

- Authorization Agreement Applies
- SO Facility Notification Required
- Commissioner Approval Required

DMHAS OOC IRB REVIEWER CHECK LIST – INITIAL APPLICATION

Title of Study: _____ Date of Review: _____

Reviewer: _____

Page 1 serves as research record face sheet

Checklist	y	n	n/a	Comment
<input type="checkbox"/> Education in human subject protection has been documented for key personnel				
<input type="checkbox"/> Investigator is qualified to conduct study				
<input type="checkbox"/> Federal funding <input type="checkbox"/> If yes, grant application is included <input type="checkbox"/> Other				
Recruitment site(s) include: <input type="checkbox"/> State operated (facility must be notified of IRB actions) <input type="checkbox"/> DMHAS funded <input type="checkbox"/> Other				
Study site(s) include: <input type="checkbox"/> State operated (facility must be notified of IRB actions) <input type="checkbox"/> DMHAS funded <input type="checkbox"/> Other				
<input type="checkbox"/> Study reviewed by another institution's IRB <input type="checkbox"/> Copy of other institution's approval has been submitted				
<input type="checkbox"/> Exemption is being requested - separate checklist <input type="checkbox"/> Eligible <input type="checkbox"/> Not eligible				
<input type="checkbox"/> Study involves collecting and recording Identifying private information about individuals other than target participants				
<input type="checkbox"/> Study involves sharing data and/or biological material with entities outside of the study				
<input type="checkbox"/> Study involves the use of FDA regulated drugs or devices				
Study involves the following population(s): <input type="checkbox"/> Children – separate checklist <input type="checkbox"/> Prisoners – separate checklist <input type="checkbox"/> Pregnant women/fetuses <input type="checkbox"/> Mentally/cognitively impaired <input type="checkbox"/> Economically/educationally disadvantaged <input type="checkbox"/> Other potentially vulnerable population <input type="checkbox"/> Non- English speaking <input type="checkbox"/> DMHAS staff <input type="checkbox"/> non-DMHAS staff				
<input type="checkbox"/> Request is made to waive requirement to obtain consent or alter some or all required elements of informed consent <input type="checkbox"/> Eligible <input type="checkbox"/> Not eligible - See waiver application <input type="checkbox"/> Request is made to waive requirement to obtain signed consent (applies to documentation of informed consent) <input type="checkbox"/> Eligible <input type="checkbox"/> Not eligible - See waiver application <input type="checkbox"/> Waiver of HIPAA Authorization requested <input type="checkbox"/> Eligible <input type="checkbox"/> Not eligible - See waiver application				
<input type="checkbox"/> Necessary study documents and materials are included (recruitment material, instruments, ROI, questionnaires, scripts, etc)				
Checklist	y	n	n/a	Comment

<p>Recruitment</p> <p><input type="checkbox"/> A detailed account of recruitment steps is outlined (who will contact potential study participants; how will they be contacted; description of any form of public announcement; where applicable, at what point will release of information forms be signed.</p> <p><input type="checkbox"/> Recruitment process, including staff assigned, does not contribute to perceived or real pressure, coercion or undue influence. Public solicitation is not misleading and free of undue influence.</p> <p><input type="checkbox"/> Adequate mechanisms exist for the use of a release of information prior to identification of prospective participants.</p> <p><input type="checkbox"/> The amount of financial reimbursement is commensurate with the activities required by the participant's participation.</p>				
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Checklist	y	n	n/a	Comment
<p>Administration of Informed Consent</p> <p><input type="checkbox"/> Staff administering informed consent is identified.</p> <p><input type="checkbox"/> Location and timing of consent process is described</p> <p><input type="checkbox"/> Where applicable procedures to determine if a participant has a conservator of person and to obtain the consent of conservators are described.</p> <p><input type="checkbox"/> Where applicable, the method of determining if participants or their conservator understand the information conveyed during the informed consent process is described.</p> <p><input type="checkbox"/> Where applicable, procedures to administer informed consent to non-English speaking participants are described.</p> <p><input type="checkbox"/> Where a release of information form is required in the recruitment process or for the exchange of information between research staff and a third party, the release of information form adequately describes the proposed exchange of information</p>				

Checklist	y	n	n/a	Comment
<p>Confidentiality</p> <p><input type="checkbox"/> Procedures are adequate to maintain confidentiality, anonymity, security and privacy of the participants.</p> <p><input type="checkbox"/> Non-computer data will be maintained in a secure manner.</p> <p><input type="checkbox"/> Computer data will be maintained in a secure manner.</p> <p><input checked="" type="checkbox"/> Confidentiality Certificate will be obtained</p>				

Checklist	y	n	n/a	Comment
<p>Consent Form **Required element as outlined in 46.116</p> <p>Invitation to Participate</p> <p><input type="checkbox"/> Participant is invited to participate.</p> <p><input type="checkbox"/> Participant is informed as to why they have been selected to participate.</p> <p><input type="checkbox"/> It is clear that what the participant is being invited to participate in is research **</p> <p><input type="checkbox"/> The purpose of the research is explained.**</p> <p><input type="checkbox"/> Participant informed that participation is strictly voluntary; that they do not have to participate; and that a decision not to participate will have no adverse effect or result in a loss of benefits. **</p> <p><input type="checkbox"/> Participant is informed that they may withdraw at any time and that withdrawal will have no adverse effect; or where there will be an effect, the effect is adequately explained **</p> <p>Procedures</p> <p><input type="checkbox"/> Participant informed exactly of what their part in the research will consist of i.e., activity; frequency of activity; approximately how long activity will take; location of activity-if known; and over what period of time the research will extend. **</p> <p><input type="checkbox"/> The consent form adequately describes the use of any instruments or data collection tools to be utilized.</p> <p><input type="checkbox"/> Participant informed of any procedures or interventions that are experimental**</p> <p><input type="checkbox"/> Disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject. **</p> <p><input type="checkbox"/> Where applicable, description of information to be exchanged between research staff and any third party.</p> <p>Risks/Benefits</p> <p><input type="checkbox"/> Any foreseeable risks, discomforts or inconveniences (physical, psychological, financial, etc) to the participant or their guardian have been adequately described**; and where applicable, participant made aware of any factors that might increase the risk to them personally should they choose to participate</p> <p><input type="checkbox"/> Participant informed of any anticipated benefit to them, and if no direct benefit is anticipated, the participant is informed of this. **</p> <p><input type="checkbox"/> Participant informed of what will be done to minimize risk.</p>				

Checklist	y	n	n/a	Comment
<p>Consent Form - risks/benefits – continued</p> <p><input type="checkbox"/> Participant informed of what will be done to respond to any foreseeable or unforeseeable adverse reactions</p> <p><input type="checkbox"/> For research involving more than minimal risk, an explanation and description of any compensation and any medical treatment that are available if participants are injured through participation and where further information can be obtained**</p> <p>Financial Considerations</p> <p><input type="checkbox"/> Participant is informed of any compensation that will be made for participation as well as the method and timing of payment.</p> <p>Confidentiality</p> <p><input type="checkbox"/> Participant is informed of the extent to which confidentiality of records will be maintained.**</p> <p><input type="checkbox"/> The conditions under which confidentiality will be broken are explained to the participant, i.e. danger to self or others, abuse of child or incapacitated adult</p> <p>Misc</p> <p><input type="checkbox"/> The language is clear, understandable, in lay terms and appropriate for the population to which the participant belongs</p> <p><input type="checkbox"/> The participant is made aware of whom to contact for questions related to the study; related to the participants' rights and related to reporting a complaint or research related injury.**</p> <p>Additional Required Elements</p> <p>When appropriate, one or more of the following elements of information shall also be provided to the participant.</p> <p><input type="checkbox"/> If the participant is or may become pregnant, a statement that the particular treatment or procedure may involve risks, foreseeable or currently unforeseeable, to the participant, or to the embryo or fetus.**</p> <p><input type="checkbox"/> A description of circumstances in which the participant's participation may be terminate by the investigator without the participant's consent.**</p> <p><input type="checkbox"/> Any cost to the participant that may result from participation in the research.**</p> <p><input type="checkbox"/> The possible consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation.**</p> <p><input type="checkbox"/> A statement that the PI will notify participants of any significant new findings developed during the course of the study that may affect them an d influence their willingness to continue participation.**</p> <p><input type="checkbox"/> The approximate number of participants involved in the study.**</p>				

Checklist	y	n	n/a	Comment
HIPAA <input type="checkbox"/> Informed consent document, alone or in combination with additional release of information/authorization is in compliance with HIPAA authorization requirements.				

Checklist	y	n	n/a	Comment
Criteria for IRB Approval (46.111) <input type="checkbox"/> 1. Risks to participants are minimized. Is the proposed research design scientifically sound; will unnecessarily expose participants to risk. Is the hypothesis clear? Is the design appropriate to prove the hypothesis? Will the research contribute to generalizable knowledge & is it worth exposing participants to risk? <input type="checkbox"/> 2. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of knowledge that may reasonably be expected to result. What is the level of risk? Is there prospect of direct benefit to the participant? <input type="checkbox"/> 3. Participant Selection is equitable. Who will be enrolled (men, women, ethnic minorities, children, ill persons, healthy persons)? Are the participants appropriate for the protocol? What is the rationale for inclusion/exclusion? <input type="checkbox"/> 4. Informed consent will be obtained from prospective participants or their legally authorized representative unless waived in compliance with 46.116 (c) (d). Does the consent document include the eight required elements? <input type="checkbox"/> 5. Informed consent will be appropriately documented unless waived in compliance with 46.117(c) <input type="checkbox"/> 6. If appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants. <input type="checkbox"/> 7. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data. <input type="checkbox"/> a) Where applicable, additional safeguards for participants likely to be vulnerable to coercion or undue influence have been implemented. Are appropriate protections in place for vulnerable participants, e.g., pregnant women, fetuses, socially or economically disadvantaged, decisionally impaired?				

Checklist	y	n	n/a	Comment
Other				