

Minimal Risk Research Status Update Report Form

For all exempt studies and qualifying expedited studies approved after January 21, 2019 as status update is now required. Status Updates/Check-Ins are submitted every 3 years. This form must be submitted 6 weeks prior to the status check-in date provided on the IRB Approval letter. This form is intended to provide the IRB with an update on the progress of minimal risk research that has been granted a status check-in.

A digital signature is required for this form.

This form must be opened and saved using Adobe or the digital signature function will not work properly.

Section A: Study Personnel

1.	Name of PI		Department	
	*PI's E-Mail		Telephone	
	Address		Pager	
2.	Name of Faculty Sponsor/Supervisor	<input type="checkbox"/> No Faculty Sponsor/Supervisor for this study	*E-Mail	
4.	Form Completed By	<input type="checkbox"/> PI or	Telephone	
	Date		*E-Mail	
5.	Principal Investigator's Conflict of Interest Statement This question applies to the Principal Investigator (PI) only and must be completed by the PI: Has any potential and/or real financial conflict of interest arisen since the last IRB review that has not yet been reported to the Financial Conflict of Interest Committee (FCOIC)? If Yes, a "Financial Conflict of Interest Detailed Disclosure Form" must be submitted to the FCOIC annually or when a change occurs. The form and more information are available at www.research.wayne.edu/coi . For additional information, contact the Conflict of Interest Coordinator at 313-577-9064			<input type="checkbox"/> Yes <input type="checkbox"/> No
	Principal Investigator's Signature: <div style="border: 1px solid black; background-color: #e0ffe0; height: 40px; width: 100%;"></div>			
	In signing this submission the PI: (I) Attests to the accuracy of the information provided in this application, (II) Agrees to accept primary responsibility for the scientific and ethical conduct of the research, as approved by the IRB. (III) Agrees to abide by the IRB's policies and procedures. (IV) Agrees to submit any unanticipated problems per IRB policies and procedures. To provide a digital signature open and save this form using Adobe, or the digital signature function will not work properly.			

Section B: Study Information

6.	IRB# (e.g.#####M1F or 11-11-111)	
7.	Project Title	
8.	Funding	<input type="checkbox"/> Federally Funded: <input type="checkbox"/> Industry/Foundation/Other: <input type="checkbox"/> No Funding
9.	(a) Status Check-In Date:	
	(b) Is the submission date on or AFTER the status check-in date?	<input type="checkbox"/> Yes <i>If Yes, please answer 8c.</i> <input type="checkbox"/> No
	(c) Please explain why the Status Update Report was submitted after the status check-in date:	

Section C: Status of Project

10.	(a) Has the project accrued participants and/or collected data/specimens?	<input type="checkbox"/> Yes <i>If yes please answer 9(b)</i> <input type="checkbox"/> No	
	(b) How many participants have been enrolled? (for purposes of this question, this includes collected data and specimens in cases where there is no active enrollment activity occurring) please also see note below.	To Date	*How many more do you expect to enroll?
11.	*How much more time is needed to complete the study?		
<p>*If for example, changes to accrual (increase or decrease in participants) or a change in duration of study participation are needed an expedited amendment must be submitted for this modification. The Expedited Amendment Form or eProtocol Amendment form must be completed to formally submit this request.</p>			

Section D: Progress Report

12.	<p>(a) Please provide a complete and concise updated progress report of the research project in non-technical language (lay terms). Information provided is intended to give the IRB a clear understanding of the research study to-date. The progress report should also include a brief description of: (a) all research related activity currently occurring and (b) research related activities that have been completed since the last IRB review</p>												
	<p>(b) Select all that apply to the study's current activities</p> <p>Note: If the remaining activities are limited to analysis of de-identified data and/or manuscript prep, the study can be closed.</p> <table border="0"><tr><td><input type="checkbox"/></td><td>Data collection</td></tr><tr><td><input type="checkbox"/></td><td>Conducting interactions and/or interventions with participants</td></tr><tr><td><input type="checkbox"/></td><td>Open to enrollment</td></tr><tr><td><input type="checkbox"/></td><td>Analysis of identifiable data</td></tr><tr><td><input type="checkbox"/></td><td>Analysis of de-identified data only</td></tr><tr><td><input type="checkbox"/></td><td>Manuscript prep</td></tr></table>	<input type="checkbox"/>	Data collection	<input type="checkbox"/>	Conducting interactions and/or interventions with participants	<input type="checkbox"/>	Open to enrollment	<input type="checkbox"/>	Analysis of identifiable data	<input type="checkbox"/>	Analysis of de-identified data only	<input type="checkbox"/>	Manuscript prep
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Section E: Changes to the study

13.	<p>**Please describe any changes to the study that have not been previously reported to the IRB.</p> <p>**Before implementing changes, an amendment must be reviewed and approved by the IRB.</p>	
13(a).	<p>**Were any changes made to research activities due to the health pandemic?</p> <p>Please see current guidance at research.wayne.edu/irb/coronavirus</p>	

Section F: Reportable Events:

14.	<p>Have all unanticipated problems been reported to the IRB?</p>	<p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No <i>If No, please explain, and submit an unanticipated problem report with this status update report form.</i></p> <p><input type="checkbox"/> N/A</p>
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Revised Common Rule Note: WSU implemented a Status Update requirement for all exempt studies and qualifying expedited studies approved after January 21, 2019. Status Updates/Check-Ins are submitted every 3 years. For more information about the Revised Common Rule and status updates see <https://research.wayne.edu/irb/common-rule-changes>.

Closing Your Study: Please note that it is the PI's responsibility to close the study by submitting a Closure Form/Final Report at the end of the study. For eProtocol submissions complete the Final Report form available via eProtocol. For non eProtocol submissions, complete the Closure Form located on the IRB's [Forms and Submissions requirements website](#)