

**RESOLUTION OF THE
WHITE MOUNTAIN APACHE TRIBE OF THE
FORT APACHE INDIAN RESERVATION**

- WHEREAS**, the Tribal Council is aware that the Mother/Infant Gestational Diabetes Project was initiated under a three year NIH/NIDDK grant which funded examination of gestational diabetes at the Whiteriver Service Unit in Whiteriver under the direction of Dr. Dorothy Hollingsworth in the Fall of 1993; and
- WHEREAS**, after enrolling several hundred patients, the project was found to have significant deficiencies in relation to IRB standards of informed consent; and
- WHEREAS**, in early 1995, the Project was permanently suspended on the combined recommendation of IRB authorities at the Indian Health Service and the University of California, San Diego, the institution which sponsored Dr. Hollingsworth; and
- WHEREAS**, during a sequence of events surrounding the Project's termination, Dr. Hollingsworth sequestered some existing data, destroyed some blood samples and dispatched an inflammatory letter to an unknown number of project participants; and
- WHEREAS**, the foregoing actions caused significant confusion among project participants as well as potential damage to future IHS/NIH/UCSD White Mountain Apache Tribal research activities; and
- WHEREAS**, the Tribal Council previously directed that a resolution of these remaining problems be attempted by IHS and UCSD authorities; and
- WHEREAS**, the Whiteriver Service Unit has distributed for Tribal Council review recommendations for closure of the Mother/Infant Gestational Diabetes Project and a methodology for same; and
- WHEREAS**, said project closure method would identify two project employees, Ms. Donna Preckshot and Ms. Mary Jane Tenijieth as qualified individuals to provide a brief presentation to project participants relative to the goals of final closure; and
- WHEREAS**, the goals of final closure of the project have been identified and explained to the Tribal Council and are attached to this resolution and incorporated by reference herein; and



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MOTHER/INFANT GESTATIONAL DIABETES PROJECT CLOSURE

INTRODUCTION

The Mother/Infant Project, a three year NIH/NIDDK grant funded examination of gestational diabetes at the WRSU, began in Whiteriver under the direction of Dr. Dorothy Hollingsworth in the fall of 1993. After enrolling several hundred patients, the project was found to have significant deficiencies in relation to IRB standards of informed consent. In early 1995, the project was permanently suspended on the combined recommendation of IRB authorities at the IHS and the University of California San Diego (Dr. Hollingsworth's sponsoring institution).

In an unfortunate sequence of events surrounding the project's termination, Dr. Hollingsworth sequestered some existing data, destroyed some blood samples, and dispatched a inflammatory letter to an unknown number of project participants. These actions have since been appreciated to have caused significant confusion among project participants, as well as the potential for damage to future IHS/NIH/UCSD/WMAT research activities. The WMAT has clearly stated that a resolution of these remaining problems must be attempted by IHS and UCSD authorities.

Through UCSD negotiations, data sequestered by Dr. Hollingsworth, including patient master lists and computer files, has been returned to UCSD. An inventory of items remaining at WRSU located approximately 150-200 "Apache Food Frequency Questionnaires" (AFFQ), a nutritional survey administered by the MI Project under the guidance of Ms. Nicolette Teufel (University of Arizona College of Medicine). A coordinated review of all the remaining data by UCSD and WRSU officials has produced the consensus recommendation that only the AFFQ possess any scientific value. Unfortunately, these surveys were obtained without proper consent, and participants must be reconsented if this collection is to be analyzed. All other data, including several hundred frozen blood samples in storage at UCSD, are deemed to be too unreliable and disorganized to be of scientific value. It is the recommendation of the IHS and UCSD that data other than the AFFQ be summarily destroyed.

PROJECT CLOSURE PURPOSE

The goals of final closure of this project are as follows:

- 1) Identify project participants who received potentially confusing verbal or written information from Dr. Hollingsworth.
- 2) Adequately inform all project participants of the exact circumstances surrounding the project's termination.
- 3) Identify and reply to any remaining concerns of project participants.
- 4) Inform project participants about the status of project data, including destruction plans.
- 5) Attempt to obtain re-consent for AFFQ.

It was the consensus opinion of IHS and UCSD authorities that these goals would be best met through individual interviews with project participants. Accordingly, NIH funding was requested and received to sponsor such interviews of all identifiable project participants.

PROJECT CLOSURE METHOD

Two former project employees, Ms. Donna Preckshot and Ms. Mary Jane Tenijeth, were identified as qualified individuals who would be accepted by project participants in providing a brief presentation relative to the above goals. Both women are knowledgeable of the projects methods, yet are not associated with the derogatory actions of the former principal investigator.

Funding has been obtained through NIH/UCSD to sponsor both women as UCSD employees for a period of approximately 6-8 weeks during the summer of 1995. During this time, an attempt will be made to contact each former project participant. Once contacted, each participant will be asked to participate in a 30-40 presentation with the following tentative format:

MOTHER INFANT CLOSURE PRESENTATION

I) Project Review

- A. Review of Participant's Status in Project
- B. Review of Initial Project Goals
- C. Review of General Issues Relating to Project Termination
 - 1) Consent Difficulties
 - 2) IRB/IHS/UCSD Roles

II) Potential Areas of Confusion

- A. Review of 1/95 Letter From DH
- B. Review of other questions/rumors


III) Project Closure Steps

- A. AFFQ Reconsent (where applicable)
- B. Review of Data Destruction Plans
- C. Dissemination of Phone Numbers/Pamphlets for Possible Future Questions

PROJECT CLOSURE TIMELINE

June 2-18	Development of AAFQ Consent Form by UCSD Development of Project Closure Presentation Outline by WRSU (above) Hiring of Donna Preckshot and Mary Jane Tenijeth on consultant basis by UCSD)
June 7	Approval of Project Closure Plan . . . (including Data Destruction Plan) by WMAT Council (to be presented by Steve Garrett/George Hess)
June 19	Finalization of Project Closure Plan (conference call - UCSD/WRSU/IHS IRB)
June 20	Begin participant interviews
August 20	Completion Participant Interviews
September 1	Destruction of Remaining Project Data Assignment of Reconsented AFFQ to N Teufel Reporting of Project Closure Activities to WMAT Council

Throughout this time period, all parties will meet on a regular (weekly or biweekly) basis by conference call.



David A. Yost, M.D.
WRSU - Clinical Director

6/2/95
Date