

**FERNALD MEDICAL MONITORING PROGRAM (FMMP)
APPLICATION FOR ACCESS TO THE FMMP DATABASE OR ARCHIVED SAMPLES**

STUDY TITLE: _____

1. **Application Date:** _____ **Approval Date:** _____

2. **Applicant's Name:** _____

Principal Investigator: Yes No

Project Name (if different from study title): _____

3. **Address:** _____

4. **Phone Number:** _____

Email address: _____

5. **Title (s):** _____

6. **Institutional Affiliation(s):** _____

7. **Do you have any affiliation with persons/agencies including but not limited to the DOE, DOD, and CDC, companies, or attorneys with an interest in the Fernald Medical Monitoring Program or Fernald Settlement Fund or related projects/litigation?**

No

Yes

If yes, please explain in detail any such affiliations (attach additional pages if necessary).

8. Are you requesting (please check one or both options):

Downloaded data file from the FMMP database

Archived biospecimens

Describe the research questions and/or hypotheses for which you intend to use the FMMP data or archived samples (attach additional pages if necessary). The research question or hypothesis should be focused with well-defined dependent and independent variables. Please identify the study design (case-control, cross-sectional, prospective, intervention, etc.)

9a. Are you requesting a data file? Yes No

If you are requesting a data file, please identify the categories of data in the FMMP Database that you would require to perform your analyses. If you have examined the FMMP database data dictionary, you may use a separate page to list the specific variables (and the file source of the variable).

Please indicate Specify type of data in each category:

- | | | |
|-----------------------------|------------------------------|---|
| <input type="checkbox"/> NO | <input type="checkbox"/> YES | Demographic Data: |
| <input type="checkbox"/> NO | <input type="checkbox"/> YES | Questionnaire Data (specify): |
| <input type="checkbox"/> NO | <input type="checkbox"/> YES | History and Physical Exam Data (specify): |
| <input type="checkbox"/> NO | <input type="checkbox"/> YES | Lab Data (specify): |
| <input type="checkbox"/> NO | <input type="checkbox"/> YES | Other Test Data (specify): |

9b. Are you requesting archived samples? YES NO

If you are requesting archived samples, specify the number and types of samples you require for your study. Additionally, present your eligibility requirements and sample size calculations or other documentation of the need for the quantity of samples you are requesting. If you are not requesting samples, write in a "0" for each type of sample.

	Number of samples requested	Amount of sample needed
Whole blood		
Plasma		
Serum		
Urine – not buffered		
Urine - buffered		

What are the eligibility requirements for the participants providing these samples (such as sex, age at sample collection, presence or absence of certain diagnoses, etc.)?

What data do you need about the participants providing the samples? (Please include these data request in your response to question 9a and also sign the data agreement in addition to the sample agreement.)

Please provide sample size calculations or other documentation of the need for the quantity of samples you have requested. (You may attach this explanation and documentation.)

10. IRB Institution: University of Cincinnati Medical IRB _____

Study IRB Number: _____ Approval Expires on _____
Please attach a copy of your latest IRB approval memo.

11. Describe how your proposed analyses will benefit the FMMP participants or the public at large.

AGREEMENT FOR USE OF THE FMMP DATABASE

STUDY TITLE:

1. I attest that I have no personal interest in the Fernald Settlement Fund, related projects, or related litigation other than what is listed on my application. I further attest that I have no affiliations with individuals, attorneys, or companies who have an interest in the FMMP or related litigation other than those listed on my application.
2. I agree to maintain strict confidentiality of the data I receive from the Fernald Program.
3. I agree that no one other than persons named in the application (s) and myself be permitted to have access to data from the Fernald Medical Monitoring Program.
4. I agree to return the original Fernald data and any copies of the original data to the Trustees for storage at the conclusion of the analyses or at the end of my approved interval of access.
5. I understand that the FMMP and the Fernald Settlement Fund are not responsible for costs incurred in downloading and analyzing the data.
6. I agree to conduct only those analyses that are outlined in my application.
7. I agree to submit a brief annual progress report to Dr. Robert Wones.
8. I agree to provide a copy of any abstract, manuscript or presentation, reporting results of analyses of the FMMP database or archived samples, to the Trustee or his designee for review prior to submission to a conference or professional journal and prior to any other publication or dissemination. Under most circumstances, the Trustee will respond within five (5) business days.
9. I agree to conduct my analyses in such a way that the identity of individuals, if known, will remain confidential.
10. I agree that all manuscripts of results from my analysis will be written so that no identification of individuals is possible. I will acknowledge the Fernald Medical Monitoring Program as the source of the data for my analyses.

Signature: _____

Print name: _____

Date: _____

AGREEMENT FOR USE OF THE FMMP ARCHIVED SAMPLES

STUDY TITLE:

1. I attest that I have no personal interest in the Fernald Settlement Fund, related projects, or related litigation other than what is listed on my application. I further attest that I have no affiliations with individuals, attorneys, or companies who have an interest in the FMMP or related litigation other than those listed on my application.
2. I agree to maintain strict confidentiality of individual information (including genotypes) that I acquire from specimens received from the Fernald Program.
3. I agree that no one other than persons named in the application (s) and myself, and staff who work directly under our supervision, will be permitted to have access to the samples from the Fernald Medical Monitoring Program.
4. Upon the conclusion of the study described in this application, I agree to either dispose of biospecimen samples remaining after my analyses and any materials derived from those samples or to amend my application to the Fernald Trustee for use of the samples another study. If I wish to retain any remaining sample, materials from the sample, or amplified DNA from the sample for additional research, I agree to first petition the Trustee with that request and obtain the Trustee's approval before conducting any additional analyses.
5. I understand that the FMMP and the Fernald Settlement Fund are not responsible for costs incurred in preparation or analysis of samples.
6. I agree to conduct only those analyses that are outlined in my application.
7. I agree to submit a brief annual progress report to Dr. Robert Wones.
8. I agree to provide a copy of any abstract, manuscript or presentation, reporting results of analyses of the FMMP database or archived samples, to the Trustee or his designee for review prior to submission to a conference or professional journal and prior to any other publication or dissemination. Under most circumstances, the Trustee will respond within five (5) business days.
9. I agree to conduct my analyses in such a way that the identity of individuals, if known, will remain confidential.
10. I agree that all manuscripts of results from my analysis will be written so that no identification of individuals is possible. I will acknowledge the Fernald Medical Monitoring Program as the source of the biospecimens used in my research, and the source of the corresponding data.

Signature: _____

Print Name: _____

Date: _____