

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

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1. Access to the Database or Archived Samples for Purposes of Analysis

- a.) 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).
- b.) 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. If the application requests data only (no biosamples requested) the Committee may meet by telephone conference to review the application and make a recommendation. Applications that request biosamples must be reviewed and voted upon at an in-person Committee meeting. .

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.

- 1.) 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.
- 2.) 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 whole genome amplified 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 amplified DNA from the sample for additional research, he/she may petition the FCC al Advisory Committee with that request and obtain approval for future studies.

- c.) 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.
- d.) 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”.
- e.) 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.
- f.) 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.
- g.) 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).
- h.) A copy of the application for Access to Data and Archived Samples will be provided to the FCC Advisory Committee for their review prior to a meeting or phone call for deciding about authorization of access.
- i.) 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.
 - 1.) 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.

- 2.) 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.

2. Biospecimens and Data

- a.) Archived biosamples will be designated as either Priority 1 or Priority 2 samples.
 - 1.) 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).
 - 2.) Priority 2 samples are all other biospecimen samples.
- b.) 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.
- c.) 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.
 - 1). 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).
 - 2). 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.
- d.) 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.
- e.) 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.

- f.) All individuals who have been granted access to bio-samples or both data and bio-samples will 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.
- g.) Researchers will take receipt of data files or archived samples in accordance with FCC procedures that will document receipt of those items.
 - 1.) 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.
 - 2.) Upon completion of analyses of archived samples or the approved access period, whichever occurs first, researchers must document the disposal of any remaining samples or materials obtained from those samples. If samples or products from those samples are to be retained for future studies, the research must petition the Fernald Trustee [see Section 1. b). 2).]
- h.) 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.
- i.) 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.
- j.) 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 is obtained every time a participant presents for a medical examination. This consent specifically states 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://eh.uc.edu/fmmp> or may be obtained from the Research Coordinator at 513-558-0487.

3. Publication of Results

- a.) 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.
- b.) 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.
- c.) All 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.
- d.) 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.

4. Confidentiality

- a.) 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.

5. Priorities

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

6. Fees for distribution of Data and Biosamples to Approved Researchers

- a.) In order to preserve the Fernald Medical Monitoring Program Research Resources, approved researchers will be required to pay an amount equal to the cost of the effort to distribute the requested research resources. Costs are determined each year by the University of Cincinnati Recharge Council and are attached.
- b.) Data files for approved users:

Basic fee: There is a basic fee for a data file (includes up to 10 hours of consultation with the Research Director or the Research Coordinator) to 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 the time associated with 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.

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.

c.) 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.

d.) The amounts stated on the attached form 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.

e.) These fees would apply to funded researchers, regardless whether their funds were from a federal agency or from a regional or local source of funding. 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.

FERNALD MEDICAL MONITORING PROGRAM (FCC)
INSTRUCTIONS AND INFORMATION FOR APPLICATIONS
FOR ACCESS TO DATA AND ARCHIVED SAMPLES

Instructions

1. Complete the enclosed application and return it to the FCC Research Director:
Susan M. Pinney, PhD.
Susan.pinney@uc.edu
Fax number for signature pages: 513-558-4240

Or by mail to:
Susan M. Pinney, PhD
Department of Environmental Health
University of Cincinnati College of Medicine
PO Box 670056
Cincinnati, OH 45267-0056

A separate form should be used for each investigator 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), on which Questions 8, 9, and 10 are not completed, should reference the exact same title of the project. Questions regarding this application may be directed to the Program Coordinator, Jeanette Buckholz at (513) 558-04887 or (buckhojm@ucmail.uc.edu) or to Dr. Susan Pinney at (513) 558-0684 (susan.pinney@uc.edu) .

2. Please enclose an up-to-date NIH biosketch, for each member of the research team, with each application form.
3. If the applications requests Access to Archived Samples, please include a copy of your signed "Determining Whether an Activity is Human Subjects Research" form, and the IRB study approval notice, if your research was determined to be human subjects research..
4. Each applicant (primary researcher and all other investigators on the research team) must review and sign the statements of agreement included in the application packet. Each investigator must sign a separate form. Please note that two types of agreement statements are included with the application forms. The scope of the request to the FCC (data file or archived samples or both) will determine whether the primary researcher of the team needs to sign one or both agreement statements. In a study where the primary investigator signs both agreement statements, the roles of the other research team members will determine whether they need to sign one or both agreements. Researchers who will work only with either data or archived samples will only need to sign the respective specific agreement.

5. Under usual circumstances, applicants will receive a written response regarding their application from the Research Director (Dr. Pinney) within twelve weeks of submission of the application.