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Clear Form

IRB Relying Site Continuing Review Worksheet

Purpose of this form: *This form is to be completed by the relying study site team at the time of Continuing Review. The completed form is to be submitted to the MetroHealth Lead Study Team for inclusion in the overall Continuing Review application.*

Instructions: *Section A is to be completed by MetroHealth Lead Study Team. Sections B through H are to be complete by the relying site study staff in coordination with the relying site IRB. Sections not applicable to the study or to the relying site's role in the study should be marked "N/A."*

A. Protocol Information *(To be completed by MHS study staff)*	
Protocol Title:	
MHS IRB Number:	
Funding Source:	
MHS Principal Investigator:	
MHS PI Phone:	
MHS PI Email:	
MHS Study Staff Contact:	
MHS Contact Phone:	
MHS Contact Email:	
MHS IRB Email:	IRBReliance@metrohealth.org

B. Relying Site Institution Information *(Sections B through H are to be completed by relying performance site)*	
Name of Institution:	
Address of Institution:	
FWA Number:	
IRB Contact:	
IRB Contact Email:	
IRB Contact Phone:	

C. Relying Site Contact Information	
Relying Site Principal Investigator:	
Site PI Phone:	
Site PI email:	
Site Study Staff Point of Contact:	
Site Study Staff Phone:	
Site Study Staff Email:	

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D. Relying Site Key Personnel

Key Personnel	**Role** *(Co-Investigator, Study Coordinator, Interviewer, Research Support Staff)*	**Human Subjects Research Training** *(Expiration Date)*	**Financial Conflict?** *(If yes, provide details in section)*
	Principal Investigator		Yes ☐ No ☐
			Yes ☐ No ☐
			Yes ☐ No ☐
			Yes ☐ No ☐
			Yes ☐ No ☐
			Yes ☐ No ☐
			Yes ☐ No ☐
			Yes ☐ No ☐

Do all individuals at your institution who are involved in this protocol have the appropriate credentials and/or qualifications, and meet your institutions standards for eligibility to conduct research? *(If no, provide details below)*	Yes ☐ No ☐

E. Subject Accrual	
1. How many subjects have been enrolled at your site since study initiation?	
2. How many subjects remain active in the study at your site?	
3. How many subjects had been enrolled at your site since the last Continuing Review?	
4. How many subjects have completed the study at your site?	
5. How many subjects have withdrawn from the study at your site since the last Continuing Review? Withdrawal refers both to subjects who decide to withdraw from participation and subjects who are withdrawn by the investigator. If subjects have withdrawn, provide the reason for each withdrawal in the text box below.	
6. Summarize any difficulties in recruitment/retainment and any study related complaints:	

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F. Reportable Events	
1. Have there been any reportable events at your site since the last Continuing Review that HAVE NOT been reported to the MetroHealth Lead Study Team? Reportable Events include Adverse Events, Protocol Deviations, Unanticipated Problems, and Breaches of Confidentiality. *If yes, what is the current overall status of review and approval by the applicable ancillary committee(s)?*	Yes ☐ No ☐
If yes, provide details below for each Reportable Event in the text box below. Additional information may be required:	

G. Data Security	
1. Have you made any changes to your data security plan (how and where data is stored)? If yes, describe in the text box below.	Yes ☐ No ☐

H. Additional Comment
1. Provide any additional information relevant to the study that you may wish to include in the text box below.