Saginaw Valley State University IRB Project Renewal/Close-Out Report Form

PROJECT STATUS

☐ RENEWAL	☐ CLOSE OUT

STUDY INFORMATION

Study Title: IRB#:	
Name of Principal Investigator(s):	
Is the PI(s) an SVSU student?	☐ YES ☐ NO (If Yes, list name of faculty advisor(s) below)
Name of Faculty Advisor:	
Are there Co-PIs?	☐ YES ☐ NO (If Yes, list below in the appropriate box below)
Names of SVSU Employee Co-PIs:	
Names of SVSU Student Co-PIs:	
Names of External Co-PIs:	
Names of International Co-PIs:	
Person completing Status Report Form: Date completed:	
Date of Initial IRB Approval:	
Is a project revision being submitted with this form?	☐ YES ☐ NO
Date IRB Approval Expires:	
Where is the study taking place?	
Total # of Subjects Enrolled:	

1. REGULATORY DOCUMENTS

Documents, which are required to be retained by the research team, differ depending on the type of study. Review your protocol to determine the documents to be retained and responsibilities according to the requirements that apply to your study.

		YES	NO	N/A
1.1	The approved RPA and consent form(s) (If applicable) are on file in IRBNet. If a paper file is kept as well, are the approved versions (original and revisions) noted in the file?	☐	☐	☐
1.2	Is there a subject enrollment log?	☐	☐	☐
	# of subjects included in the study? N =			☐
	# of subjects excluded in the study? N =			☐
1.3	Has the protocol been carried out by the PI or others as described in the RPA? If carried out by others, how often does the PI monitor the study? *(indicate weekly, monthly, etc)*:	☐	☐	☐
1.4	Are all personnel who interact with subjects listed on the protocol?	☐	☐	
	Have all personnel completed the required training?	☐	☐	
1.5	Does the PI or Co-PIs have a Conflict of Interest (COI) on this protocol?	☐	☐	☐
	If so, has the approved IRB COI management plan been adhered to?	☐	☐	☐

Comments:

2. IRB DOCUMENTATION

		YES	NO	N/A
2.1	**IRB Initial Approval**			
	Is the data collected/information stored as stated in the RPA?	☐	☐	☐
	If you collected signed consent forms, where are they stored?			
	Is the information potentially identifying the participants stored in a manner maintaining confidentiality?	☐	☐	☐
2.2	**Reporting Violations & Other IRB Notifications** *If attaching a separate sheet, please check here:* ☐			
	List below (if any) the number of unanticipated problems/deviations reported to IRB in the past year.	Date Submitted	Date Acknowledged	Violation/ Deviation
	a.			
	b.			
	c.			
	d.			

Comments:

3. SUBJECT RECRUITMENT PROCEDURES

		YES	NO	N/A
3.1	Have the subjects been recruited as stated in the RPA?	☐	☐	☐
3.2	Are recruitment materials (original and all revisions) on file in IRBNet?	☐	☐	☐
3.3	If recruitment materials or methods have changed, have they been approved through a revision submitted to the IRB?	☐	☐	☐

Comments:

4. SUBJECT SELECTION CRITERIA

		YES	NO	N/A
4.1	Does the approved RPA describe how subjects will be included/excluded?	☐	☐	☐
4.2	Has there been a deviation from the approved inclusion/exclusion protocol?	☐	☐	☐
4.3	If a subject was included inappropriately**,** was a protocol deviation or violation submitted to the IRB?	☐	☐	☐
4.4	If a subject inclusion/exclusion criteria checklist for each subject was created and approved for this project, does the checklist include the dated signature/initials of the person obtaining the information?	☐	☐	☐

Comments:

5. SUBJECT ENROLLMENT

		YES	NO	N/A
5.1	Were the number of subjects enrolled the same as the number of subjects you intended to enroll?	☐	☐	☐
5.2	Were there any withdrawals of subjects from the research since the last IRB review?	☐	☐	☐
5.3	Have you received any complaints about your research since the last IRB review?	☐	☐	☐
5.4	If you wish to renew your project, will you be enrolling new subject?	☐	☐	☐
5.5	If you plan on enrolling new subjects, please list the number of subjects you hope to enroll in the coming year.	n=		

Comments:

6. INFORMED CONSENT

6.1	Is the document, email or script that you are using to gain consent approved by the IRB?	**YES** ☐	**NO** ☐	**N/A** ☐
6.2	If the approved consent form(s) was stamped, are you using the stamped version?	☐	☐	☐
6.3	If you are requesting a renewal, do you need consent form(s) to be re-stamped?	☐	☐	☐
6.4	How many different consent forms (i.e. adult subjects, minors) are being used in this study?	n=		
6.5	How many times have the consent form(s) been revised after initial approval?	n=		
6.6	Provide the approval and expiration date for each revised version of the consent form.	Approval date	Expiration date	
	a.			
	b.			
	c.			
	d.			

For projects that **require written consent**, please randomly select subject files to inspect and **complete sections 6.7 – 6.13**. (You may use a sample of subject files or all subject files.)

If your project has obtained a **waiver of written documentation of consent** or a **waiver of consent**, check this box ☐ and **proceed to section 7**.

6.7	Subject file #	Did the Subject Sign? YES	NO	Date subject signed	Which version is signed? *Use expiration date*	Name of PI/Co-PI that signed	Date PI/CoPI signed
a.		☐	☐				
b.		☐	☐				
c.		☐	☐				
d.		☐	☐				

		YES	NO	N/A
6.8	Did each subject (or representative for minors, etc.) sign their own consent form?	☐	☐	☐
6.9	Is each consent form dated?	☐	☐	☐
6.10	Did each subject receive a copy of the signed consent form?	☐	☐	☐
6.11	Is subject's receipt of a copy of the signed consent form documented?	☐	☐	☐
6.12	Was any invalid consent form used?	☐	☐	☐
6.13	If yes, was a protocol deviation or violation submitted to IRB?	☐	☐	☐

Comments:

7. RISKS AND BENEFITS

		YES	NO
7.1	Were the actual risks and benefits as anticipated? (If No, please explain in comments section.)	☐	☐
7.2	Did any new findings come to light that changed the risks/benefits of the study? (If Yes, please describe the findings and any actions taken in the comments section.)	☐	☐
	If yes, were these findings communicated to the subjects?	☐	☐

Comments:

8. ADVERSE EVENT REPORTING

8.1	Were there any Serious, AND/OR Unanticipated AND/OR Related Adverse Events **reported** to the IRB since last continuing review?	**YES** ☐	**NO** ☐	**N/A** ☐
	If so, how many? _____ *(list each event below)* If attaching a separate sheet, please check here: ☐	Date of event	Date of report	Date of IRB Acknowledgment
	a.			
	b.			
	c.			
	d.			

8.2	Were there any Serious, AND/OR Unanticipated AND/OR Related Adverse Events **not reported** to the IRB since last continuing review?	**Yes** ☐	**No** ☐	**Reason(s) for not reporting** ☐ Omission (Report immediately) ☐ Other:

8.3	Any **off-site** Serious AND/OR Unanticipated AND/OR Related Adverse Events (safety reports, data monitoring board reports) since last continuing review?	**Yes** ☐	**No** ☐	**N/A** ☐
	If yes, have they been forwarded to the IRB?	☐	☐	☐

Comments: