

APPLICATION FOR IRB APPROVAL

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

Date of Application:
Title of study:
Principal investigator
 Name and title:
 Institutional Affiliation:
 Address:
 Phone:
 Fax:
 E-mail:

Alternate contact if applicable
 Name and title:
 Address:
 Phone:
 Fax:
 E-mail:

PLEASE NOTE that for research not sponsored or conducted by DMHAS, State-operated facility endorsement and Commissioner approval is required. Research conducted by student employees of DMHAS whose research is related to educational requirements is considered to be non-DMHAS sponsored. See *“Guidelines for Investigators”*

Co-investigators and institutional affiliation

Name:	Title:	Institution:
Name:	Title:	Institution:
Name:	Title:	Institution:
Name:	Title:	Institution:
Name:	Title:	Institution:

Please list key personnel not noted above

Name:	Title:
Name:	Title:
Name:	Title:
Name:	Title:
Name:	Title:

Education in the protection of human research participants: please provide a letter that includes the names of the key personnel who are responsible for the design and conduct of the study; the title of the education program completed by each named personnel; the date of completion; plus

a one sentence description of the program. This letter should be signed by the principal investigator and co-signed by an institution official. Where available, the following may be substituted: copy of similar documentation letter used in relation to the funding application or for documentation for other purposes; and/or copies of certificates documenting training.

Source(s) of funding: Note: copy of grant application should be included with IRB application

Other IRB reviews (note date of approval and include copy, or note if pending)

Approval date:

Institution:

Approval date:

Institution:

Dates of study (start/end dates):

Is an exemption being requested? yes no

If yes, please cite qualifying regulation and explain how the study design qualifies :

Recruitment Sites:

Study Sites (where will study intervention(s) occur):

Check here if study involves record/chart review only

Total number of participants to be recruited:

Number of participants to be recruited from DMHAS sites:

If record/chart review only, how many records will be reviewed:

Background information and purpose of study:

Do study procedures involve collection of identifying private information about individuals other than those enrolled in the study? yes no

If yes, please describe:

Do study procedures include sharing of any participant data and/or biological material with any other entity outside of the research study? yes no If yes, please describe and also address within the consent document:

Will application be made for a Confidentiality Certificate? yes no

Will or may study enrollment begin before receipt of a Confidentiality Certificate? yes no

PLEASE NOTE that participants must be made aware of the status of the application at the time of enrollment, and documentation must be forwarded to the IRB upon receipt of the certificate.

Does the study involve the use of FDA regulated drugs or devices: yes no

If yes, please describe:

Will any of the following populations be enrolled in this study?

Children: yes no

If yes, please cite the applicable regulation under which their inclusion is permitted:

Where applicable, please include copy of the children's consent form.

Prisoners: yes no

If yes, please cite the applicable regulation under which their inclusion is permitted:

Will any participant be originally enrolled in the study while in a prison setting? yes
 no Please note specifically what intervention(s) will occur in the prison setting, the number of planned contacts in the prison setting; the time involved in each contact and the period of time over which contact in the prison setting will occur:

Will the intervention(s) that occur in the prison setting be the same for all participants?
 yes no. If no, please describe any differences

Please include copy of consent form to be utilized in the prison setting (a separate consent form developed specifically for prisoner participants is required).

Mentally/cognitively impaired yes no

Economically/educationally disadvantaged yes no

Individuals with a conservator yes no

Other potentially vulnerable population yes no If yes, please describe:

Non-English speaking yes no

If yes, will study materials be translated? yes no

If yes, please note which materials will be translated and describe the process followed for translating study materials. (Translated versions of consent forms, recruitment material and other applicable study materials must be submitted to the IRB for approval. It is suggested that translations be submitted following approval of the English version):

DMHAS employees yes no

Employees from non-DMHAS institutions yes

Target Population: please describe characteristics of study population; please note inclusion criteria, and exclusion criteria and rationale:

Number of Participants Targeted for Enrollment by Ethnicity and Race			
Ethnic Category	Sex Gender		
	Female	Male	Total
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”

Recruitment: please be specific about each step; who will contact potential study participants; how will they be contacted; describe the use of any form of public announcement that participants will hear or see (e.g., brochure, poster, letter, radio, etc. - please note that

recruitment material must be submitted for review and approval); where applicable, at what point will release of information forms be signed:

Informed Consent:

Is a waiver or alteration of informed consent requirements being requested? yes no If yes, please complete *Application for Waiver of Consent Requirement*.

Identify who (e.g., research interviewer, research assistant, clinical staff, etc) will administer informed consent:

When and where will informed consent be administered?

Where applicable, describe procedures to determine if a participant has a conservator of person and to obtain the consent of conservators:

Where applicable, describe the method of determining if participants and/ or their conservator or guardian understand the information conveyed during the informed consent process:

Where there will be periodic contacts with participants over an extended period of time, please describe the manner in which the participant's ongoing consent is ensured and how they are reminded that they may withdraw at any time:

For non-English speaking participants only, please check one:

Informed consent will be: translated in its entirety or presented orally, and accompanied by a short form, and written summary

Note: consent forms and other relevant study forms should include version date.

HIPAA/Protected Health Information:

Do study procedures involve the use or disclosure of Protected Health Information (PHI) as defined by the Privacy Rule? yes no – see *Guidelines for Investigators for info on HIPAA*

Do study procedures involve the use or disclosure of PHI without informing the research participant? yes no If yes, please complete the *Application for Waiver of HIPAA Authorization Requirements*.

Procedures/Methods: please provide full description and sequence of activities, interactions, interventions that the participant will be expected to take part in; identify and describe all procedures to be utilized, i.e., blood test, interview, GAF, focus group, etc.; anticipated location of research activities/intervention(s) and time involved; expected duration of participants' involvement over the course of the study; number of expected contacts with the participant over the course of the participant's involvement; other information as appropriate. If research activity involves collection or review of data please describe the type of data and how and where it will be accessed:

List all surveys, questionnaires, interviews or other instruments to be utilized (please submit one hard copy of all instruments and, if over 5 pages, also submit an electronic copy):

May the participant decide not to consent to any aspect of the research and still continue in the study ,i.e., audio taping of interview, storage of genetic material, contacting family members, etc.? yes no n/a If yes, please describe how the participant may exercise this option:

Risks: describe any possible physical, psychological, social and economic/financial risk and/or discomfort to participants AND how risk and/or discomfort will be minimized:

Benefits: will participants derive any benefit from study involvement? yes no If yes, please describe:

Does the research include a data or safety-monitoring plan? yes no If yes, please describe and identify those responsible for data monitoring:

Confidentiality: describe procedures to ensure participant confidentiality; describe the manner in which computer and non-computer research data will be stored to ensure confidentiality; indicate who will have access (type of personnel versus specific individuals) to identifiable information about the participants; what provisions have been made for the preservation of anonymity and confidentiality in the transmittal of data; describe any confidentiality agreements signed by research staff:

Financial Arrangements: describe any exchange of funds or other compensation from the study to participants, staff at study sites or centers/hospitals where the study is being conducted (please note specific amounts and method of payment/ transfer):

Please describe the plan to provide participants with an opportunity to learn about the findings of the study:

Attachments checklist

Where applicable, attachments should include:

- Funding application
 - Informed consent form
 - Recruitment material such as posters, flyers, letters, information sheet public announcements, etc.
 - Any questionnaires or data collection instruments (where instruments consist of more than 5 pages an electronic copy of the instruments should be submitted to the chair in addition to 1 hard copy).
 - Release of information form
 - HIPAA Authorization form
 - Scripts to guide interviews or presentations of verbal information
 - General outline or focus of interview/interaction where interaction will be semi structured.
- Other as applicable**

Conflict of Interest Declaration

Does the Principal Investigator or other key personnel have a financial interest or relationship or an administrative affiliation with the entity providing funds for the study? yes no

If yes, please specify the nature of the interest or relationship:

Is there a possibility that the Principal Investigator or other key personnel will gain financial benefit from the conduct of the study? yes no

If yes, please explain:

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.

Investigators Continuing Responsibilities Following IRB Approval

The study must be re-approved in order for research activities to continue beyond the approval expiration date. It is the investigators’ responsibility to submit an Application for Continued Approval in a timely manner.

If any changes are contemplated following the date of approval, an Application for Approval of Revision must be submitted to the IRB for review and approval before implementation. No changes to the approved protocol, informed consent, or other study documents utilized with participants (documents or material signed, seen or heard by participants, including instruments) may be made without IRB approval.

Where applicable, approved changes must be incorporated into the IRB application/protocol and submitted to the IRB.

The IRB committee requests that they are informed of any adverse events as outlined in the OOC IRB Guidelines for Investigators.

No changes to the approved protocol or informed consent may be made without IRB approval.

I have listed any conflict of interest; understand my continuing responsibilities following IRB approval; and agree to comply with DMHAS IRB procedures as outlined in the OOC IRB Guidelines.

Principal Investigator - Signature

Date