

PROCEDURES FOR AUTHORIZING ACCESS TO THE FERNALD MEDICAL MONITORING PROGRAM
DATABASE AND ARCHIVED BIO-SAMPLES

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Access to the Database or Archived Samples for Purposes of Analysis

Only individuals and groups specifically approved by the Fernald Community Cohort (FCC) Advisory Committee will be permitted access to the FCC database or archived samples (frozen whole blood, serum, plasma and urine).

Application

1. Any individual or group who wishes access to the FCC database or archived samples for purposes of analysis will submit an application to the FCC-Research Resources Director, who, in turn, will obtain the decision of the FCC Advisory Committee. The completed application will include the individual's name, title and affiliations, qualifications, categories of interest in the FCC data or archived specimens, and disclosure of any affiliations with persons, agencies, companies, or attorneys with an interest in the Fernald project or related projects/litigation. The application must contain a focused research question or hypothesis statement, and all of the requests for data or biosamples must relate directly to the research question or hypothesis statement. The completed application also will include a list of specific items in the database to which he/she needs access AND/OR a description of the number and types of archived samples requested. Applications requesting access to archived samples also must include a sample size calculation or statement of the number of samples needed with accompanying rationale. Applications also must include a copy of the updated NIH biosketch or curriculum vita of each investigator (but not required for lab personnel).
2. Each application for access to the database will include a confidentiality statement signed by the applicant that includes assurances that no one other than the approved person or persons will be permitted to have access to downloaded information. In addition, applicants must agree to return the downloaded data to the FCC-Research Resources program within the UC Department of Environmental Health for storage at the conclusion of their analyses or at the end of their approved access to the database. If an approved researcher wishes to retain data until a manuscript has been accepted, he/she may petition the Research Director with that request. In all cases, information/data must be returned when authorization for use expires.
3. Each application for access to archived samples will include a statement signed by the applicant specifying the disposition of the remaining sample or materials derived from the samples, once the specified analyses have been concluded. Any remaining biospecimen materials, including DNA, must be returned to the FCC Research Resources Program after the research and analyses are completed. If an approved researcher wishes to retain the remaining sample, materials from the sample, or DNA from the sample for additional research, he/she may petition the FCC Advisory Committee with that request and obtain approval for future studies.
4. The cost for extraction of DNA from the 1-1.5 ml whole blood samples must be borne by the investigator. The DNA not used for genetic or genomic analyses must be returned to the FCC.
5. Researchers asking for archived bio-samples must submit a request to the IRB for "Determining Whether an Activity is Human Subjects Research As Defined by Federal Regulations". Directions for submitting that request, specific to using FCC bio-samples, can be found in Appendix A. The application for Access to Data and Archived Samples must be accompanied by a copy of the request form, with the IRB determination and signature. (Under usual circumstances, the IRB makes a decision within one week.) If the IRB should determine that the proposed research is "Determined to be human research" then the researcher must have an approved IRB protocol prior to receiving any biosamples.
6. Researchers requesting data only do not need to submit a request to the IRB for "Determining Whether an Activity is Human Subjects Research As Defined by Federal Regulations".

7. If a researcher initially requests only bio-samples, and then later amends the application for Access to Data and Biosamples to include data about those participants, another request for “Determining Whether an Activity is Human Subjects research As Defined by Federal Regulations” must be submitted to the IRB, and a copy of the signed form must accompany the amendment to the Access to Data and Biosamples application.
8. If a researcher initially requests only data, and then later amends the application for Access to Data and Biosamples to include biosamples of those participants, another request for “Determining Whether an Activity is Human Subjects Research As Defined by Federal Regulations” must be submitted to the IRB, and a copy of the signed form must accompany the amendment to the Access to Data and Biosamples application.
9. Researchers who are approved to receive bio-samples, and then add a clinician member to the research team, must submit a request to the IRB for “Determining Whether an Activity is Human Subjects Research As Defined by Federal Regulations”, and a copy of the signed form must accompany the amendment to the Access to Data and Biosamples application (to add the clinician researcher to the project).
10. Each applicant (primary researcher and all other investigators on the research team) must read the entire policy, review and sign the statements of agreement included in the application packet. A separate form should be used for each investigator or member of the research group though only one member of a team needs to answer Questions 8, 9, and 10 if all will be working on the same project. Application forms of the other investigators (Access_Co-Investigator), which do not include answers to Questions 8, 9, and 10 should reference the exact same title of the project.
11. Everyone who either touches the data or the biospecimens is expected to submit signature pages. Each investigator must sign a separate form. Researchers who will work only with either data or archived samples will only need to sign the respective specific agreement.
12. Any change or addition to the research questions, types of data or bio-samples requested, or additional members of the research team, will require an amendment to the Access to Data and Biosamples application.
13. Graduate students may be added to the protocol at the discretion of the Research Director, without the prior approval of the Advisory Committee, if they meet the eligibility criteria currently in place pursuant to the protocol for access to the FCC Database and Biosamples.
14. Requests for additional data, necessary for the analysis of the research questions originally posed, may be approved by the Research Director without the prior approval of the Advisory Committee.

Fernald Advisory Committee Review

1. The Fernald Advisory Committee shall consist of not less than six (6) and not more than ten (10) members of the Fernald Community Cohort (participated in the Fernald Medical Monitoring Program). The Committee shall include three (3) ex officio non-voting members of the University, which shall include the Research Director and the Research Coordinator of the FCC and the Chair of the Department of Environmental Health. Finally, the Committee shall include the Trustee, if any, and Class Counsel as non-voting ex officio members. There will be no other members of the Committee.
2. The purpose of the Committee shall be to review and provide a recommendation on applications for access to and use of the FMMP Database and Bio-Specimen Collection. The University shall give due consideration to the views and recommendations of the FMMP Community members and the rest of the Committee.
3. Applications for access to and use of the FMMP Database and Bio-Specimen Collection will first be reviewed by the Research Coordinator and Research Director of the FCC to ensure that the application is responsive to the purpose of the FCC program of distributing data and biospecimens and that all necessary information is provided in the application.

4. The Research Director of the FCC cannot approve an application that would violate the anonymity or confidential information of the members of the FCC or that would violate Human Subject Research protections under federal law.
5. Following review by the Research Coordinator and Research Director of the FCC, applications will be reviewed by two faculty members from the University who will provide written feedback on the value of the research question, the credentials of the proposed principal investigator, and the methods of the proposed study.
6. Following review by the two University faculty members, applications will be mailed or e-mailed to members of the Committee prior to the Committee meeting at which the applications will be reviewed. A copy of the University faculty members' review of each application will also be included with the applications sent to Committee members prior to the Committee meeting.
7. Completed applications will be mailed (and emailed) to members of the Fernald Advisory Committee at least 5 days prior to the committee meeting at which they will be reviewed.
8. Three-fourths (3/4) of the FMMP Community members on the Committee must be present during an application review in order to establish a quorum for voting on any application. Applications for access only to data may be voted on via email, provided the number of e-mail votes of FMMP Community members on the Committee meets the voting quorum requirement. Applications that include a request for a bio-specimen will require either a conference call meeting or in-person meeting that meets the voting quorum requirement. An application must receive at least two-thirds (2/3) affirmative votes of the FMMP Community members voting quorum in order for the Committee to recommend approval.
9. The University may choose not to approve a research application that the Committee has selected for approval. If the University determines a proposed research application selected by the Committee for approval would be detrimental to the biospecimen resources, would violate the anonymity or confidentiality of the Cohort, would violate protections for human subject research or other applicable laws or regulations, is based on unsound scientific principles, and/or is likely to provide unreliable research results, then the University may choose not to approve the proposed research application. If for any of these reasons the University opts to disapprove a research application that the Committee has selected for approval, the University will provide the Committee with its specific reasons for disapproving. In the event any unusual, unforeseen, or extraordinary circumstances arise not listed above, the parties agree to jointly request an in-person or telephone conference with the Court, which shall make the final determination whether there is good cause for denying the proposed research application."
10. Under usual circumstances, applicants will receive a written response regarding their application from the Research Director within twelve weeks of submission of the application.

Biospecimens and Data

1. Studies incorporating uranium or radiation exposure are asked to use the exposure estimates that have previously been calculated as part of or using the algorithms from the Fernald Dosimetry Reconstruction project.
2. Archived biosamples will be designated as either Priority 1 or Priority 2 samples.
 - Priority 1 samples are:
 - a) All samples (all of the 15 aliquots collected at the time of the first examination, and any whole blood, serum or urine samples collected subsequently) of the 1000 FCC participants with the highest Exposure Index scores and,

b) The last sample of any type (whole blood, serum, plasma, unbuffered urine, buffered urine) of those with an exposure greater than background, as determined by the Exposure Index score (approximately 30% of participants).

Priority 2 samples are all other biospecimen samples.

3. For studies where exposure to radiation or uranium is an eligibility requirement or a measurement, the Research Director will inform the Citizens' Advisory Committee, prior to their consideration of the application, of the type and number of Priority 1 samples required for the study.

4. For studies requesting biosamples, for which radiation or uranium exposure is not an eligibility requirement nor a measurement, Priority 2 biosamples will be provided after the Access application is approved.

4. If some Priority 1 samples also are needed for the sample size requirements for the study (as with a relatively rare disease or condition), the Research Director will submit to the Citizens' Advisory Committee the type and number of Priority 1 samples needed. In most cases, the information will be given to the committee at the meeting after the meeting at which they approved the application (and use of the Priority 2 samples for the study).

5. The Citizens' Advisory Committee then will be asked to make a recommendation regarding whether the Priority 1 samples should be provided to the Investigator in addition to the Priority 2 samples.

6. Investigators must describe the specific analyses they will perform on the samples in Section 8 of the application, including specific marker, genes or polymorphisms they will be examining. Prior to receiving any samples, investigators must demonstrate proof of having funding to perform these analyses, and the time frame in which they will be performed. Investigators must also obtain from the laboratory the amount of sample needed for the assay. The FCC will aliquot stock sample to provide just that amount for the study. If additional sample is required and the reason is justifiable, the FCC will then provide the additional sample.

7. If the study requires DNA, the DNA will be isolated from the whole blood sample. The investigator must pay for the isolation, which will be done by the DEH genotyping Core or another laboratory designated by the FCC. Sufficient DNA for the experiment will be distributed to the investigator and the remaining DNA will remain with the FCC archive.

8. All individuals who have been granted access to data only will be provided with a downloaded data file with records identified by the FCC "Research ID", a record identifier that is distinctly different from the FCC participant ID. Only the program will have access to a linkage file of Research ID's and participant ID's.

9. All individuals who have been granted access to bio-samples or both data and bio-samples may receive both with the FCC medical record number as the identifier. The bio-samples, collected as early as 1990, are labeled with the FCC medical record number and cannot be re-labeled. If aliquots are created, the aliquot will be labeled with the Research ID.

10. Researchers will take receipt of data files or archived samples in accordance with FCC procedures that will document receipt of those items.

11. All data files and copies of data must be returned to the FCC at either the conclusion of the data analyses or the approved access period, whichever occurs first. The return of data must follow FCC procedures that will document its return.

12. Upon completion of analyses of archived samples or the approved access period, whichever occurs first, researchers must either return the remaining sample to the FCC or document the disposal of any remaining samples or materials obtained from those samples. (The FCC Research Director will decide whether the sample should be returned or disposed.) If samples or products from those samples are to be retained for future studies, the research must petition the FCC Research Director and also submit a new application to the FCC [see Section 1. b). 2).]

13. Any environmental biomarker measurement data obtain through use of the FCC biospecimens must be returned to the FCC data archive within six months of the publication using those data. Other investigators will not be permitted to use these data unless they have first obtained the written permission of the investigator who provided the data.

14. Any genetic or genomic data obtained through the use of the FCC biospecimens must be returned to the FCC archive within six months of the publication using those data. Other investigators will not be permitted to use these data unless they have first obtained the written permission of the investigator who provided the data.
15. If the use of the FCC biospecimens results in a patent application, the FCC will receive 10% of the investigators' and/or university departmental proceeds of the patent.
16. All individuals or groups who have been granted access to either data or samples are required to provide an annual progress report to the Research Director annually in order to continue to use the data files or specimens for analyses. The FCC Research Director then will report annually to the FCC-Custodial Citizen's Advisory Committee on the progress of specific analyses being conducted by approved individuals or groups.
17. Researchers approved for access to data or archived samples have permission to use the data or samples only for the analyses that address the research questions detailed in the application.
18. The FCC, including the FCC-Research Resources Program, has received expedited review and approval from the University of Cincinnati Institutional Review Board. An informed consent was obtained every time a participant presented for a medical examination. This consent specifically stated that the data may be made available for epidemiologic studies. The consent obtained at the medical examination when blood biosamples were obtained specifies that specimens will be stored and used for research. A copy of the FCC IRB approval and consent form is available on the website <http://med.uc.edu/eh/research/projects/fcc> or may be obtained from the Research Coordinator at 513-558-0487.

Publication of Results

1. All abstracts, manuscripts or presentations reporting results of analyses of the FCC database or archived samples will be submitted to Research Director, or designee, for review prior to submission to a conference or professional journal and prior to any other publication or dissemination.
2. The purpose of this request is to ensure that the FCC eligibility and procedures are correctly stated, the role of the FCC is appropriately acknowledged, and the confidentiality of all participants is preserved. Under most circumstances, the Research Director will respond within five (5) business days.
3. All abstracts, posters, manuscripts and presentations must acknowledge the Fernald Medical Monitoring Program as the source of the data or biosamples used in the research and analyses. It is desirable to include the FCC website url in the document. Funding to the FCC must be acknowledged by inclusion of the grant number in the acknowledgements section; the investigator must obtain these grant numbers from the Research Director.
4. Studies that use the FCC exposure estimates should include as an author one of the investigators that created those exposure estimates.
5. A copy of an accepted manuscript or abstract must be provided to the Research Director or designee prior to publication (including online publication). A copy of accepted abstracts or manuscripts also will be shared with the FCC Citizen's Advisory Committee. On a quarterly basis, members of the Citizens' Advisory Committee will be apprised of publications resulting from these studies. Whenever possible without copyright infringement, copies full publications or abstracts will be posted on the FCC website.
6. All analyses will be conducted in such a way that the identity of individuals remains confidential. Also, all manuscripts will be written so that no identification of individuals is possible.

Priorities

1. Neither data downloading and analysis functions, nor sample removal and transfer functions, will be permitted to interfere with the ordinary functioning of the FCC.
2. Analyses that are directly relevant to the Class should be given priority over those that are non-Fernald related.

Fees for distribution of Data and Biosamples to Approved Researchers

1. In order to preserve the Fernald Medical Monitoring Program Research Resources, approved researchers will be required to pay an amount determined by the University of Cincinnati Recharge Council following the direction of government cost compliance. Costs are determined each year by the University of Cincinnati Recharge Council and are attached.

2. Each investigator should determine that they have the most current cost schedule each time they submit a grant proposal, including at the time of a resubmission. Please contact the Research Coordinator to verify that you have the current costs.

3. Data files for approved users:

Basic fee: There is a basic fee for a data file. The Research Director or Research Coordinator will assist the applicant by providing answers to questions about the database, identifying the exact data elements requested and their associated variable names, submitting a request to the data manager. This fee will also cover later answering questions about the data and addressing needs for additional data, and up to 2 hours of effort from data manager to prepare the data files.

Additional data file needs: There is a per hour fee for additional data needs for the research consultation and for the data manager.

4. Medical record retrieval: There is a fee for each request for medical record retrieval. This fee covers obtaining the signed release from the FCC participant, requesting the medical record from the clinical site, assuring that the correct information was sent, redacting all identifying information, and providing the medical record information to the research scientist.

5. Biosamples for approved users: Basic fee: There is a small fee per specimen to cover the personnel effort to actually locate and remove the specimens from the freezers, assuming a team of 4 persons, of which 3 are supplied from the FCC group and the 4th comes from the researcher's lab.

The amounts stated above represent actual costs, and include no indirect costs. The amounts also do include some fees for business administration for drafting an agreement for charges, billing for charges, etc.

6. These fees would apply to all researchers using federal funds to pay for the FCC data and biospecimens. For others, the market rate will apply.

7. The Advisory Group may elect to subsidize these fees for unfunded researchers (using data and biosamples for preliminary data for grant proposal) or graduate students.

Completed applications should be sent to the FCC Research Director:

Susan M. Pinney, PhD.

Susan.pinney@uc.edu

Fax number for signature pages: 513-558-4240

Questions regarding this application may be directed to the Research Coordinator, Menahil Rahman at (513) 558-0487 or (rahmanml@ucmail.uc.edu) or to Dr. Susan Pinney at (513) 558-0684 (susan.pinney@uc.edu).