**UMMS Central Biorepository (CBR) Biospecimen or Data Use Proposal Form**

**And Cardiovascular Health Improvement Project (CHIP)**

Please submit this form to indicate your interest in discussing and entering into a research agreement with the CBR for use of human biospecimens and/or associated data. Use proposals are developed through collaboration with the Principal Investigator(s) who have contributed biospecimens to the CBR and according to policies of the CBR, the U-M, and regulatory authorities. Unless otherwise stipulated by a funding or other agreement, CBR research materials are owned by the University of Michigan.

CBR staff will use the information you provide in this form to make contact with the investigator(s) who collected the materials that might be useful to your project, begin to identify candidate samples, and assess and advise on any potential regulatory and ethical issues.

On initial submission, please provide as much information as possible to describe your proposal and indicate which materials may be fit and useful for it. After collaboration with the relevant contributing Principal Investigator(s), the final, completed form will be submitted for committee review.

1. **Submission Type:** *(Please mark appropriate box with an “X”)*

[ ] Follow-up to a Data Direct query. Query number or uniqname and Query name:

[ ] Request that CBR staff start a new search for CBR biospecimens, according to parameters below.

[ ] Request CHIP start a new REDCap data search, according to parameters below.

1. **Date Submitted:**
2. **Title of proposed study; If UM study, please include HUM#:**
3. **Principal Investigators:**

Name: Suffix (e.g., M.D., Ph.D.):

Institution:

Email:

1. **Co – Investigators:**

Name: Suffix (e.g., M.D., Ph.D.):

Institution:

Email:

1. **Study Objectives**
2. **Methods:**
3. Experimental research techniques/tests employed (*if performing genetic analysis, please list the gene(s) under consideration; if performing genomic analyses (e.g. GWAS, NGS), please list the chip and/or vendor*):
4. **Biospecimens** *(Description of samples sought):*
5. Disease entity *(Please describe the disease status of the participant, e.g. Type A dissection; if applicable, please be as specific as possible, e.g. if looking for tissues from patients, include anatomical region)*:
6. Type of Specimens:

|  |  |  |
| --- | --- | --- |
|  | **N samples requested** | **Amount/volume of material requested (select the minimum required to preserve samples)** |
| *Cell Pellet*  |  |  |
| *Plasma* |  |  |
| *Serum* |  |  |
| *Frozen Aortic Tissue* |  |  |
| *Paraffin embedded Tissue*  |  |  |
| *DNA* |  |  |
| *Other:*  |  |  |
| *Other:* |  |  |

1. If aortic tissue is requested, please provide anatomic site (thoracic or abdominal aorta):
2. Other requirements for processing the requested samples prior to shipment to your facility *(e.g. Pico Green, realiquoting)*:
	1. If applicable, specific specimen attributes:
3. **Clinical, family history outcomes, GWAS**

|  |  |
| --- | --- |
|  | **Requested** |
| *Demographics and Medical History* | [ ]  |
| *Aortic Disease Diagnosis* | [ ]  |
| *Heart Failure, CVD Diagnosis* | [ ]  |
| *Connective Tissue Disorder Diagnosis*  | [ ]  |
| *Clinical Genetic Testing*  | [ ]  |
| *Surgical History*  | [ ]  |
| *Medications*  | [ ]  |
| *Labs* | [ ]  |
| *Patient-reported outcomes (depression, anxiety, sleep, nutrition and sleep behavior*  | [ ]  |
| *Family history related to CVD* | [ ]  |
| *GWAS* | [ ]  |

1. **Inclusion and Exclusion criteria:**
2. **Statistical Design:**
3. Primary Comparisons:
4. Power Justification:
	1. Samples size estimate (*i.e., number of cases required to achieve the primary objectives of your study)*:
	2. Number of available specimens and source of this information:
5. Data analysis will be performed by:
6. **Disclosure of Conflict of Interest, if known:**
7. **Foreseeable Use Agreement and other Contract Issues:**
	1. After proposal approval, principal investigators will be required to sign documentation agreeing to the terms and conditions for biospecimens and data access (See Appendix A and B).

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**Appendix A.**

**Biospecimens and Data Access Provisions:**

Note: As with all human tissues and blood products, biospecimens should be handled with extreme care using Universal Precautions.

1. The University of Michigan Health System (UMHS) - Cardiovascular Health Improvement Project (CHIP) assumes no responsibility for claims including, but not limited to, malpractice or injury arising from research or investigation from use of biospecimens and/or data.
2. IRB approval or exemption, when appropriate, must be obtained prior to release of any identifiable biospecimens or data. If de-identified or coded data are released, investigators must not make any attempt to identify participants. If identifiable data are released, investigators must take appropriate precautions to protect confidentiality of research subjects such as encrypting data, etc.
3. Biospecimens or data may not be distributed to alternate sites or any Co-Investigators not named on the proposal without prior written permission from UMHS - CHIP. To obtain permission, the principal investigator is required to submit a request via e-mail (CHIPadmin@med.umich.edu) outlining the request along with documentation of IRB approval from alternate sites.
4. Information on approved projects including the PI, study team members, title, and lay summary, may be made public.
5. Biopecimens and data derived from this proposal cannot be used for any project, topic, or analysis beyond the scope indicated. If additional analyses and/or projects are necessary, prior written permission from UMHS - CHIP is required (CHIPadmin@med.umich.edu).
6. There may be recharge fees associated with accessing UMHS – CHIP biospecimens or data.
7. All primary data generated from CHIP participants (e.g., DNA sequence, genotypes, RNA sequence, metabolite measures, deeper phenotyping, clinical information, etc.) must be returned to UMHS – CHIP within 6 months of data generation and may be released to other investigators in the future. An embargo of 12 months from data generation or upon publication of a manuscript containing these data (i.e., online publication date), whichever date comes first, will be respected prior to releasing any primary data to other investigators. Additional time may be requested, but written permission from UMHS-CHIP is required. We encourage collaboration with investigators who generated the data. UMHS - CHIP Access Committee will be responsible for controlling subsequent access to data derived from CHIP biospecimens. It is expected that primary data in both raw and cleaned forms will be provided to UMHS-CHIP (e.g. for sequencing both BAM and VCF files will be provided) within 6 months of raw data generation.
8. If a request is made for data derived from biospecimens (e.g., DNA sequence, genotypes, RNA sequence, metabolite measures, etc.), data will only be released under the following conditions: IRB approval, embargo date has passed, and PI agrees to acknowledge UMHS-CHIP and the funding source for data generation.
9. UMHS - CHIP must be recognized in the Acknowledgements section of posters or publications resulting from research in which CHIP biospecimens or data are utilized.The wording is as follows: *“The collection of samples and/or data for the University of Michigan Health System – Cardiovascular Health Improvement Project was supported by the Frankel Cardiovascular Center.”* Acknowledgment of CHIP Biobank personnel on publications resulting from CHIP biospecimens and/or data is encouraged if appropriate.
10. Abstracts, posters, and/or publications resulting from research in which CHIP biospecimens or data were utilized must be reviewed and approved by UMHS - CHIP prior to submission. Please email (CHIPadmin@med.umich.edu) an electronic copy at least 7 days prior to expected submission date.
11. The use of CHIP biospecimens or data for development of any product (e.g. pharmaceutical agents, device, etc.) is strictly prohibited unless permission has been obtained. To obtain permission, the principal investigator is required to submit a request via e-mail (CHIPadmin@med.umich.edu) outlining request.
12. The UMHS - CHIP will:
	1. Coordinate delivery of approved biospecimen – requesting entity is responsible for payment associated with the retrieval and shipment of biospecimen.
	2. Coordinate the export of data to requesting entity
	3. Provide information about the biospecimen relevant to the use of the biospecimen without compromising study participant confidentiality.
	4. Maintain confidentiality of participant information, including information obtained from medical records, in accordance with applicable law.
	5. Provide a protocol for the handling of biospecimen prior to and after experimentation. It will be the recipient’s responsibility to follow the biospecimen handling protocol provided by the UMHS - CHIP as well as provide a summary of the manipulations performed to the biospecimen. This way, the integrity of the biospecimen will be maintained. This document serves as the material transfer agreement.
	6. Track and confirm the delivery of biospecimen.
13. The Recipient will:
	1. Send an email (CHIPadmin@med.umich.edu) to confirm the delivery of biospecimen or data.
	2. Collect and provide information to UMHS - CHIP (CHIPadmin@med.umich.edu) on any adverse events linked to the provided biospecimen or data within 24 hours of the event occurrence.
	3. Notify the UMHS - CHIP as soon as possible if the requested biospecimen or data are no longer needed.
	4. Maintain IRB approval for use of UMHS – CHIP samples and data.
	5. Not attempt to identify research subjects for coded or de-identified data.
	6. Maintain confidentiality of all data, particularly identifiable data (PHI).
	7. Provide billing information requested by the UMHS – CHIP for retrieval, shipping or recharge costs.
	8. Return unused biospecimens to UMHS - CHIP within 12 months of project completion.
	9. Provide both raw and QC (clean) data from CHIP biospecimens within 6 months of data generation.
	10. Consider collaboration, acknowledgement or authorship positions as appropriate for investigators or biobank team members which contributed to the project in manuscripts that result from UMHS-CHIP data.
	11. Follow the biospecimen handling protocol provided by the UMHS - CHIP as well as provide a summary of the manipulations performed to the biospecimens upon its return to the CHIP biobank.
	12. Investigators are required to provide a plain language summary of their results to UMHS - CHIP for public dissemination upon publication.

**I have read and understand the aforementioned, and agree to accept biospecimen and data for research under these terms indicated herein. I agree to obtain written consent from the UMHS – CHIP prior to using these biospecimen or data outside the scope of this proposal request.**

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 Investigator Name (print)

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 Investigator Signature Date

**Appendix B.**

**Investigator Agreement**

University of Michigan Health System - Cardiovascular Health Improvement Project, Samuel and Jean Frankel Cardiovascular Center has approved the research proposal and as the principal investigator, I agree to the following:

Recipient acknowledges that the conditions for use of this research material are governed by the Institutional Review Board in accordance with Department of Health and Human Services regulations at 45 CFR 46. Recipient agrees to comply with all conditions and to promptly report to UMHS – CHIP any proposed changes in the proposal and any unanticipated problems involving risks to subjects or others. Recipient remains subject to applicable State or local laws or regulations and institutional policies which provide additional protections for human subjects.

This research material may only be utilized in accordance with the conditions stipulated by the UMHS – CHIP Internal Review Board. Any additional use of this material requires prior review and approval by the UMHS - CHIP and, where appropriate, by an Internal Review Board at the recipient site, which must be convened under an applicable Office of Human Research Protections (OHRP) - approved Assurance.

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 Investigator Name (print)

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 Investigator Signature Date