

INFORMATION ONLY * NOT TO BE USED BY INVESTIGATORS *** INFORMATION ONLY**

Expedited Reviewer’s Worksheet for New Application Form

Protocol Title:	Protocol Number:
Reviewer:	Date:
Risk level	<input type="checkbox"/> Minimal <input type="checkbox"/> Greater than minimal
Eligible for Expedited Review Category	<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> Flex1
Continuing Review Required?	<input type="checkbox"/> No <input type="checkbox"/> Yes Rationale if Yes:

“111” Criterion	Additional Material
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(1) Risks to subjects are minimized.	<input type="checkbox"/> Survey <input type="checkbox"/> Form H <input type="checkbox"/> Form I <input type="checkbox"/> Form K <input type="checkbox"/> Form L <input type="checkbox"/> Form M
Is Criterion 1 met? <input type="checkbox"/> Yes <input type="checkbox"/> No Stipulation(s) if Criterion 1 is not met:	

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.	
Is Criterion 2 met? <input type="checkbox"/> Yes <input type="checkbox"/> No Stipulation(s) if Criterion 2 is not met:	

(3) Selection of subjects is equitable.	<input type="checkbox"/> Recruiting material <input type="checkbox"/> Form A*,C* <input type="checkbox"/> Form D <input type="checkbox"/> Form F
Is Criterion 3 met? <input type="checkbox"/> Yes <input type="checkbox"/> No Stipulation(s) if Criterion 3 is not met:	

(4) Informed consent will be sought from each prospective subject.	<input type="checkbox"/> Form A* <input type="checkbox"/> Form E1* <input type="checkbox"/> Form K <input type="checkbox"/> Form N
Is Criterion 4 met? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Waived Stipulation(s) if Criterion 4 is not met:	

(5) Informed consent will be appropriately documented.	<input type="checkbox"/> Consent Form <input type="checkbox"/> Form E2* <input type="checkbox"/> HIPAA Authorization Form <input type="checkbox"/> FERPA Authorization Form
Is Criterion 5 met? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Waived Stipulation(s) if Criterion 5 is not met:	

(6) <u>When appropriate</u> , the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.	
Is Criterion 6 met? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> NA Stipulation(s) if Criterion 6 is not met:	

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.	<input type="checkbox"/> Form SchRec <input type="checkbox"/> Form MedRec <input type="checkbox"/> Form J <input type="checkbox"/> Form K <input type="checkbox"/> IT Consult
Is Criterion 7 met? <input type="checkbox"/> Yes <input type="checkbox"/> No Stipulation(s) if Criterion 7 is not met:	

Additional Determination	
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Community Involvement: <input type="checkbox"/> NA	Comments:
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Additional Comments

Friendly Suggestions for Investigator

Confidential Comments for IRB and Staff

* Please use associated checklist to make required determinations