Directions for Submitting a Continuation Form

This form must be submitted at minimum **six weeks before the expiration date**.

Single IRB Submissions: Submit the IRB continuation submission **at least 8 to 10 weeks before the date of expiration.**

- **Please include time to secure any administrative approvals (if applicable) (i.e. PRMC, CIC review) before submitting to the IRB.**
- Requests for continuation of a currently approved research protocol will be reviewed at a regularly convened meeting of the IRB committee that issued the original approval unless the criteria for expedited review are met.
- For full board submissions please be mindful of the submission deadline dates. It is recommended that a full board continuation is submitted at least 2 meetings before the expiration date.
- Continuation forms will not be accepted for studies 60 days past the expiration date of a study; a new submission is required. Studies that are expired are lapsed in IRB approval and this is non-compliance.
- **Please ensure that the PI and all key personnel have completed the Basic or Refresher CITI Course for Human Subjects within the last 3 years. Your continuation will be returned if this step is not completed before you submit (https://www.citiprogram.org/Default.asp).**
- All IRB submission forms must be the current form date and typed or computer generated (down load each time from http://irb.wayne.edu/forms-requirements-categories.php).
- Once you receive approval to conduct research, it is the **PI's responsibility** to gain approval to continue the research at the interval set by the IRB for your study as well as **to close the study by submitting a Closure Form** at the end of the study.
- Please call us if you have any questions along the way: (313) 577-1628

Expedited Continuing Review Qualifications

Submit for Expedited Review if:

The study was initially reviewed full board and

a. no participants have been enrolled
b. enrollment is permanently closed and all participants have completed all research-related interventions
c. the only research activity remaining is data analysis
d. the research remains active only for the long-term follow-up of participants, and
e. no additional risks or increase in existing risks have been identified which justified a full board amendment during the approval period under review*

**If a study was initially reviewed via expedited review procedures and additional risks or an increase in existing risks have been identified which justified a full board amendment during the approval time under review, then full board review procedures must be followed.*

Research that qualifies for expedited review generally does not require continuing review unless the IRB determines that continuing review is required. For example, the IRB may determine that continuing review is required when:

- The study is subject to FDA regulations (Investigational Drug or Device studies)
- Continuing review is required by the terms of a grant, contract, or other agreement;
- The research involves topics, procedures, or data that may be considered sensitive or controversial;
- The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
- An investigator has minimal experience in research or the research type, topic or procedures
- An investigator has a history of noncompliance.

Full Board Continuing Review Qualifications

Submit for Full Board Review If:

The study was initially reviewed full board and the study:

a. has accrued participants in the current approval period.

b. has not yet accrued participants in the current approval period; however, an amendment identifying a new risk and/or increased risk to participants was reviewed by the full board in the current approval period.

c. continues to complete research-related intervention is ongoing.

d. Has undergone a full board review of an amendment during the approval period under review

e. Submission is a Humanitarian Use Device

What to Submit?

Expedited Review	Full Board Review
All required continuation documents must be submitted **prior** to the expiration date as noted above. • Submit the Continuation Form with **the PI's digital signature** • **eProtocol Submissions STOP do not use this form. The Continuation form for eProtocol must be used.** • **Clean unstamped** copies of the currently approved informed consent/assent/information sheet (unless permanently closed to accrual) • **Clean unstamped** copy of the currently approved advertisements/notices/flyers currently (unless permanently closed to accrual). • Note: Data collection tools do not require re-stamping	All required documents must be submitted **prior** to the expiration date as noted above for the applicable meeting's deadline date. • Submit the Continuation Form with **the PI's digital signature** • **eProtocol Submissions STOP do not use this form. The Continuation form for eProtocol must be used.** • **Clean unstamped** copies of the currently approved informed consent/assent/information sheet (unless permanently closed to accrual) • **Clean unstamped** copy of the currently approved advertisements/notices/flyers currently (unless permanently closed to accrual). • Note: Data collection tools do not require re-stamping

Submission Process

Please submit the continuation application as follows:

Email Expedited and Full Board Submissions in a **single zip file to eIRBManager@wayne.edu**

Include the following:

- **Continuation Form**
  - **A digital signature is required for this form. This form must be opened and saved using Adobe or software that allows for digital signature or the digital signature function will not work properly**
- **Consent, Assent, Recruitment Materials, Scripts, Participant Materials**
- **All documents that require re-stamping**
- Note: **Data collection tools do not require re-stamping**
- **Subject line of the email should read:**

CONTINUATION SUBMISSION (PI Name and IRB #).

Transition to Revised Common Rule (45CFR 46) Information

On January 21, 2019, the DHHS Office of Human Research Protections (OHRP) revised Common Rule went into effect. All research approved on or after that day must be compliant with the revised Common Rule. All research approved prior to January 21, 2019 will continue under the original version of the Common Rule, however, the IRB may transition qualifying research protocols to the revised rule.

Research approved before January 21, 2019 that meets the following criteria will be transitioned to the OHRP revised Common Rule.

- The study is sponsored by a Federal agency
- The study was approved prior to January 21, 2019
- The study is closed to enrollment
- Study is in data analysis only
- Study is not subject to FDA regulations.

If your study meets all of the conditions above, we ask that you submit the **Common Rule Transition Appendix** with your Continuation documents.

Helpful Resources from the IRB

On-Going IRB Training and Helpful Tools

Our Website has the on-going training calendar (weekly sessions at a variety of locations and times); helpful tools, resources and documents; policies; and helpful links to federal agencies: http://www.irb.wayne.edu/education.php Always download the forms from our website for the most recent version.

Join the WSU IRB Info Listserv

The WSU IRB Administration Office has created a listserv for all researchers and research staff using the WSU IRB. This listserv provides a means for us to occasionally share information, make announcements, advertise the training calendar, share answers to questions, etc. with the research community.

It is easy to join: To subscribe send an email to WSUIRBInfo@wayne.edu. To unsubscribe at any time, send an e-mail to WSUIRBInfo@wayne.edu.

Join the WSU Study Coordinators' Advisory Network

Are you a research staff person? Join the Study Coordinator' Advisory Network (SCAN). The Wayne State University (WSU) Study Coordinators' Advisory Network (SCAN) aspires to provide guidance, networking and mentoring to study coordinators under the auspices of WSU Institutional Review Board (IRB).

In addition, the SCAN acts as a liaison to the IRB for the WSU research community to discuss areas of concern regarding human research. To learn more about SCAC, visit their website at: https://research.wayne.edu/irb/advisory-committee

IRB Administration Office
87 E. Canfield, Second Floor
Detroit, MI 48201
(313) 577-1628
irb.wayne.edu

Continuation Form

- All IRB submission forms must be the current form date and typed or computer generated (down load each time from http://irb.wayne.edu/forms-requirements-categories.php).
- * **Forward *@wayne.edu*** e-mail to ***@med.wayne.edu, @karmanos.org***, etc. e-mail in order to receive important e-mail communications regarding the study. Non-WSU employees, please enter your e-mail. An e-mail address is required.
- ****A digital/electronic signature must be provided by the Principal Investigator. If the PI does not provide a digital signature, the IRB Administration Office may request additional verification/acknowledgement of the submission from the PI. To provide a digital signature this form must be opened and saved using Adobe or software that allows for digital signature.**

Type of review requested:	
	☐ **Full board** It is recommended that a full board continuation is submitted at least 2 meetings before the expiration date.
	☐ **Expedited** **Note**: Expedited Continuation review is only required under the circumstances described below. If your research protocol was approved under expedited review procedures and your study does not fit the circumstances below, a continuation form is not required. If a continuation is not required, a Status Update Report form must be submitted prior to the date indicated in your last approval memo. This form is available on our website. • The research protocol received an initial full board review has no participants have been enrolled at any site subject to WSU IRB oversight and no additional risks have been identified by the IRB or investigator from any site or relevant source at the time the continuation application is submitted • The expedited review research protocol involves investigational drugs or devices subject to FDA regulations. • The research protocol received an expedited or exempt approval prior to January 21, 2019

Section A: Principal Investigator (PI)

1.	Name of PI		Department	
	Address		Pager	
			***E-Mail**	
			Telephone	
2.	Faculty Sponsor/Supervisor's Name:	☐ No Faculty Sponsor/Supervisor	***E-Mail**	
3.	***Name* of** Dept. Chair, Dean or Authorized Signatory Official		***E-Mail**	
4.	Form Completed By:	☐ PI or	Telephone	
	Date form completed		***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)? ☐ Yes ☐ No

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.

PI's Signature:

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 this open and save this form using Adobe or software that allows for digital signature or the digital signature function will not work properly. (For assistance see instructions for digital signature)

If the Principal Investigator is not available, the co-investigator or Dept/College authorized signatory can sign. Please state why the PI is not available. The IRB may require additional information.

Section B: Study Information

6.	COEUS #/Protocol#	
	IRB # (e.g. #######MP2F)	
7.	Project Title	
8.	a) **Expiration Date** **Expedited Review:** Submit for continuation review 6-8 weeks before this the expiration date. It is recommended not submitted more than 90 days in advance) **Full Board Review:** Submission is recommended at least 2 meetings before the expiration date. **Single IRB studies where WSU is the IRB of Record submit 8-10 weeks before expiration.**	
	b) **Date form will be submitted**	
	c) Is the submission date AFTER or on the expiration date?	☐ Yes ***If yes,*** please answer below ☐ No
	If yes, your study has a lapse in IRB approval. Please indicate whether or not any research activities have taken place during the lapse in IRB approval. See note below for important information.	☐ Yes, I did conduct research activities during the lapse in approval. ***Please attach an Unanticipated Problems & Event Reporting Form.*** ☐ No research activities occurred during the lapse.
	Note: If your protocol does not receive approval prior to the expiration date, no new participants can be enrolled, no data can be collected or used for research if collected during the period of non-IRB approval (lapsed approval). No research activities can be conducted unless it is for the safety of study participants. Repeat lapses of IRB Approval may be deemed non-compliance. Refer to IRB policy "Continuation/Renewal of Protocol" for further information: www.irb.wayne.edu	
9.	Current Source of Funding:	
	a. Is this a change from the time of the last approval? **NOTE**: If there is a change, an amendment should have been submitted. If not done, an amendment form must be submitted.	☐ Yes ☐ No
10.	If this is a multi-site study?	☐ Yes ☐ No ☐ N/A
	(a) If Yes to question 10, is WSU the Coordinating Center or lead institution?	☐ Yes ☐ No **If Yes,** submit the WSU Coordinating Center Application

	(b) If yes to 10a, Is WSU the IRB of record for this single IRB study?	☐ Yes ☐ No **If Yes,** submit the WSU Coordinating Center Application	
11.	Is this study a clinical trial? ☐ Yes **If Yes, the clinical trials must be provided Clinical Trial Registration Number:** http://research.wayne.edu/irb/clinicaltrials.php https://clinicaltrials.gov/ct2/about-studies/learn#WhatIs ☐ No **WSU IRB Administration will conduct periodic review of ClinicalTrials.gov registration completion. This includes a review at the point of continuation submission.**		
12.	If research personnel will be accessing in-patient and/or out-patient medical records from WSU or affiliated sites, or from databases created from in-patient and/or out-patient medical records, have appropriate HIPAA documentation been submitted (HIPAA Summary Form and HIPAA Authorization Form-if applicable)?	☐ Yes ☐ No	☐ N/A

Section C: Status of Project

13.	Were there any amendments with full board review in the last year (since the last approval of this protocol)?	☐ Yes ☐ No	
14.	Has this project accrued participants (consented) and/or collected data/specimens?	Since the last approval? ☐ Yes (go to question #15) ☐ No If over 1 year, since the study began? ☐ Yes (go to question #15) ☐ No	
	If no, please list all of the reasons for not accruing participants/data/specimens:	☐ Insufficient staff ☐ Insufficient funding ☐ Lack of eligible participants ☐ Other (explain):	
15.	Is this protocol closed to accrual, recruitment or review of new records?	☐ Yes ☐ No (go to question #16)	Date when study recruitment ended:
	If yes, have **all** the participants completed **all** research related interventions? Long term follow-up without intervention is **not** considered research-related intervention.	☐ Yes, ***if yes,*** this submission qualifies for expedited review. ☐ No ***if no,*** this will go to the full board for review.	

	NOTE: It is not necessary to submit copies of the informed consent/assent if the protocol is **closed to accrual unless** the informed consent has been changed, re-consenting of participants continues, and/or re-consenting of participants may be needed in the future.		
16.	**(a)** Is this the *first* continuation for this study?	☐ Yes ☐ No: *indicate the cycle number:* ☐ 2nd ☐ 3rd ☐ 4th ☐ Other:	
	(b) Flexible Review & Oversight Eligibility Criteria		
	Select all that apply to the proposed study. If none apply, the study may be eligible for flexible review and oversight. **Flexible Review and Oversight:** Eligible studies may receive extended approval periods (up to a 3 year approval period) and have fewer requirements related to some vulnerable participant groups (pregnant women, fetuses, neonates, and participants incarcerated after enrollment). See the "Flexible Review and Oversight of Research Not Covered by Federalwide Assurance" policy: http://irb.wayne.edu/policies-human-research.php	☐ The study presents more than minimal risk to participants ☐ The study is federally funded/sponsored ☐ An application for federal funding/sponsorship for this study will be submitted in the future ☐ The PI is paid or supported from a federal training grant or otherwise paid or supported from a supervisors' or advisors' federal funds ☐ The study has Food and Drug Administration (FDA) regulated components (drugs, biologics, medical devices, etc.) ☐ Data from this study will be used to support applications to the Food and Drug Administration (FDA) ☐ This is a Department of Veterans Affairs (VA) study ☐ The study will target prisoner participants ☐ The study sponsor, outside collaborators, or other entities require annual IRB review of the study ☐ There are contractual obligations with the study sponsor, outside collaborators, or other entities to adhere to federal research regulations	☐ None

17.	**Number of participants or documents/specimens:** What is the current IRB approved number of participants* ***or*** documents, charts, or specimens for recruitment/collection at WSU or its approved sites: *approved # expected to be consented	**Current Approved #**
18.	a) Indicate the number of participants ***or*** documents, charts, or specimens consented ***or*** collected/reviewed at WSU or approved sites: *Note, **a)** do not subtract the number of withdrawals or removals from the # consented; **b)** If the same individual was consented multiple times, count once; and **c)** Complete, even if closed to accrual.*	**# Since Last IRB Approval** (# in this past approval period) ☐ N/A
		Total # to Date (total # in all of the years of the study, including the approval period)
	b) Is the answer for Q17 *less than* the number given for question 18, "Total # to Date"?	☐ No – go to Q#19 ☐ Yes – *answer below*
	If yes, Did you submit an amendment *prior to* recruiting over the approved number? **If not done,** submit an Unanticipated Problem Report and an Amendment form immediately, as these need to be processed *before* your continuation can be reviewed.	☐ Yes: date submitted: ☐ No: The date I am submitting the Amendment and Unanticipated Problem Report:

19.	**What happened with the participants?** ☐ **N/A—*record or specimen only study***	**Total # to Date**	**Activity of any participants within the last approval period*** ☐ N/A- This is the 1st Continuation.
	a) How many participants **withdrew** their consent from the study at WSU and/or approved sites?		
	b) Summarize the reasons why they withdrew since initial approval:		
	c) How many participants did the PI **remove** from the study at WSU and/or approved sites? Examples include not eligible, non-compliant, didn't meet criteria, screening failures, or lost to follow-up. Also include any participants that passed away.		
	d) Summarize the reasons why they were removed since initial approval and if any were dropped due to a reportable Unanticipated Problem:		
	e) How many participants **completed** the study? Include participants who were removed due to disease progression who also completed all follow-up		
	f) How many participants are **still in** the study? Include those in follow-up. Include participants removed from study due to disease progression who are in follow-up. If they did not complete follow-up, note them under removed from study, as appropriate.		
	g) Add-up the total numbers in **a - f**. *Note: the #s in the 2nd column may reflect participants that consented in the last approval period, but w/d or completed this period.	**Total of a-f:** This should equal the "*Total # to Date*" in 18(a)	

20. Vulnerable Groups

If enrolled participants could be classified as belonging to a vulnerable group, ***IRB approval may be required.*** *If indicated below* and not previously approved by the IRB, submit an amendment and an Unanticipated Problem Report (and appendix if applicable) to request the inclusion of this vulnerable group into the study. VA studies, please answer all columns.

Vulnerable Group	**Have you enrolled anyone from this group? *If yes,*** answer the next columns	**** If yes,* is this group a focus of your study?** *If yes,* answer the next column.	***** If yes,* do you have prior IRB approval to enroll this group?**	***VA only:*** Enter # enrolledor "0"
Children	☐ Yes** ☐ No		☐ Yes ☐ No -*submit an amendment and UP report.*	
Persons with diminished capacity, a cognitive impairment, or mental illness	☐ Yes* ☐ No	☐ Yes** ☐ No: the number enrolled in the last year was: *If no,* an amendment is not needed.	☐ Yes ☐ No -*submit an amendment and UP report.*	
Non-consenting participants (in emergency situations)	☐ Yes** ☐ No		☐ Yes ☐ No -*submit an amendment and UP report.*	
Pregnant women	☐ Yes* ☐ No	☐ Yes** ☐ No: the number enrolled in the last year was: *If no,* an amendment is not needed.	☐ Yes ☐ No -*submit an amendment and UP report.*	
Fetus or neonates	☐ Yes** ☐ No		☐ Yes ☐ No -*submit an amendment and UP report.*	
Terminally ill	☐ Yes* ☐ No	☐ Yes** ☐ No: the number enrolled in the last year was: *If no,* an amendment is not needed.	☐ Yes ☐ No -*submit an amendment and UP report.*	
Students, employees, or trainees	☐ Yes* ☐ No	☐ Yes** ☐ No: the number enrolled in the last year was: *If no,* an amendment is not needed.	☐ Yes ☐ No -*submit an amendment and UP report.*	
Prisoners	☐ Yes** ☐ No		☐ Yes ☐ No - *submit an amendment and UP report.*	

21. **Race and Ethnicity, and Gender:** Complete the table below regarding the cumulative number of participants (consented)/documents/ charts reviewed/specimens accrued at WSU or its approved sites **since the project was initiated**. *If Hispanic ethnicity is unknown, you may enter "unknown".

Race →	American Indian or Alaskan Native	Asian	Black	Native Hawaiian or Pacific Islander	White	Other or Unknown	Multiple Race Groups	***Total***
*Hispanic or Latino *Ethnicity*								
*NOT Hispanic or Latino *Ethnicity*								
Unknown								
Total								

Gender →	Female	Male	Unknown Gender	Total

22. Is there an equitable distribution of race groups?

- ☐ N/A
- ☐ Race data not being collected
- ☐ Yes
- ☐ No: ***answer below***

If no, provide justification for the inequity:

- ☐ Sample size too small to judge
- ☐ Reflects site/clinic population
- ☐ Research on specific race or ethnic groups
- ☐ Other, explain below:

	If no: If the inequity cannot be justified, what actions will be taken during the next year to address this issue?		☐ N/A
23.	Is there an equitable distribution of gender?	☐ N/A ☐ Gender data not being collected ☐ Yes ☐ No: ***answer below***	
	If no, provide justification for the inequity	☐ Sample size too small to judge ☐ Reflects site/clinic population ☐ Research on specific gender ☐ Other, ***explain:***	
	If no: If the inequity cannot be justified, what actions will be taken during the next year to address this issue?		☐ N/A

24. Please indicate **all** of the following protocol amendment ***categories*** that received IRB approval since the inception of this study. For each of these **approved** amendments, provide a concise narrative summary explaining the reasons for the amendment. You may attach an addendum page if needed.

Not enough space? You may attach an addendum page if needed. However first use the space provided. Note: **Please list the latest amendment approvals on the continuation form below.**

☐ **Addendum page attached**

☐ N/A

Amendment Category	Date of Approval	Concise Narrative Summary
Key Personnel Additions/Deletions ☐ **None**		

	Change in PI ☐ **None**		
	Amendment Category	**Date of Approval**	**Concise Narrative Summary**
	Recruiting and Advertising ☐ **None**		

	Protocol Revisions:		
	Administrative changes ☐ **None**		

	Study design ☐ **None**		
	Enrollment criteria ☐ **None**		
	Change in treatment ☐ **None**		
	Data collection methods ☐ **None**		

	Risks and/or benefits ☐ **None**		
	Other Protocol Revisions ☐ **None**		
	Informed Consent ☐ **None**		

	HIPAA Summary/ Authorization ☐ **None**		
	Investigator's Brochure/Package Insert ☐ **None**		
	Data safety monitoring minutes ☐ **None**		

	Study on hold notification ☐ **None**		
	Other ☐ **None**		
25.	Has the **non-English** short form consent been used for this study? ***Please note non-English speaking participants must have the short form used plus the long form verbally translated into their language.**	☐ Yes ***If yes,*** answer below ☐ No	

If yes, indicate language used and number of occurrences

Language Used	Number of uses/occurrences
☐ Spanish	
☐ Arabic	
☐ Other:	
☐ Other:	
☐ Other:	

Investigator Initiated Studies

26. Is this an **Investigator-initiated** study involving an IND, IDE, ***or*** a study that the IRB previously approved with the provision (see approval letter) that a literature search be performed on an annual or other basis? IND- drug study, IDE- device study

☐ Yes, If ***yes,*** answer below

☐ No

If yes, What date was the most recent literature search or review was completed?	

If yes, define the strategy of the literature search and describe how the results of the search might impact the protocol.

Device Study

27. Is this an **IDE** (device) study?

☐ No

☐ IDE Study – with Significant Risk Device

☐ IDE Study – with Non-Significant Risk determination- ***answer below***

For a **Non-Significant Risk Device** study, are you abiding by the criteria for use of this device as was previously approved by the IRB?

☐ Yes

☐ No

If no, explain:

28. **Reportable Adverse Events:**

☐ None

List all **reportable** unexpected Adverse Events (Serious Adverse Event-**SAE**) associated with this protocol (i.e., **only those that met IRB reporting guidelines**) in a concise narrative including the number of separate occurrences (attach separate page if necessary). These should match the specific SAE reports submitted on the Problem Report Form on file for this protocol. Follow-up reports are not counted as a separate SAE. (*Example only: 3 episodes of septic shock, 1 seizure, 5 episodes of elevated liver enzymes)*
Not enough space? You may attach an addendum page if needed. However first use the space provided. **Note: Please first list the latest events on the continuation form below.**

☐ **Addendum page attached**

Site	**Current** Approval Period	Period Since **Initial** Approval
WSU Sites and/or approved sites		

Site	**Current** Approval Period	Period Since **Initial** Approval
Non-WSU Sites:		

29.	Please provide a **concise** narrative description that explains the relevance of all reported SAE to the study interventions; any effects on study participants; and if a change in SAE frequency, severity, and/or specificity have occurred. Please indicate if any "possibly related" events have relevance on the study interventions.	☐ N/A
	Narrative:	

30. Please indicate **all** of the following protocol events that occurred since the initiation of this study. For each of these events, provide the dates of occurrence and a concise narrative summary explaining the reasons for the incidents. **These events are reported to the IRB on an Unanticipated Problems and Event Reporting Form.**

Not enough space? You may attach an addendum page if needed. However first use the space provided.

Note: Please first list the latest events on the continuation form below.

☐ **Addendum page attached**

Event:	Date of Event	Concise Narrative Summary	
Audits (internal/external)			☐ None
Hold notifications			☐ None
Death that has happened at WSU or one of its affiliates within 30 days of the last study intervention, and not related to progressive disease			☐ None
Death that PI feels that it is significant, regardless of when it occurred.			☐ None

	Violations or deviations			☐ None
	Event:	**Date of Event**	**Concise Narrative Summary**	**Event:**
	Event that required prompt reporting to the sponsor			☐ None
	Suspensions (institutional or sponsor)			☐ None
	Participant complaint			☐ None

	Information that indicates a change to the risks or potential benefits of the research			☐ None
	Breach of confidentiality			☐ None
	Change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.			☐ None
	Event:	**Date of Event**	**Concise Narrative Summary**	**Event:**
	Period of non-IRB approval			☐ None
	Change to protocol without IRB review and/or approval			☐ None
	Incarceration of a participant in the study which was not approved for prisoners			☐ None

	Unanticipated adverse device effect			☐ None
	Other events			☐ None
31.	What processes are in place to prevent any of these events from reoccurring?			☐ N/A

32.	Since **last** approval, indicate **all** of the following information obtained about the study. **Provide a concise narrative summary explaining the significance to the protocol.**		
	Information:	**Concise Narrative**	
	Data safety reports pertinent to the study?		☐ None
	Change in FDA labeling or withdrawal from marketing of drug, device or biologic used in the protocol?		☐ None
	Reports with relevant scientific interim findings?		☐ None
	Change in the risk/benefit ratio?		☐ None

33.	**Public Health Pandemic**
a.	Were research activities paused due to a Public Health Crisis (i.e. COVID-19)? ☐ Yes, complete item 33(b) ☐ No, study activities were necessary to sustain life (go to question 34) ☐ No, study activities were remote with no in-person visits (go to question 34) ☐ Other - Describe and then (go to question 33b):
b.	Did the research resume upon lifting of the State of Michigan's Executive Orders? ☐ Yes Describe the Precautionary Standard Operating Procedures that were put in place to inform and protect study participants: ☐ No, study was closed to accrual and research interventions completed ☐ Other - Describe:

Section D: Publications & Progress Report

34.	Since the last IRB approval, have any publications, abstracts, and/or presentations resulted from this research protocol? If yes, attach complete copies. ☐ Yes If yes, documents are attached ☐ ☐ No

35.	**Progress Summary** 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 all members of the IRB (scientists and non-scientists) **a clear understanding of the research study to-date**. This should incorporate all IRB approved amendments to the original research.
	State the current goals, aims, and/or hypothesis of the study:
	Provide a brief description of methods and procedures of the study:

Provide a brief summary of the progress of the study:

For participant research only:
Has the study intervention or treatment helped? ☐ Yes ☐ No
Are goals being met? ☐ Yes ☐ No

Address your responses:

36.	**Provide justification** as to why this protocol should receive IRB approval for continuation: do not cut and paste from progress question.

Closing Your Study & Change in PI:

Please note that it is the **PI's responsibility** to close the study by submitting a Closure Form at the end of the study. This form is located on the forms page of our website: http://irb.wayne.edu/

If a PI is leaving the institution and the study will remain open, a Change in PI request must be submitted to the IRB. The PI and their Department Chair or Dean should discuss data retention and storage in preparation of the PI leaving the institution. For more information regarding WSU research data guidelines visit https://guides.lib.wayne.edu/c.php?g=859947&p=6161966