**APPLICATION FOR IRB APPROVAL**

**Email this form and all study documents in Microsoft® Word format to** **mhadmhasirb@ct.gov**

**TITLE OF STUDY:**

**DATE OF APPLICATION:**

**PRINCIPAL INVESTIGATOR**

 **Name and title:**

 **Institutional Affiliation:**

 **Address:**

 **Phone:**

 **E-mail:**

**CO-INVESTIGATORS AND INSTITUTIONAL AFFILIATION**

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

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

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

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

**ALTERNATE CONTACT IF APPLICABLE**

 **Name and title:**

 **Institutional Affiliation:**

 **Address:**

 **Phone:**

 **E-mail:**

**OTHER KEY PERSONNEL NOT LISTED ABOVE**

 **Name:**       **Title:**

 **Name:**       **Title:**

 **Name:**       **Title:**

 **Name:**       **Title:**

 **Name:**       **Title:**

**EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS**

**Attach certificate of completion of education in the protection of human subjects for all study personnel.**

**IF RESEARCH IS NOT SPONSORED BY DMHAS, DESCRIBE QUALIFICATIONS TO CONDUCT RESEARCH**

**For all key personnel, describe education and experience in conducting research:**

**SOURCE(S) OF FUNDING**

**OTHER IRB REVIEWS**

 **Approval date:**       **Institution:**

 **Approval date:**       **Institution:**

 **Approval date:**       **Institution:**

**NOTE: IF IRB approval is pending, enter “pending” instead of approval date. Attach copies of all other IRB determinations.**

**START AND END DATES OF STUDY**

**REQUEST FOR EXEMPTION FROM REGULATIONS**

**Is an exemption from the regulations being requested?** **[ ] Yes [ ] No**

**If yes, please cite the applicable §46.104(d) category and explain how the study design meets the criteria for exemption:**

**REQUEST FOR** **NON-RESEARCH DETERMINATION**

**Is a non-research determination being requested? [ ] Yes [ ] No**

**Is this research designed to contribute to generalizable knowledge beyond the present study?**

**[ ] Yes [ ] No**

**If yes, please explain why this study does not constitute research:**

**PURPOSE OF RESEARCH**

**Describe the purpose of the study:**

**What specific question(s) will the research answer?**

**References for works cited:**

**PROCEDURES**

**[ ]  Check here if the ONLY procedure is to obtain, use, study, analyze, or generate identifiable private information or identifiable biospecimens.**

**Describe the type of information or biospecimen and how these items will be accessed.**

**[ ]  Check here if the research involves obtaining information or biospecimens through intervention or interaction with participants, and the use, study, or analysis of the information or biospecimens.**

**Describe, in the order in which they will occur, all interventions or interactions in which study participants will take part and the amount of time each contact will take:**

**What is the number of expected contacts with participants over the course of the study?**

**What is the expected duration of participants' involvement in the study?**

**METHODS**

**Describe data analysis methods:**

**Describe how data analysis will answer the research questions:**

**INSTRUMENTS**

**List all surveys, questionnaires, interviews or other instruments to be used:**

**RECRUITMENT SITES**

**List all locations where participant recruitment or access to identifiable private information or identifiable biospecimens will take place:**

**Total number of participants to be recruited or whose identifiable private information or identifiable biospecimens will be obtained:**

**Number of participants to be recruited or whose identifiable private information or identifiable biospecimens will be obtained from DMHAS sites:**

**STUDY SITES**

**List all locations where study activities, interventions, or interactions involving contact with participants will occur:**

**STUDY POPULATION**

# Describe characteristics of study population and rationale:

**Inclusion criteria:**

**Exclusion criteria:**

**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, include copy of the children’s consent form.**

**Prisoners:** **[ ] Yes** **[ ] No. If yes, cite the section of Subpart C under which their inclusion is permitted:**

**Will any participant be initially enrolled in the study while in a prison setting? [ ] Yes [ ] No.**

**If yes, describe in order all activities, interventions, or interactions that will occur in the prison setting:**

**What is the number of planned contacts with participants in the prison setting and the amount of time each contact will take?**

**What is the expected duration of participants' involvement in the study in the prison setting?**

**Will the intervention(s) that occur in the prison setting be the same for all participants? [ ] Yes [ ] No**

**If no, please describe any differences:**

**NOTE: A separate consent form must be developed specifically for prisoner participants.**

**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 indicate which materials will be translated and describe the process that will be used for translating study materials:**

**NOTE: Translated versions of all study materials must be submitted to the IRB for review and approval. It is suggested that translations be submitted following approval of the English version.**

**DMHAS employees:** **[ ] Yes** **[ ] No**

**Employees from non-DMHAS institutions:** **[ ] Yes** **[ ] No**

| **Planned Number of Participants by Ethnicity and Race (Complete one chart for each study population (e.g., consumers, staff, etc.)** |
| --- |

| **Study Population Name:**  | **Sex/Gender** |
| --- | --- |
| **Female** | **Male** | **Total** |
| **Ethnic Category** |  |  |  |
|  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\*** |  |  |  |

| **Study Population Name:**  | **Sex/Gender** |
| --- | --- |
| **Female** | **Male** | **Total** |
| **Ethnic Category** |  |  |  |
|  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.” |

**INFORMED CONSENT**

**Recruitment**

**Who will recruit potential study participants (e.g., research staff, clinical staff, etc.)?**

**How participants will be recruited (e.g., in-person, phone, or email)?**

**Describe any form of public announcement that participants will hear or see (e.g., brochure, poster, letter, media, etc.):**

**Waiver of Documentation of Consent**

**Is a waiver of documentation of consent being requested? [ ] Yes [ ] No**

 **If yes, submit an Application for Waiver or Documentation of Consent and submit the information sheet that will serve as informed consent and complete the informed consent form section.**

**Waiver or Alteration of Consent**

**Is a waiver or alteration of consent being requested? [ ] Yes [ ] No**

 **If yes, submit an Application for Waiver or Alteration of Consent.**

 **If no, complete the following section.**

**Informed Consent Form**

**Please check to indicate that you have included each of the following required elements in the informed consent form.**

 **Key Information: Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or conservator in understanding the reasons why one might or might not want to participate in the research, including the following:**

 **[ ]**  **The fact that consent is being sought for research and that participation is voluntary**

 **[ ]**  **The purposes of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research**

 **[ ]**  **The reasonably foreseeable risks or discomforts to the prospective subject**

 **[ ]**  **The beneﬁts to the prospective subject or others that may reasonably be expected from the research**

 **[ ]**  **Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the prospective subject**

 **[ ]  Procedures: A description of the procedures to be followed and identification of any procedures that are experimental.**

 **[ ]  Risks: A description of any reasonably foreseeable risks or discomforts to the subject.**

 **[ ]  Benefits: A description of any benefits to the subject or to others that may reasonably be expected from the research.**

 **[ ]  Incentives: Describe any incentives that will be given to study participants, including specific amounts and method of payment.**

 **[ ]  Alternative Procedures: A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.**

 **[ ]  Confidentiality: A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.**

 **[ ]  If Injury Occurs: For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.**

 **[ ]  Contacts: An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject.** Also include: If you have any questions about your rights as a participant in research, please contact Janet Storey, Chair of the Department of Mental Health and Addiction Services Institutional Review Board at 860-418-6823 or janet.storey@ct.gov.

 **[ ]  Voluntary Participation: A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and**

 **[ ]  Future Research: One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:**

 **[ ]**  **A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or**

 **[ ]**  **A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.**

**Additional Elements: When appropriate, one or more of the following elements of information shall also be provided to each subject or the legally authorized representative. (Enter NA if not applicable to study:**      **)**

 **[ ]  A statement that the particular treatment or procedure may involve risks to the subject that is currently unforeseeable**

 **[ ]  Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative’s consent**

 **[ ]  Any additional costs to the subject that may result from participation in the research**

 **[ ]  The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject**

 **[ ]  A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject**

 **[ ]  The approximate number of subjects involved in the study**

 **[ ]  A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;**

 **[ ]  A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and**

 **[ ]  For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).**

 **[ ]  A statement regarding whether study procedures include sharing of any participant data and/or biological material with any other entity outside of the research study.**

**Administration of Informed Consent**

**Who will administer informed consent (e.g., research staff, clinical staff, etc.)?**

**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 the conservator:**

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

**Where there will be periodic contacts with participants over an extended period of time, describe the manner in which the participant’s ongoing consent will be ensured and how they will be 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.**

**HIPAA/PROTECTED HEALTH INFORMATION:**

**Do study procedures involve the use or disclosure of Protected Health Information (PHI) as defined by the HIPAA Privacy Rule? [ ] Yes [ ] No. See DMHAS Commissioner's IRB Policy 8.1 for information on HIPAA.**

**If yes, at what point will a Release of PHI form be signed?**

**Do study procedures involve the use or disclosure of PHI without informing the research participant?**

**[ ] Yes [ ] No. If yes, complete the Application for Waiver of HIPAA Authorization Requirements.**

**Do study procedures involve collection of identifying private information about individuals other than those enrolled in the study? [ ] Yes [ ] No. If yes, please describe:**

**CERTIFICATE OF CONFIDENTIALITY**

**Will application be made for a Confidentiality Certificate? [ ] Yes [ ] No**

**Will or may study enrollment begin before receipt of a Confidentiality Certificate? [ ] Yes [ ] No**

**NOTE: 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.**

**SAFETY MONITORING**

**Does the research include a plan to monitor study data to ensure the safety of participants?**

**[ ] Yes [ ] No**

**If yes, describe the plan and identify those responsible for data monitoring:**

**FDA**

**Does the study involve the use of FDA regulated drugs or devices: [ ] Yes [ ] No. If yes, please describe:**

**ATTACHMENTS CHECKLIST**

**[ ]  Recruitment material (i.e., posters, flyers, letters, information sheet, script, public announcements, etc.)**

**[ ]  Informed consent form**

**[ ]  Application for Waiver of Required Elements of Informed Consent**

**[ ]  Application for Waiver of Documentation of Informed Consent**

**[ ]  Release of Information/HIPAA Authorization form**

**[ ]  Application for Waiver of HIPAA Authorization Requirement**

**[ ]  All questionnaires or data collection instruments**

**[ ]  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:**

**DISPOSAL OF MATERIAL**

**Based on DMHAS IRB and OHRP policy of three-year retention of records, state the date and method in which study documentation will be destroyed:**

**By printing my name below, I certify the following:**

* ***I will conduct the research as described in this application and approved by the DMHAS IRB.***
* ***No changes in approved staff, procedures, methods, informed consent forms, other study documents signed, seen or heard by participants, including instruments, will be made without prior DMHAS IRB approval.***
* ***I will promptly report to the DMHAS IRB any adverse events, protocol deviations, or unanticipated problems involving risks to subjects or others participating in the approved research.***
* ***I will comply with the requirements of the DMHAS Commissioner's IRB Policy Chapter 8.1 and HHS regulations at*** [***45 CFR 46***](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html) ***Protection of Human Subjects.***

**Principal Investigator Name Date Time**