of Consent (when written/signed consent will not be obtained): If you are not requesting a waiver of documentation of consent, type “N/A” and delete the bullets below. Otherwise, provide rationale for the waiver.
* Review “[CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)](https://research.umn.edu/units/irb/toolkit-library/checklists)” and provide rationale as to why a waiver of written documentation of consent is appropriate for this research study.
* If you will obtain consent, but not document consent in writing, submit a consent script in ETHOS.

# **Risks**

8.1 Risks: Include any known potential risks of this study. For example, a risk can include the breach of confidentiality.

# **Benefits**

9.1 Benefits: Describe any benefits. Generally, these studies do not have a direct benefit to participants. However, the study should have some benefit for the purpose of knowledge and benefit to others in the future. For example, the protocol could include the following statement:

The participants are not likely to receive any benefit from the proposed research; however, society and investigators will benefit from the knowledge gained.

**Appendix A. Types of Materials**

This list does not include all possible materials that will be collected, used, or studied. The following are examples (in red). Add or remove materials that will be collected, used, or studied. Adjust the final list font to black.

|  |  |  |
| --- | --- | --- |
| **Material Type** | **Material Quantity or Volume** | **Preservation Format (Specimens)** |
| Whole Blood |  |  |
| Plasma |  |  |
| Serum |  |  |
| Buffycoat/Lymphocytes |  |  |
| Isolated DNA/RNA |  |  |
| Specific Organ(s): |  |  |
| Specific Tissue Types(s) (i.e. Skin, Pancreas, etc.) |  |  |
| Urine |  |  |
| Saliva |  |  |
| Ascites |  |  |
| CSF |  |  |
| Nail Clippings |  |  |
| Hair Clippings |  |  |
| Breast milk |  |  |
| Stool |  |  |
| Photographs |  |  |
| Journals or Diaries |  |  |
| Questionnaires (i.e., Quality of Life), Surveys, or instruments (depression scales) |  |  |
| Long Term Follow Up Surveys |  |  |
| Intake form(s) |  |  |
| Counseling record(s) |  |  |
| Lab report(s) |  |  |

**Appendix B. List of Identifiable Data Elements**

Indicate whether any of the following identifiable data elements will be collected, used, or studied. The following are identifiable data elements per HIPAA. Select Yes or No for each element.

|  |  |
| --- | --- |
| **Identifiable Data Element** | **Included in this research study?** |
| Names | Choose an item. |
| Dates, except year | Choose an item. |
| Telephone numbers | Choose an item. |
| Geographic data | Choose an item. |
| FAX numbers | Choose an item. |
| Social Security numbers | Choose an item. |
| Email addresses | Choose an item. |
| Medical record numbers | Choose an item. |
| Account numbers | Choose an item. |
| Health plan beneficiary numbers | Choose an item. |
| Certificate/license numbers | Choose an item. |
| Vehicle identifiers and serial numbers including license plates | Choose an item. |
| Web URLs | Choose an item. |
| Device identifiers and serial numbers | Choose an item. |
| Internet protocol addresses | Choose an item. |
| Full face photos and comparable images | Choose an item. |
| Biometric identifiers (i.e. retinal scan, fingerprints) | Choose an item. |
| Any unique identifying number or code | Choose an item. |