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 Data Sharing and Public Access Policy (2023).

All researchers follow the same procedure (**Appendix A**) to apply for data or specimen use. Although co-authorship is not a requirement for accessing the MEC resource, 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 (and mentor for students) is also submitted. If approved, applicants agree to provide any new research materials (e.g., results of lab assays, exposure variables, 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. All future correspondences must include the MEC application tracking number.

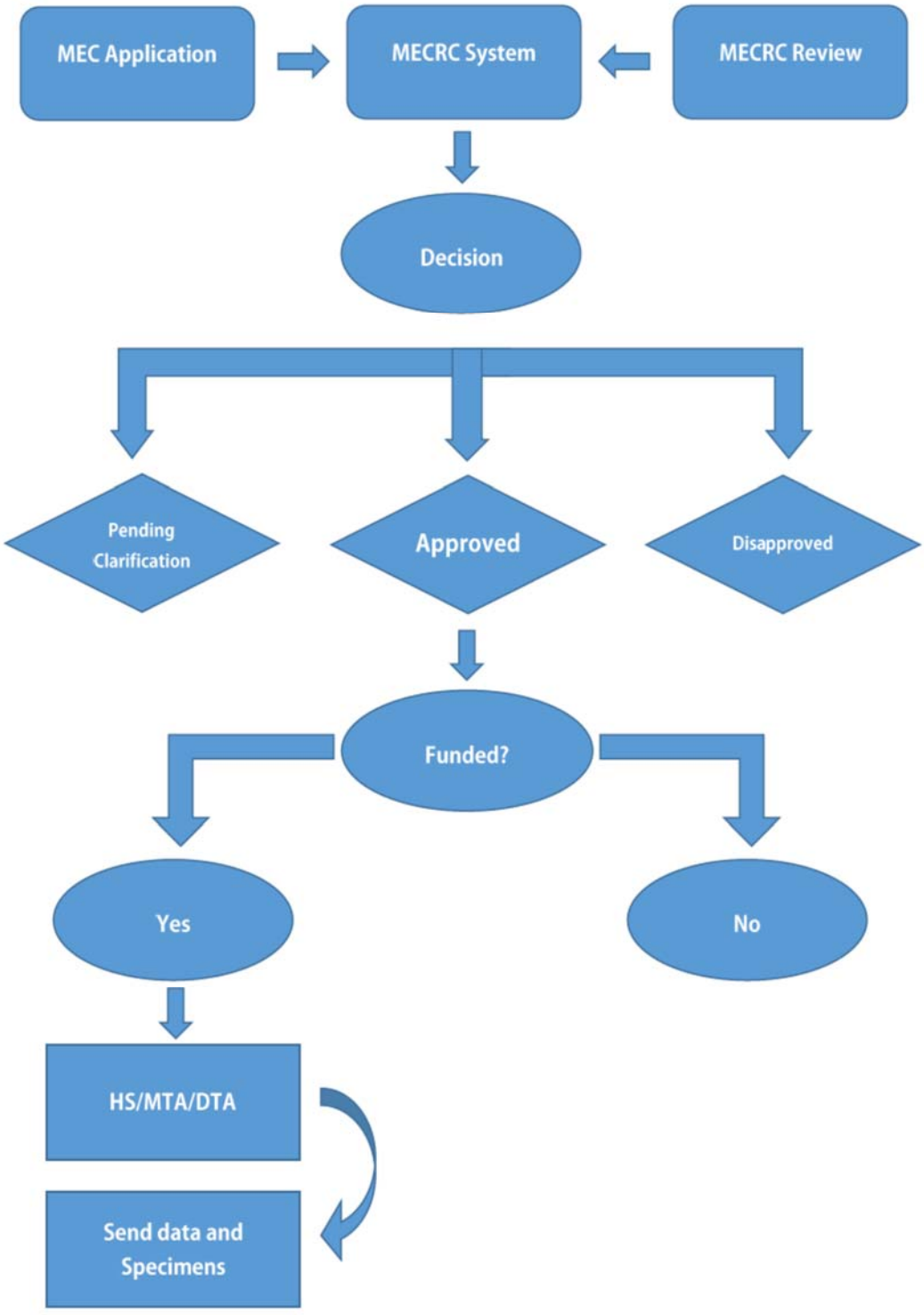
Reviews are conducted by the MECRC addressing specific pre-defined criteria (**Appendix C**). The review of data-only requests does not consider overlap. However, for requests that include biospecimens, overlap with a previously approved application may be a reason for disapproval, considering the finite 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 applicant 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 - 2023, over 577 applications were reviewed, 93% were approved and 7% rejected or withdrawn (typically because the MEC did not collect the material needed or the project overlapped with an ongoing 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. Cost reimbursement is requested for administrative support (IRBs and agreements); data requests, such as preparation of a custom data file, selection of cases and controls, etc., and provision of specimens. See the cost-recovery table in **Appendix D**. 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. 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 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, IRB applications are filed with the applicable MEC institutions (UH/USC/UCSF) and a Data Transfer and Use Agreement (DTUA), Material Transfer Agreement (MTA), and/or other relevant agreements are prepared. MEC DTUAs are based on Federal Demonstration Partnership (FDP)

Data Transfer and Use Agreement (DTUA) templates (see **Appendix E**) and are non-negotiable (meaning they cannot be modified). Templates are subject to change based on FDP and other regulatory updates. 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 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 for review. 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: 2024-2029, 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;*
    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/Material Transfer and Use Agreement (as applicable), prior to the commencement of the research. DTUA templates are non-negotiable.*
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 data	
De-identified or Limited Data Set (LDS)?	
DTUAs/MTAs are based on FDP templates (see Appendix E) and are non-negotiable. Do you agree to this requirement?	Yes: ___ No: ___
Are geospatial data requested?	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

(effective 04/01/2024)

Administrative costs	Per applicable MEC institution*
IRB support	$3,000
Data/Material Transfer and Use Agreement support	$3,000/agreement
Lab related costs	Per sample**
Pull a buffy straw, extract DNA and provide aliquot	$75
DNA aliquoting (from existing DNA)	$35
Pull a straw/nunc (not buffy)	$35
Pull a straw (not buffy), cut and aliquot	$75
Data related costs	Flat rate***
Selection of cases and controls for nested case-control studies	$7,500
Creation of straightforward dataset	$7,500
Additional cost for creation of a dataset that includes genetic data	$7,500
Additional cost for creation of a dataset that includes geospatial data	$7,500

Notes:
Rates subject to change.
*Administrative costs will be charged by each applicable MEC institution (UH, USC, UCSF) providing the services.
**Cost of shipping will be covered by applicant.
***Data related costs: Projects that require more than 40 hours of effort will be charged an hourly rate of $125 for each excess hour.

APPENDIX E

DATA TRANSFER AND USE AGREEMENT TEMPLATES

(non-negotiable)

1. De-identified Data (3-party: UH-USC-Requesting Institution)
2. Limited Data Set (3-party: UH-USC-Requesting Institution)

3. De-identified Data (4-party: UH-USC-UCSF-Requesting Institution)
4. Limited Data Set (4-party: UH-USC-UCSF-Requesting Institution)

Note: Templates are subject to change based on FDP and other regulatory updates.

FDP Collaborative Data Transfer and Use Agreement ("Agreement") **with or without FDP branding**	
Project Title: [MEC RC #: Project Title]	
Agreement Term	Start Date: Date of last signature below
	End Date: Three (3) years after the Start Date

Terms and Conditions

This Agreement is binding upon the following Parties who have executed the Signature Pages:

University of Hawaii

University of Southern California

[Requesting Institution]

1) Each Party shall provide the data set(s) described in its respective Signature Page (the "Data") to the other Parties for the research purpose set forth in Attachment 1 (the "Project"). Each Party is a Providing Party when providing Data and a Receiving Party when receiving Data. Providing Party shall retain ownership of any rights it may have in its Data and does not transfer any rights in the Data to the other Parties other than as set forth herein.

2) Receiving Party shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Receiving Party's Scientist and Receiving Party's faculty, employees, fellows, students, and agents ("Receiving Party Personnel") and Third Party Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons").

3) Except as authorized under this Agreement or otherwise required by law, Receiving Party agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Providing Party. Receiving Party agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in the applicable Attachment 2.

4) The Parties agree to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.

5) The Parties are encouraged to make publicly available the results of the Project. Before any Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the other Parties will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. The Parties contributing to each jointly authored publication will together make decisions on authorship of such publications. Authorship will be in accordance with academic and/or scholarly standards.

6) Publishing Parties agree to recognize the contribution of the Providing Parties as the source of the Data in all written, visual, or oral public disclosures concerning research using the Data, as appropriate in accordance with academic and/or scholarly standards and in any specific format that has been indicated in the applicable Providing Party's Signature Page.

7) Receiving Party shall follow all Special Instructions included in the relevant Providing Party's Signature Page applicable to the Data that Receiving Party receives.

8) This Agreement shall be effective upon the Start Date set forth above. Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this

Agreement shall expire as of the End Date set forth above. All provisions which by their nature are intended to survive termination or expiration of this Agreement shall survive.

a. Any Party may terminate their involvement in this Agreement with thirty (30) days written notice to the other Parties' Authorized Official(s) as set forth in the Signature Pages. With regards to the non-terminating Parties, this Agreement shall continue unaffected, unless mutually agreed upon between the non-terminating Parties. The terminating Party shall reasonably attempt to allow the non-terminating Parties to use the Data to complete the Project, if possible and consistent with the terminating Party's other obligations, and shall follow the reasonable written instructions of the non-terminating Parties regarding disposition of any Data obtained by it under this Agreement. The non-terminating Parties shall follow the reasonable written instructions of the terminating Party as to disposition of the terminating Party's Data; provided, however, that each Receiving Party may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.

b. Any Party may terminate this Agreement at any time if such Party has reasonably determined that another Party has materially breached its obligations to appropriately use and secure the Data in accordance with this Agreement. If appropriate pursuant to applicable law, the non-breaching Party(ies) may provide the breaching Party a thirty (30) day period to cure the alleged breach. Otherwise, this Agreement shall terminate immediately upon receipt of notification from the terminating Party to the Contact for Formal Notices listed on the Signature Page for each of the other Parties. All Parties shall promptly return or destroy the Data received under this Agreement as directed by the relevant Providing Party(ies), unless such Parties have entered into a new Data Transfer and Use Agreement to permit their continued use of the Data.

9) EXCEPT AS PROVIDED BELOW OR PROHIBITED BY LAW, ANY DATA DELIVERED PURSUANT TO THIS AGREEMENT IS UNDERSTOOD TO BE PROVIDED "AS IS." PROVIDING PARTY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Providing Party, to the best of its knowledge and belief, has the right and authority to provide the Data to Receiving Party for use in the Project.

10) Each Receiving Party shall be liable for damages, losses, claims, and demands which may arise from its use, storage, disclosure, or disposal of the Data except to the extent (a) prohibited by law and/or (b) caused by the negligence, willful misconduct, or violation of applicable privacy or security laws and regulations by the Providing Party. No indemnification for any damage, loss, claim, demand, or liability is intended or provided by any Party under this Agreement.

11) No Party shall use the other Parties' names, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of the Party whose name is to be used. The Parties agree that each Party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other Parties provided that any such statement shall accurately and appropriately describe the relationship of the Parties and shall not in any manner imply endorsement by the Party whose name is being used.

12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between the Parties regarding the transfer of the Data for the Project:

I. Signature Page for each Party, including description of such Party's Data and Disposition and Other Special Instructions
II. Attachment 1: Project Description and Public Access Requirements
III. Attachment 2: Data-specific Terms and Conditions
IV. Attachment 3: Identification of Permitted Third Parties (if any)

In the event of any conflict between the obligations set forth in the applicable Attachment 2 and this

Agreement, the obligations set forth in the applicable Attachment 2 shall prevail.

13) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly authorized representatives of all Parties.

14) In its performance of the Project, each Party shall be an independent entity and not an employee or agent of the other Parties.

15) This Agreement constitutes the entire understanding between the Parties concerning the use of and/or access to the Data transferred hereunder and supersedes any prior understanding or written or oral agreement. The illegality or invalidity of any provision of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement.

Signature of the Authorized Official of each Party appears on the Signature Page attached for such Party.

Signature Page
[MEC RC #: Project Title]

For: *University of Hawaii*
This Party is a: Both Provider and Recipient
Attachment 2 type that applies to Data Provided by this Party: De-identified Data about Human Subjects
Description of Data Provided by this Party:

The University of Hawaii will provide a dataset to [Recipient Institution] to [brief project description], as specified in Attachment 1, and subject to Attachment 2 – Other.

Disposition Instructions:

At the end of the services or when the data is no longer needed for the original intended purposes, [Recipient Institution] agrees to delete all Data provided by the University of Hawaii and/or University of Southern California in accordance with Section 8.

Other Special Instructions:

Data may be used only for the approved [MEC RC #] project.

Signature Page for University of Hawaii continued
[MEC RC #: Project Title]

Scientist Signature:
Scientist Name:
Scientist Email:

Send Data electronically to:
Name: Lynne Wilkens, DrPH
Email: lynne@cc.hawaii.edu
Address: University of Hawaii Cancer Center, 701 Ilalo St, Honolulu, HI 96813-5516

Phone: 808-564-5848

Contact Information for Formal Notices:
Name: Garret T. Yoshimi
Email: gyoshimi@hawaii.edu
Address: Information Technology Center (ITC), 2520 Correa Road, Honolulu, HI 96822

Phone: (808) 956-3501

The undersigned Authorized Official of University of Hawaii expressly represents and affirms that the contents of any statements made herein are truthful and accurate and that the undersigned is duly authorized to sign this Agreement on behalf of this institution.

UH HIPAA Approvals:
By:
Name:
Title: UH Mānoa Provost
Date:
By:
Name: Garret Yoshimi
Title: HIPAA Compliance Officer/ VP for Information Technology and Chief Information Officer
Date:
By:
Name: Loic Le Marchand
Title: Principal Investigator, MEC
Date:

Signature Page
[MEC RC #: Project Title]

For: *University of Southern California*
This Party is a: Both Provider and Recipient
Attachment 2 type that applies to Data Provided by this Party: De-identified Data about Human Subjects
Description of Data Provided by this Party:

The University of Southern California will provide a dataset to [Recipient Institution] to [brief project description], as specified in Attachment 1, and subject to Attachment 2 – Other.

Disposition Instructions:

At the end of the services or when the data is no longer needed for the original intended purposes, [Recipient Institution] agrees to delete all Data provided by the University of Hawaii and/or University of Southern California in accordance with Section 8.

Other Special Instructions:

Data may be used only for the approved [MEC RC #] project.

Signature Page for University of Southern California continued
[MEC RC #: Project Title]

Scientist Signature:
Scientist Name:
Scientist Email:

Send Data electronically to:
Name: Lynne Wilkens, DrPH
Email: lynne@cc.hawaii.edu
Address: University of Hawaii Cancer Center, 701 Ilalo St, Honolulu, HI 96813-5516

Phone: 808-564-5848

Contact Information for Formal Notices:
Name: Director of Operations
Email: mta@stevens.usc.edu
Address: University of Southern California, 1150 S. Olive Street, Suite 2300, Los Angeles, CA 90015

Phone: 213-740-5864

The undersigned Authorized Official of University of Southern California expressly represents and affirms that the contents of any statements made herein are truthful and accurate and that the undersigned is duly authorized to sign this Agreement on behalf of this institution.

Signature:

Name: Melissa Whorton
Title: Contracts Manager, USC Stevens Center for Innovation
Date:

Signature Page
[MEC RC #: Project Title]

For: *[Recipient Institution]*
This Party is a: Both Provider and Recipient
Attachment 2 type that applies to Data Provided by this Party: De-identified Data about Human Subjects
Description of Data Provided by this Party:

[Recipient Institution] shall provide any new research materials for inclusion in the MEC study database to the University of Hawaii (UH) and the University of Southern California (USC), where such new research materials shall be for research purposes only, as determined by the MEC Research Committee, per Attachment 1, and subject to Attachment 2 – Other.

Disposition Instructions:

At the end of the services or when the data is no longer needed for the original intended purposes, [Recipient Institution] agrees to delete all Data provided by the UH and/or USC in accordance with Section 8.

Other Special Instructions:

Data may be used only for the approved [MEC RC #] project.

Signature Page for [Recipient Institution] continued
[MEC RC #: Project Title]

Scientist Signature:
Scientist Name:
Scientist Email:

Send Data electronically to:
Name:
Email:
Address:

Phone:

Contact Information for Formal Notices:
Name:
Email:
Address:

Phone:

The undersigned Authorized Official of [Recipient Institution] expressly represents and affirms that the contents of any statements made herein are truthful and accurate and that the undersigned is duly authorized to sign this Agreement on behalf of this institution.

Signature:

Name:
Title:
Date:

Attachment 1
Project Description and Public Access Requirements

Project Description:
[MEC RC # and approved application**]**

Public Access Requirements:
None

Attachment 2
Data Transfer and Use Agreement
Data-specific Terms and Conditions:
De-identified Data about Human Subjects

Additional Terms and Conditions:

1. The Data will not include personally identifiable information as defined in NIST Special Publication 800-122. If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

2. If Provider is a Covered Entity, the Data will be de-identified data, as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

3. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board (IRB) approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.

4. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.

5. Recipient shall promptly report to the Provider any use or disclosure of the Data not provided for by this Agreement of which it becomes aware.

Attachment 2
Data Transfer and Use Agreement
Data-specific Terms and Conditions:
Other: MEC-Specific Terms and Conditions

Additional Terms and Conditions:

❑ None. No additional terms and conditions are required.

-OR-

✓ The additional terms and conditions are as set forth below and agreed upon between the Parties:

The University of Southern California (USC) will provide [Recipient Institution] with USC Data and the University of Hawaii (UH) will provide [Recipient Institution] with UH Data. USC Data and UH Data are proprietary to USC and UH, respectively. Notwithstanding the foregoing, UH shall provide USC Data to [Recipient Institution] on behalf of USC, upon agreement by the USC Scientist as to what of data is to be provided for the Project; such data shall continue be USC Data for purposes of the terms and conditions of this Agreement. Each of USC and UH reserves the right to distribute its own Data to others and to use its Data for its own purposes, including publishing any document relating to the Data. Furthermore, [Recipient Institution] shall provide any new research data (e.g., results of lab assays or new questionnaire data) for inclusion in the MEC study database, where such new research data shall be and remain vested in USC or UH, as determined by the MEC Research Committee, as specified in Attachment 1.

California Cancer Registry (CCR) Data - The MEC includes data obtained from the CCR specifically for purposes of MEC research. Access to CCR data is strictly limited under California law.

Safeguards must be maintained to protect the medically sensitive and confidential information on all research subjects whose information is contained in the CCR data. All cancer patient data are protected by the confidentiality requirements of the California Health and Safety Code, Sections 100330 and 103885. The confidentiality of medical information is further protected under provisions of the Government Code, Sections 6250-6265 (California Public Records Act). Provisions of the Civil Code, Section 1798-1798.70 (Information Practices Act), govern the release of personal identifiers or information that may allow identification of an individual.

By agreeing to this DTUA, you are confirming:

Office space will be secured and access to the premises limited to staff and visitors who are authorized to work with MEC data. It is the responsibility of all individuals who have access to MEC data to ensure that no confidential data are visible to visitors.
All data must be protected in a manner consistent with the current guidelines established by the institution and in accordance to requirements for access and use of CCR data.
The MEC data should never be faxed, mailed, or printed.
Any breach of confidentiality must be immediately reported to a) the individual's supervisor and b) the MEC PIs, Drs. Le Marchand, Wilkens and Haiman.
When employees who have access to MEC data are no longer employed by the institution, computer accounts (username and password) will be terminated. Employees whose accounts are terminated are responsible for ensuring that their work is confidential in nature, and this confidentiality should continue to be followed.

All individuals who request access to MEC data agree to have read, understand, and will adhere to this MEC DTUA; and to understand that any breach of confidentiality, as described in this DTUA, will be subject to disciplinary action.

Attachment 3
Identification of Permitted Third Parties (if any)

For all purposes of this Agreement, the definition of "Third Party Personnel" checked below will pertain:

- ✓ "Third Party Personnel" means: None. No Third Parties are permitted on the Project.

  -OR-

- ❑ "Third Party Personnel" means as set forth below and agreed upon between the Parties:

FDP Collaborative Data Transfer and Use Agreement ("Agreement") **with or without FDP branding**	
Project Title: [MEC RC #: Project Title]	
Agreement Term	Start Date: Date of last signature below
	End Date: Three (3) years after the Start Date

Terms and Conditions

This Agreement is binding upon the following Parties who have executed the Signature Pages:

University of Hawaii

University of Southern California

[Requesting Institution]

1) Each Party shall provide the data set(s) described in its respective Signature Page (the "Data") to the other Parties for the research purpose set forth in Attachment 1 (the "Project"). Each Party is a Providing Party when providing Data and a Receiving Party when receiving Data. Providing Party shall retain ownership of any rights it may have in its Data and does not transfer any rights in the Data to the other Parties other than as set forth herein.

2) Receiving Party shall not use the Data except as authorized under this Agreement. The Data will be used solely to conduct the Project and solely by Receiving Party's Scientist and Receiving Party's faculty, employees, fellows, students, and agents ("Receiving Party Personnel") and Third Party Personnel (as defined in Attachment 3) that have a need to use, or provide a service in respect of, the Data in connection with the Project and whose obligations of use are consistent with the terms of this Agreement (collectively, "Authorized Persons").

3) Except as authorized under this Agreement or otherwise required by law, Receiving Party agrees to retain control over the Data and shall not disclose, release, sell, rent, lease, loan, or otherwise grant access to the Data to any third party, except Authorized Persons, without the prior written consent of Providing Party. Receiving Party agrees to establish appropriate administrative, technical, and physical safeguards to prevent unauthorized use of or access to the Data and comply with any other special requirements relating to safeguarding of the Data as may be set forth in the applicable Attachment 2.

4) The Parties agree to use the Data in compliance with all applicable laws, rules, and regulations, as well as all professional standards applicable to such research.

5) The Parties are encouraged to make publicly available the results of the Project. Before any Party submits a paper or abstract for publication or otherwise intends to publicly disclose information about the results of the Project, the other Parties will have thirty (30) days from receipt to review proposed manuscripts and ten (10) days from receipt to review proposed abstracts to ensure that the Data is appropriately protected. The Parties contributing to each jointly authored publication will together make decisions on authorship of such publications. Authorship will be in accordance with academic and/or scholarly standards.

6) Publishing Parties agree to recognize the contribution of the Providing Parties as the source of the Data in all written, visual, or oral public disclosures concerning research using the Data, as appropriate in accordance with academic and/or scholarly standards and in any specific format that has been indicated in the applicable Providing Party's Signature Page.

7) Receiving Party shall follow all Special Instructions included in the relevant Providing Party's Signature Page applicable to the Data that Receiving Party receives.

8) This Agreement shall be effective upon the Start Date set forth above. Unless terminated earlier in accordance with this section or extended via a modification in accordance with Section 13, this

Agreement shall expire as of the End Date set forth above. All provisions which by their nature are intended to survive termination or expiration of this Agreement shall survive.

a. Any Party may terminate their involvement in this Agreement with thirty (30) days written notice to the other Parties' Authorized Official(s) as set forth in the Signature Pages. With regards to the non-terminating Parties, this Agreement shall continue unaffected, unless mutually agreed upon between the non-terminating Parties. The terminating Party shall reasonably attempt to allow the non-terminating Parties to use the Data to complete the Project, if possible and consistent with the terminating Party's other obligations, and shall follow the reasonable written instructions of the non-terminating Parties regarding disposition of any Data obtained by it under this Agreement. The non-terminating Parties shall follow the reasonable written instructions of the terminating Party as to disposition of the terminating Party's Data; provided, however, that each Receiving Party may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any law, and for the purposes of research integrity and verification.

b. Any Party may terminate this Agreement at any time if such Party has reasonably determined that another Party has materially breached its obligations to appropriately use and secure the Data in accordance with this Agreement. If appropriate pursuant to applicable law, the non-breaching Party(ies) may provide the breaching Party a thirty (30) day period to cure the alleged breach. Otherwise, this Agreement shall terminate immediately upon receipt of notification from the terminating Party to the Contact for Formal Notices listed on the Signature Page for each of the other Parties. All Parties shall promptly return or destroy the Data received under this Agreement as directed by the relevant Providing Party(ies), unless such Parties have entered into a new Data Transfer and Use Agreement to permit their continued use of the Data.

9) EXCEPT AS PROVIDED BELOW OR PROHIBITED BY LAW, ANY DATA DELIVERED PURSUANT TO THIS AGREEMENT IS UNDERSTOOD TO BE PROVIDED "AS IS." PROVIDING PARTY MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Providing Party, to the best of its knowledge and belief, has the right and authority to provide the Data to Receiving Party for use in the Project.

10) Each Receiving Party shall be liable for damages, losses, claims, and demands which may arise from its use, storage, disclosure, or disposal of the Data except to the extent (a) prohibited by law and/or (b) caused by the negligence, willful misconduct, or violation of applicable privacy or security laws and regulations by the Providing Party. No indemnification for any damage, loss, claim, demand, or liability is intended or provided by any Party under this Agreement.

11) No Party shall use the other Parties' names, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of the Party whose name is to be used. The Parties agree that each Party may disclose factual information regarding the existence and purpose of the relationship that is the subject of this Agreement for other purposes without written permission from the other Parties provided that any such statement shall accurately and appropriately describe the relationship of the Parties and shall not in any manner imply endorsement by the Party whose name is being used.

12) Unless otherwise specified, this Agreement and the below listed Attachments embody the entire understanding between the Parties regarding the transfer of the Data for the Project:

I. Signature Page for each Party, including description of such Party's Data and Disposition and Other Special Instructions
II. Attachment 1: Project Description and Public Access Requirements
III. Attachment 2: Data-specific Terms and Conditions
IV. Attachment 3: Identification of Permitted Third Parties (if any)

In the event of any conflict between the obligations set forth in the applicable Attachment 2 and this

Agreement, the obligations set forth in the applicable Attachment 2 shall prevail.

13) No modification or waiver of this Agreement shall be valid unless in writing and executed by duly authorized representatives of all Parties.

14) In its performance of the Project, each Party shall be an independent entity and not an employee or agent of the other Parties.

15) This Agreement constitutes the entire understanding between the Parties concerning the use of and/or access to the Data transferred hereunder and supersedes any prior understanding or written or oral agreement. The illegality or invalidity of any provision of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement.

Signature of the Authorized Official of each Party appears on the Signature Page attached for such Party.

Signature Page
[MEC RC #: Project Title]

For: *University of Hawaii*
This Party is a: Both Provider and Recipient
Attachment 2 type that applies to Data Provided by this Party: Limited Data Set
Description of Data Provided by this Party:

The University of Hawaii will provide a dataset to [Recipient Institution] to [brief project description], as specified in Attachment 1, and subject to Attachment 2 – Other.

Disposition Instructions:

At the end of the services or when the data is no longer needed for the original intended purposes, [Recipient Institution] agrees to delete all Data provided by the University of Hawaii and/or University of Southern California in accordance with Section 8.

Other Special Instructions:

Data may be used only for the approved [MEC RC #] project.

Signature Page for University of Hawaii continued
[MEC RC #: Project Title]

Scientist Signature:
Scientist Name:
Scientist Email:

Send Data electronically to:
Name: Lynne Wilkens, DrPH
Email: lynne@cc.hawaii.edu
Address: University of Hawaii Cancer Center, 701 Ilalo St, Honolulu, HI 96813-5516

Phone: 808-564-5848

Contact Information for Formal Notices:
Name: Garret T. Yoshimi
Email: gyoshimi@hawaii.edu
Address: Information Technology Center (ITC), 2520 Correa Road, Honolulu, HI 96822

Phone: (808) 956-3501

The undersigned Authorized Official of University of Hawaii expressly represents and affirms that the contents of any statements made herein are truthful and accurate and that the undersigned is duly authorized to sign this Agreement on behalf of this institution.

UH HIPAA Approvals:
By:
Name:
Title: UH Mānoa Provost
Date:
By:
Name: Garret Yoshimi
Title: HIPAA Compliance Officer/ VP for Information Technology and Chief Information Officer
Date:
By:
Name: Loic Le Marchand
Title: Principal Investigator, MEC
Date:

Signature Page
[MEC RC #: Project Title]

For: *University of Southern California*
This Party is a: Both Provider and Recipient
Attachment 2 type that applies to Data Provided by this Party: Limited Data Set
Description of Data Provided by this Party:

The University of Southern California will provide a dataset to [Recipient Institution] to [brief project description], as specified in Attachment 1, and subject to Attachment 2 – Other.

Disposition Instructions:

At the end of the services or when the data is no longer needed for the original intended purposes, [Recipient Institution] agrees to delete all Data provided by the University of Hawaii and/or University of Southern California in accordance with Section 8.

Other Special Instructions:

Data may be used only for the approved [MEC RC #] project.

Signature Page for University of Southern California continued
[MEC RC #: Project Title]

Scientist Signature:
Scientist Name:
Scientist Email:

Send Data electronically to:
Name: Lynne Wilkens, DrPH
Email: lynne@cc.hawaii.edu
Address: University of Hawaii Cancer Center, 701 Ilalo St, Honolulu, HI 96813-5516

Phone: 808-564-5848

Contact Information for Formal Notices:
Name: Director of Operations
Email: mta@stevens.usc.edu
Address: University of Southern California, 1150 S. Olive Street, Suite 2300, Los Angeles, CA 90015

Phone: 213-740-5864

The undersigned Authorized Official of University of Southern California expressly represents and affirms that the contents of any statements made herein are truthful and accurate and that the undersigned is duly authorized to sign this Agreement on behalf of this institution.

Signature:

Name: Melissa Whorton
Title: Contracts Manager, USC Stevens Center for Innovation
Date:

Signature Page
[MEC RC #: Project Title]

For: *[Recipient Institution]*
This Party is a: Both Provider and Recipient
Attachment 2 type that applies to Data Provided by this Party: Limited Data Set
Description of Data Provided by this Party:

[Recipient Institution] shall provide any new research materials for inclusion in the MEC study database to the University of Hawaiii (UH) and the University of Southern California (USC), where such new research materials shall be for research purposes only, as determined by the MEC Research Committee, per Attachment 1, and subject to Attachment 2 – Other.

Disposition Instructions:

At the end of the services or when the data is no longer needed for the original intended purposes, [Recipient Institution] agrees to delete all Data provided by the UH and/or USC in accordance with Section 8.

Other Special Instructions:

Data may be used only for the approved [MEC RC #] project.

Signature Page for [Recipient Institution] continued
[MEC RC #: Project Title]

Scientist Signature:
Scientist Name:
Scientist Email:

Send Data electronically to:
Name:
Email:
Address:

Phone:

Contact Information for Formal Notices:
Name:
Email:
Address:

Phone:

The undersigned Authorized Official of [Recipient Institution] expressly represents and affirms that the contents of any statements made herein are truthful and accurate and that the undersigned is duly authorized to sign this Agreement on behalf of this institution.

Signature:

Name:
Title:
Date:

Attachment 1
Project Description and Public Access Requirements

Project Description:
[MEC RC # and approved application**]**

Public Access Requirements:
None

Attachment 2
Data Transfer and Use Agreement
Data-specific Terms and Conditions:
Limited Data Set

Additional Terms and Conditions:

1. Nothing herein shall authorize the Recipient to use or further disclose the Data in a manner that would violate the requirements of Provider under 45 CFR 164.514.

2. Recipient shall not use or further disclose the Data other than as permitted by this Agreement or as otherwise required by law.

3. Recipient shall report to the Provider any use or disclosure of the Data not provided for by this Agreement within 5 business days of when it becomes aware of such use or disclosure.

4. Provider is a HIPAA Covered Entity, and the Data will be a Limited Data Set as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). In accordance with Section 164.514(e)(2) of the HIPAA Privacy Rule, the Data shall exclude the following direct identifiers of the individual or of relatives, employers, or household members of the individual:
   (i) Names;
   (ii) Postal address information, other than town or city, State, and zip code;
   (iii) Telephone numbers;
   (iv) Fax numbers;
   (v) Electronic mail addresses;
   (vi) Social security numbers;
   (vii) Medical record numbers;
   (viii) Health plan beneficiary numbers;
   (ix) Account numbers;
   (x) Certificate/license numbers;
   (xi) Vehicle identifiers and serial numbers, including license plate numbers;
   (xii) Device identifiers and serial numbers;
   (xiii) Web Universal Resource Locators (URLs);
   (xiv) Internet Protocol (IP) address numbers;
   (xv) Biometric identifiers, including finger and voice prints; and
   (xvi) Full face photographic images and any comparable images.
   If the Data being provided is coded, the Provider will not release, and the Recipient will not request, the key to the code.

5. Recipient will not use the Data, either alone or in concert with any other information, to make any effort to identify or contact individuals who are or may be the sources of Data without specific written approval from Provider and appropriate Institutional Review Board approval, if required pursuant to 45 CFR 46. Should Recipient inadvertently receive identifiable information or otherwise identify a subject, Recipient shall promptly notify Provider and follow Provider's reasonable written instructions, which may include return or destruction of the identifiable information.

6. By signing this Agreement, Recipient provides assurance that relevant institutional policies and applicable federal, state, or local laws and regulations (if any) have been followed, including the completion of any IRB or ethics review or approval that may be required.

7. The parties agree to take such action as is necessary to amend this Agreement, from time to time, in order for the Provider to remain in compliance with the requirements of HIPAA.

Attachment 2
Data Transfer and Use Agreement
Data-specific Terms and Conditions:
Other: MEC-Specific Terms and Conditions

Additional Terms and Conditions:

❑ None. No additional terms and conditions are required.

-OR-

✓ The additional terms and conditions are as set forth below and agreed upon between the Parties:

The University of Southern California (USC) will provide [Recipient Institution] with USC Data and the University of Hawaii (UH) will provide [Recipient Institution] with UH Data. USC Data and UH Data are proprietary to USC and UH, respectively. Notwithstanding the foregoing, UH shall provide USC Data to [Recipient Institution] on behalf of USC, upon agreement by the USC Scientist as to what of data is to be provided for the Project; such data shall continue be USC Data for purposes of the terms and conditions of this Agreement. Each of USC and UH reserves the right to distribute its own Data to others and to use its Data for its own purposes, including publishing any document relating to the Data. Furthermore, [Recipient Institution] shall provide any new research data (e.g., results of lab assays or new questionnaire data) for inclusion in the MEC study database, where such new research data shall be and remain vested in USC or UH, as determined by the MEC Research Committee, as specified in Attachment 1.

California Cancer Registry (CCR) Data - The MEC includes data obtained from the CCR specifically for purposes of MEC research. Access to CCR data is strictly limited under California law.

Safeguards must be maintained to protect the medically sensitive and confidential information on all research subjects whose information is contained in the CCR data. All cancer patient data are protected by the confidentiality requirements of the California Health and Safety Code, Sections 100330 and 103885. The confidentiality of medical information is further protected under provisions of the Government Code, Sections 6250-6265 (California Public Records Act). Provisions of the Civil Code, Section 1798-1798.70 (Information Practices Act), govern the release of personal identifiers or information that may allow identification of an individual.

By agreeing to this DTUA, you are confirming:

Office space will be secured and access to the premises limited to staff and visitors who are authorized to work with MEC data. It is the responsibility of all individuals who have access to MEC data to ensure that no confidential data are visible to visitors.
All data must be protected in a manner consistent with the current guidelines established by the institution and in accordance to requirements for access and use of CCR data.
The MEC data should never be faxed, mailed, or printed.
Any breach of confidentiality must be immediately reported to a) the individual's supervisor and b) the MEC PIs, Drs. Le Marchand, Wilkens and Haiman.
When employees who have access to MEC data are no longer employed by the institution, computer accounts (username and password) will be terminated. Employees whose accounts are terminated are responsible for ensuring that their work is confidential in nature, and this confidentiality should continue to be followed.

All individuals who request access to MEC data agree to have read, understand, and will adhere to this MEC DTUA; and to understand that any breach of confidentiality, as described in this DTUA, will be subject to disciplinary action.

Attachment 3
Identification of Permitted Third Parties (if any)

For all purposes of this Agreement, the definition of "Third Party Personnel" checked below will pertain:

- ✓ "Third Party Personnel" means: None. No Third Parties are permitted on the Project.

  -OR-

- ❑ "Third Party Personnel" means as set forth below and agreed upon between the Parties: