

APPLICATION FOR CONTINUED APPROVAL

FINAL REPORT

Application and related materials should be forwarded to the IRB chair electronically and should then be followed by hard copies, including signed application.

<p>Date of Application: Current Expiration Date: Title of study: DMHAS Study ID Number: Principal investigator Name and Title: Institutional Affiliation : Address: City: State: Zip code: Phone: Fax : E-mail:</p> <p>Alternate contact if applicable Name and Title: Address: City: State: Zip code: Phone: Fax : E-mail:</p>
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<p>Co-investigators/institutional affiliation</p> <table><tr><td>Name:</td><td>Title:</td><td>Institution:</td></tr><tr><td>Name:</td><td>Title:</td><td>Institution:</td></tr><tr><td>Name:</td><td>Title:</td><td>Institution:</td></tr><tr><td>Name:</td><td>Title:</td><td>Institution:</td></tr><tr><td>Name:</td><td>Title:</td><td>Institution:</td></tr></table>	Name:	Title:	Institution:	Name:	Title:	Institution:	Name:	Title:	Institution:	Name:	Title:	Institution:	Name:	Title:	Institution:
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<p>Please list the addition of any key personnel since time of last review. Please attach documentation of education in the protection of human subjects.</p> <table><tr><td>Name:</td><td>Title:</td></tr><tr><td>Name:</td><td>Title:</td></tr><tr><td>Name:</td><td>Title:</td></tr></table> <p>Current IRB approvals from other institutions (please include copy of most recent approval)</p> <table><tr><td>Approval date:</td><td>Institution:</td></tr><tr><td>Approval date:</td><td>Institution:</td></tr></table>	Name:	Title:	Name:	Title:	Name:	Title:	Approval date:	Institution:	Approval date:	Institution:
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If, at time of initial approval, the plan was to obtain a Confidentiality Certificate, please note date of issuance: n/a

Has a waiver or alteration of consent requirements been approved? yes no
Are any changes in procedure planned in relation to the informed consent process? yes no If yes, please describe:

Anticipated or actual end date of study:

Current recruitment sites:
Please identify any DMHAS site where recruitment has ended since last review:

Current study sites (where study intervention(s) occur):
Please identify any DMHAS site where research activity has ended since last review:

Is the study permanently closed to enrollment of new participants? yes no
Is the remaining research activity limited to data analysis only? yes no If yes, have all identifiers or links to identifiers been removed from the data being analyzed? yes no.
If all data has been de-identified with no way to link the data to participants a Final Report should be filed at this time.

Total number of participants targeted for enrollment in study:
Total number of DMHAS participants targeted for enrollment in the study:
Total number of participants enrolled since initial approval:
Total number of DMHAS participants enrolled since initial approval:
Total number of participants enrolled since last review:
Number of participants enrolled from DMHAS sites since last review:
Number of participants still active in the study:
If the number of participants enrolled differs significantly from stated plan please explain discrepancy:

Total Number of Participants Enrolled to Date by Ethnicity and Race

Ethnic Category	Sex Gender			Total
	Female	Male	Unkn	
Hispanic or Latino				
Not Hispanic				

Ethnic Category: Total of All Study Participants *

Racial Categories
American Indian/Alaska Native
Asian
Native Hawaiian or Other Pacific Islander
Black or African American
White
Other

Racial Categories: Total of all Study Participants*

- The “Ethnic Category: Total of All Study Participants” must be equal to the “Racial Categories: Total of All Study Participants”

Please describe the manner in which computer and non-computer research data is being stored to ensure security and confidentiality:

Total number of people who began consent process but declined to participate since beginning of study:
Number of people who began consent process but declined to participate since last review ; and their reasons:
Total number of participants who have withdrawn since beginning of study:
Number of participants who have withdrawn from the study since last review ; and their reasons:
Total number of participants who have been withdrawn from the study by the investigator since beginning of study:
Number of participants who have been withdrawn from the study by the investigator since last review ; and the reasons:

Brief summary of the course of the study so far including the experience of the participants:

Brief summary of findings to date:

Total number of adverse events since beginning of study:
Total number and summary of any adverse events that have occurred since last review:
In addition to unanticipated and serious adverse events, please include anticipated adverse events or reactions. Please describe action taken to ameliorate any discomfort or negative consequence related to the adverse event(s) occurring since last review and/or to eliminate recurrence:

Total number of complaints received since beginning of study:
Number and summary of any complaints received since last review regarding the study:
Please note any actions taken as a result of complaint(s):

Total number of protocol deviations since beginning of study:
Number and summary of each protocol deviation since last review: Please note any actions taken as a result of deviation(s):

Does recent literature or findings obtained thus far suggest a change in the level of risk or represent additional information that might impact a subject's decision to participate or to continue participation in the study. yes no If yes, please summarize and indicate if the appropriate information has been shared with participants?

List changes in protocol, informed consent or other study documents that have been approved by the IRB since the last review:

Change:	Date of IRB Approval:
Change:	Date of IRB Approval:
Change:	Date of IRB Approval:
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The Principal Investigator should review the consent document to ensure that the description of the purpose and procedures and the disclosure of the risks and benefits are still adequately addressed in the informed consent form.

At this time would you like the IRB to review any new proposed changes in the protocol, informed consent form, recruitment material, instruments, investigators, or other aspect of or material related to the study? yes no If yes, please summarize request and rationale and include copy of proposed revised protocol and/or consent form or other material as appropriate (please highlight, underline or otherwise clearly identify proposed changes and note revision date on material(s) where applicable; Please also submit clean copy (s)) to be stamped following approval.

For ongoing studies, please attach a copy of the current approved protocol that includes any changes that have been approved since the last IRB review, consent form and as applicable, release of information, recruitment materials, and other approved materials. If enrollment has ended the consent form and related documents do not need to be submitted.

Disposal of Material

DMHAS IRB Policy states “Records related to the conduct and documentation of IRB activities will be maintained for three years. Specific research files will be maintained for at least three years after completion of the research.” The Office for Human Research Protections (OHRP) states, “All signed consent documents are to be retained for at least three years after the completion of the research and according to institutional policy.”

Based on the DMHAS IRB policy and the OHRP policy of a three-year retention of records, please state when and how you plan to dispose of all study material.

Principal Investigator – Signature

Date