

## MULTIETHNIC COHORT DATA SHARING POLICY and PROCEDURES

The MEC investigators and institutions affirm their intention to share the research data consistent with all relevant NIH resource/data sharing policies, such as the NIH policy on Sharing Research Data as outlined in the NIH Guide (2/26/2003 and 5/7/2004), the GDS policy (08/27/2014) and with the recommendations in the 21st Century Cure Act (12/13/2016).

All researchers follow the same procedure (**Appendix A**) to apply for data or specimen use, including those from USC and UH, and those from other universities. Although co-authorship is not a requirement for accessing the MEC resource, the applicants are encouraged to discuss their proposal with a MEC researcher prior to submission to ensure that the data/material needed is available and adequate to answer the research question. This MEC researcher can assist the applicant on issues of sample size, case definition, availability of covariates and specimens and interpretation of results. For projects requiring and/or desiring long-term commitment, this MEC investigator and others, as appropriate, may serve as a co-investigator(s). All applications are reviewed by the MEC Research Committee (MECRC) following a standard procedure. Applications to use data/specimens from the MEC are made online by the applicant (<https://www.uhcancercenter.org/for-researchers/mec-data-sharing>). The application form (**Appendix B**) addresses specific questions about the research hypotheses, background/significance, preliminary data, justification for using MEC, approach and type of data and/or samples being requested. The NIH biosketch of the requestor is also submitted. If approved, applicants agree to provide any new research materials (e.g., results of lab assays, new Qx. data) for inclusion in the MEC study database, and that publications resulting from the use of the MEC resources will acknowledge the MEC grant number (U01 CA164973). The MECRC system is also used to review the applications and track them through all down-stream milestones and outcomes, and for future reference.

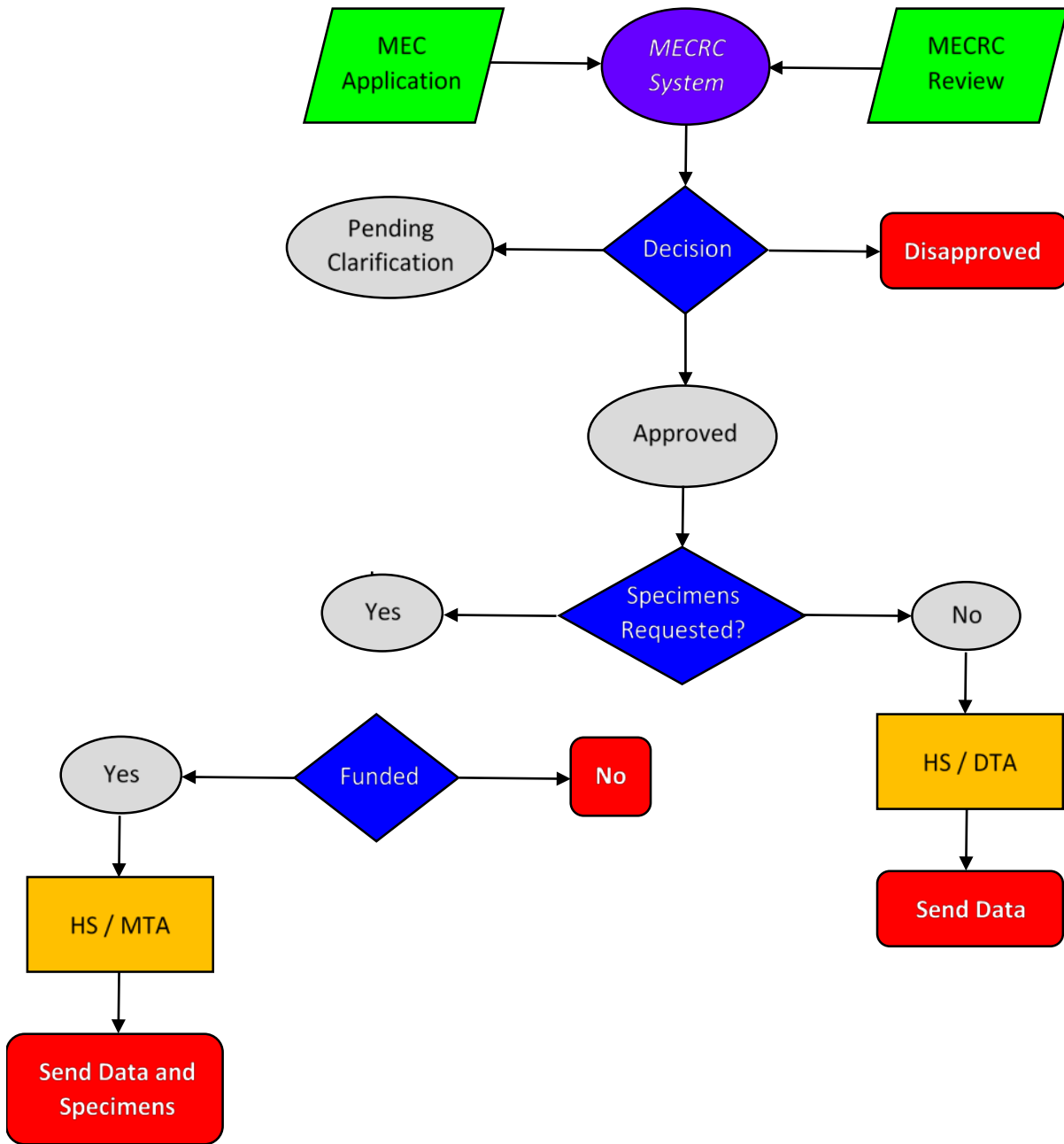
Reviews are conducted by the MECRC addressing specific pre-defined criteria (**Appendix C**). The review of data-only requests does not consider overlap. However, for requests that include biospecimens, overlap with a previously approved application may be a reason for disapproval, considering the finite nature of biospecimens. . Once the MECRC members complete their review, the chair writes a summary of the review. In the rare situation where MECRC members are divided in their opinions, a consensus is reached through further discussion. The PI is informed of the outcome by the chair and is provided comments from the reviewers. The outcome can be approved, disapproved, or decision pending further clarification. Between 1997 - 2019, over 375 applications were reviewed, 95% were approved and 5% rejected or withdrawn (typically because the MEC did not collect the material needed or the project overlapped with an on-going one). Many applications are approved after additional information is supplied by the applicant. About half of the applications are from researchers outside of UH and USC. Simple data only requests are completed without extra resources. Cost reimbursement is requested for complex data requests, such as preparation of a custom data file, selection of cases and controls, etc. Specimens are typically not provided without the project being nationally peer-reviewed, as more scrutiny is needed since they are a finite, non-renewable resource, based on a single blood draw and urine collection. Approval of a request for specimens is conditional on the funding of a grant application. However, approval for important preliminary exploratory studies for which the MEC would be uniquely suited may be considered. Remuneration is required for provision of specimens, as they require substantial staff time to retrieve. See the cost-recovery table in **Appendix D**. Due to its unique multiethnic composition, the MEC is particularly relevant to studying ethnic/racial disparities. It is also of greater value for assessing generalizability of findings obtained in another ethnic/racial group, rather than for straight replication. Therefore, special consideration is given to studies of ethnic/racial disparities. Applications are reviewed four times a year. The application deadlines are March 1, June 1, September 1 and December 1. Investigators can expect to hear back from the Research Committee Chair within four weeks of the application deadline. A progress report by the applicants is due three years after approval. If no funding was obtained or if there has not been any progress on the project, the approval may be canceled.

When the applicant is ready to receive the data or samples, an IRB application is filed with the UH and USC IRB and a Data Transfer Agreement (DTA), or Material Transfer Agreement (MTA), is prepared between UH and USC and the

receiving outside institution(s). When these documents are finalized, the data and samples are prepared for transmission, based on communication with the requestor. Shipments are tracked in the MECRC database that allows identification of the specific samples shipped and destination. All laboratory results are required to be shared with the MEC and any specimen remainders are required to be shipped back to the MEC for inclusion in a remainder biorepository. If the project is altered substantially from the time of approval, the applicants are requested to provide an amendment to their MEC application. Publications of findings using MEC and authorship on these publications must follow the Vancouver Convention (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>).

# APPENDIX A

The diagram below shows the flow of applications for the MECRC.



# APPENDIX B

## APPLICATION FOR USE OF MEC DATA OR SPECIMENS

### Date of Application:

**Lead Investigator:** *if not an investigator on the MEC study, please provide a NIH biosketch*

Name:

Institution:

e-mail:

**MEC Liaison:** *a senior investigator for the MEC study should be named, if the lead investigator is not a senior MEC investigator*

Provide a brief description of the study not to exceed 4 pages of text. The application should include the following sections:

1. Title
2. Summary: *one short paragraph*
3. Four or Five Keywords
4. Hypothesis: *clearly state the hypotheses to be tested*
5. Specific Aims
6. Background: *indicate why the hypotheses are of considerable scientific interest*
7. Rationale for using MEC resources: *indicate why a multiethnic population (in contrast to a single ethnic group) is beneficial for the study*
8. Preliminary Results: *include any preliminary findings in support of the proposed study*
9. Experimental Approach: *indicate the study population, study design, data and biospecimen requirements (table below), and a justification of the type of markers, data, methods and biospecimen needs*
10. Statistical power: *include power computation*
11. Statistical analysis: *identify the institution where the analysis will be done, the biostatistician who will assist with the analysis, and the statistical methods that will be used.*
12. Time frame for the proposed study: *example: 2018-2022, 5 years*
13. Reference list: *include authors and title.*
14. Funding: *include source and status.*
15. Acknowledgment agreement: *When given access to the MEC data/samples, the investigators agree to the following:*
  - a. *To conduct research only as approved by the MEC Research Committee (MEC RC ) and as further described in the consent form(s); no other use of the MEC resources is permitted without prior written approval from the MEC RC; an amendment to this Application is required for additional requests, and approval of the amendment from the MEC RC is required;*

- b. *To provide any new research materials (e.g., results of lab assays or new Qx. data) for inclusion in the MEC study database, where such new research materials shall be and remain vested in USC or UH, as determined by the MEC RC;*
- c. *To acknowledge UH and USC’s contribution of the MEC resources, as applicable, including acknowledgment of the MEC grant number U01CA164973 on any publication or presentation resulting from the use of the MEC resources;*
- d. *To include as authors those UH and/or USC employees who have contributed significantly to the approved project in any publication or presentation covering or arising from the results of the research; and*
- e. *To obtain IRB approval, ensure that all staff handling MEC data/samples have NIH-approved human subjects protection training, and establish a Data Transfer and Use Agreement (as applicable), prior to the commencement of the research.*
- f. *Investigators can expect to hear back from the Research Committee Chair within four weeks of the application deadline. A progress report by the applicants is due three years after approval. If no funding was obtained or if there has not been any progress on the project, the approval may be canceled.*

**Data and Biospecimen Requirements:**

Does the study require re-contacting MEC participants?	Yes: ___ No: ___
Type of specimen	Amount/volume
DNA from affected participants	
DNA from unaffected participants	
Plasma from affected participants	
For confidentiality reasons, we prefer the genotyping to be done at UHCC or USC. Do you agree to this requirement?	Yes: ___ No: ___
Plasma from unaffected participants	
Serum from affected participants	
Serum from unaffected participants	
Red cells from affected participants	
Red cells from unaffected participants	
Urine from affected participants	
Urine from unaffected participants	
Slides from paraffin embedded blocks	

# APPENDIX C

**Review Form  
Multiethnic Cohort Study  
MEC RESEARCH COMMITTEE**

**Application Number:**

**Lead Investigator:**

**Date Submitted:**

**MEC Investigators:**

**Reviewer:**

**Title:**

**Critique:**

1. The question being addressed is of considerable scientific and/or medical interest.  
Yes \_\_\_\_ No \_\_\_\_ (provide explanation below)

Comments:

2. Did the investigator justify the need for a multiethnic study population?  
Yes \_\_\_\_ No \_\_\_\_ (provide explanation below)

Comments:

3. The design is appropriate for addressing the question.  
Yes \_\_\_\_ No \_\_\_\_ (provide explanation below)

Comments:

4. The sample size is sufficient to provide a good chance of answering the question.  
Yes \_\_\_\_ No \_\_\_\_ (provide explanation below)

Comments

5. The amounts of material requested by the researchers are appropriate for the specified study, and are not excessive given the finiteness of the available material.

Yes \_\_\_\_ No \_\_\_\_ (provide explanation below) Not Applicable \_\_\_\_

Comments

6. The researchers have appropriate qualifications and experience to conduct the study.

Yes \_\_\_\_ No \_\_\_\_ (provide explanation below)

Comments

7. The proposed work could not be undertaken without the data and/or materials of the sort collected by the MEC.

Yes \_\_\_\_ No \_\_\_\_ (provide explanation below)

Comments:

Additional Comments:

**REVIEWER'S RECOMMENDATION:**

1. Approved: \_\_\_\_ *High Priority* \_\_\_\_ *Medium Priority*: \_\_\_\_ *Low Priority* \_\_\_\_

2. Approved Pending Clarification: (Explain)

3. Disapproved:

## APPENDIX D

# Cost Recovery Rates

<b>MEC RATES</b> (effective 07/01/2022)			
	<b>USC RATES</b>	<b>UH RATES*</b>	<b>UCSF RATES</b>
<b><u>Administrative costs</u></b>			
IRB support	\$2,500	\$2,573	\$2,498
Data Use Agreement, Material Use Agreement support	\$2,500	\$2,573	\$2,496
<b><u>Lab related costs (rate per sample)</u></b>			
Pull a buffy straw, extract DNA and provide aliquot	\$ 60	\$ 62	n/a
DNA aliquoting (from existing DNA)	\$ 25	\$ 26	n/a
Pull a straw/nunc (not buffy)	\$ 25	\$ 26	n/a
Pull a straw (not buffy), cut and aliquot	\$ 50	\$ 52	n/a
<b><u>Data related costs (flat rate**)</u></b>			
Selection of cases and controls for nested case-control studies		\$5,000	
Creation of dataset		\$5,000	
Additional cost for creation of a dataset that includes genetic data		\$5,000	
Additional cost for creation of a dataset that includes geospatial data		\$5,009	
<b>Notes:</b>			
* USC and UH-1 rates are the same. However, a 2.9% service fee is included for all activities managed by the Research Corporation of the UH (RCUH). Higher rates may be charged if UH involvement is needed (e.g., for legal review of unusual terms and conditions, as well as for foreign institutions) as its indirect costs are higher than RCUH's.			
Cost of shipping will be covered by applicant.			
** Data Related Costs will be charged by the institution (USC, UH, and/or UCSF) preparing the data files. Projects that require more than 40 hours of effort for any data related activities will be charged an hourly rate of \$110 for each excess hour.			