Directions for Closing a Protocol

- **If this is an exempt study and concurrence of exemption was granted after 1/21/2019 submission of a closure form is now required.**

- **If this is an exempt study and exemption was granted before 1/21/2019 then a closure form is not required.**

Criteria for Study Closure

- A study may be closed when ***all*** of the following apply:

1. All collection of data involving interventions and interactions has been completed for all participants. No further contact with participants is necessary.
2. All collection or receiving of private identifiable information (including identifiable biological specimens) from any source (i.e., not already in the possession of the investigator) has been completed. No further data or information will be obtained.
3. **All using, studying, or analyzing of identifiable information (including identifiable biological specimens) will no longer occur.** This includes all identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings, or other recordings already in the possession of the investigator or provided to the investigator from any source. This includes using, studying, or analyzing any of the following:
   a. Identifiable private information obtained by interacting or intervening with the human participants;
   b. Identifiable private information stored in documents, records, images, *provided to* the investigators from any source;
   c. Identifiable private information stored in documents, records, photographs, images, video recordings, or audio recordings *already in the possession of the investigator before the research begins*;
   d. Identifiable private information obtained about an individual by interviewing other people (e.g., an individual's healthcare provider or teacher);
   e. Identifiable biological specimens provided to the investigators from any source; or
   f. Identifiable biological specimens already in the possession of the investigator before the research begins.
4. If the study is funded and the sponsor agrees to or recommends closure and no further participant follow-up or data analyses will take place at the local performance site.

- Note: you may ***not close*** a study if data analysis that involves private identifiable information is not complete. You ***may close*** a study if all that remains is the analysis of aggregate data sets ***without*** individual participant identifiers or identifiable private information.
- **Note:** For National Institutes of Health (NIH) funded/sponsored projects, the study should not be closed until data sharing with NIH has been completed.
- You ***must*** close your protocol if your study has been expired for 60 or more days— it is the federal regulation.
- Sponsor queries cannot be answered after closure unless the protocol is re-opened. For funded studies, concurrence from the sponsor should be obtained prior to closing the protocol at WSU.
- Investigators should honor any commitments that were agreed to as part of the approved research (e.g., providing information about the study results to participants, compensation to participants, etc.).
- If study was approved via eProtocol this form is not required, complete the Final Report form via eProtocol

Personally Identifiable Information – Defined as recorded information in any format (e.g., oral, written, or electronic) regarding the physical or mental condition of an individual, health care provision, or health care payment. It contains demographic information able to specifically distinguish an individual.

Name
Home Address
Elements of Dates (Birth Date, Admission Date, Date of Service, Date of Death, etc.)
Telephone Number or Fax Number
E-Mail Address
Social Security Number
Medical Record Number
Health Beneficiary Number
Account Numbers (School id, Credit Card, etc.)

Certificate/License Numbers
Vehicle Identification/Serial Numbers
Device Identification/Serial Numbers
Website URLs
Internet Protocol (IP) Addresses
Biometric Identifiers (Voice, Fingerprints, etc.)
Full Face Images
Any other unique identifying numbers, codes, descriptions, or characteristic (linked study identification numbers, etc.)

Retention of Identifiers after Study Closure

- The identifiable private information may be retained so that secondary analyses of the data can be performed (i.e., a later follow-up study with IRB approval). You may maintain this information **only if** you are not using, studying, or analyzing the information.
- If the database containing identifiers is transferred or shared with another investigator, IRB review and approval must be obtained.
- Private Identifiable information must be kept securely at WSU or an affiliate site. It must be kept on a secure University or Affiliate server and physical data or specimens must be kept in a locked and secure location. Private Identifiable Information ***may not*** be kept off location, at home, or stored on CDs, DVDs, hard drives or jump drives or with the intent to take the data off the secure premises.

Retention of Specimens after Study Closure

- If a PI conducted a study on specimens that constituted human participant research, those specimens may be retained for future use in research if the participant, at the time of consent for the study, permitted the retention for this purpose.
- If the specimens were originally collected solely for clinical purposes, but are later used for research purposes, these may be retained with IRB approval.
- If the specimens are identified and/or have private identifiable information, these identifiers may be retained to allow for the possibility of new analysis to occur, following IRB review and approval of a ***new*** protocol.
- If the specimen bank containing identifiers is transferred or shared with another PI, IRB review and approval of the new research study must be obtained.
- Specimens and private identifiable information must be kept securely at WSU or an affiliate site or at an alternative site, if this was previously stated in the protocol currently approved by the IRB.
- If specimens are de-identified, they can be kept as well.

Lapse of IRB Approval

When a closure form or continuation review of a research protocol does not occur prior to the expiration of the approval period specified by the IRB, then IRB approval expires on the expiration date (lapse in approval). When there is a lapse in IRB approval:

- **All research activities must stop** (including: analyses involving human participant data/specimens, recruitment and Informed Consent procedures, collection of data/information/specimens from or about living individuals, all research-related interventions or interactions with currently enrolled participants-- unless the IRB finds that it is in the best interests of the individual participants to continue participating in the research interventions or interactions).
- **Data that is collected during a period of non-IRB approval can never be used for research purposes.** Relevant study data must be sent to the Data and Safety Monitoring Committees and appropriate federal regulatory agencies as required. If applicable, IRB policy requires the PI to notify the funding agency of the lapse of IRB approval. An Unanticipated Problems & Event Reporting Form must also be filed.

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

Medical/Behavioral Closure Form

- All IRB submission forms must be the current form date (down load from http://irb.wayne.edu/forms-requirements-categories.php) and typed or computer generated.
- ***Forward your @wayne.edu e-mail** to your @med.wayne.edu, @karmanos.org, etc. e-mail in order to receive important e-mail communications regarding your study if you do not access your @wayne.edu e-mail ***OR*** go to ***Academica*** and enter the e-mail account that you wish to use. Non-WSU employees, please enter your e-mail. An e-mail address is required.
- **If the PI is no longer with the institution and cannot be successfully reached, the *Department Chair, Dean* or *Authorized Signatory* may sign. If this was a student project the Faculty Sponsor/Supervisor may submit the closure form, however the Faculty member must notify the Chair/Dean of the closure.
- Submit this form with a **digital signature**—no faxed or copied signatures accepted. The PI or Authorized Signatory must digitally sign the closure form (no proxy signatures).
- 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
- Please call us if you have any questions along the way: (313) 577-1628

A digital signature is required for this form.
Open and save form using Adobe or software that allows for digital signature.

Section A: Principal Investigator (PI) & Study Closure Authorization

1.	Name of PI		Department	
2.	**PI's Signature****			
	PI's email:		PI's Telephone number	
	Address		Pager	
	If the current PI is no longer with the **institution and has not responded to repeated communication, is the Dean or Dept. Chair, or Faculty Supervisor signing instead of the PI? ☐ **Yes** ☐ **No** ☐ **N/A**, PI has authorized and signed ***If yes,* state Dean/Department Chair/Authorized Signatory's name:** **Dean/Department Chair/Authorized Signatory signature:**			
	***If yes*, Faculty Supervisor Signature:**			
3.	Name of Faculty Sponsor/Supervisor:	☐ This study does not have one	*E-mail	

4.	Form Completed By		Date	
	Telephone		*E-Mail	
	Address			

Section B: Protocol Information

5.	IRB Number (ex, #######M1F)		**If the study is exempt, see instructions at the beginning of this form.**	
6.	Project Title			
7.	Expiration Date or Status Check-In Date		Date the closure form will be submitted to the IRB	

8.	Will this closure form be submitted after the expiration date?	☐ Yes ☐ No **– go directly to Q#9**
	***If yes,* <u>this study has a lapse in IRB approval</u>. See the Directions page for the implications on this research study.** Please indicate whether or not any research activities took place during the lapse in IRB approval and note this lapse under Q #15.	☐ Yes, research activities were conducted during the lapse in IRB approval - ***answer a) below:*** **a)** What was the date of last research activities? ***Please attach an <u>Unanticipated Problems & Event Reporting Form</u>*** ***Note this lapse <u>under Q #14 of this form</u>.*** ☐ No research activities occurred during the lapse in IRB approval. ***answer a) below:*** **a)** What was the date of last research activities? ***Note this lapse <u>under Q #14 for this form</u>.***
9.	Is this a multi-site study?	☐ No **– go directly to Q#10** ☐ Yes
	b) Is WSU the Coordinating Center or reviewing IRB?	☐ No ☐ Yes
	c) Are the other sites still open?	☐ No ☐ Yes **If yes and WSU is the Coordinating Center or reviewing IRB and sites are still open the study cannot be closed.**

10.	Reason for closure	☐ Research is complete ☐ Closing study due to lack of enrollment ☐ DMC Review Auth. never gained, so study never started **– STOP, you are done with this form.** ☐ The study was never done. State why below and **go directly to Q#18** ☐ This was an Administrative Application **– go directly to Q#18** ☐ PI is leaving the institution with no Change in PI for the study ☐ Other:
	Sponsor queries cannot be answered after closure unless the protocol is re-opened. For funded studies, concurrence from the sponsor should be obtained prior to closing the protocol at WSU.	

11.	**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 #**
12.	a) Indicate the number of participants ***or*** documents, charts, or specimens consented ***or*** collected/reviewed at WSU or approved sites: *Note: Do not subtract the number of withdrawals or removals from the # consented; if the same individual was consented multiple times, only count once.*	**# Since Last IRB Approval:** (# in this past approval period) ☐ N/A **Total # to Date:** (total # in all years of the study, including the current approval period)
	b) Is the **Total # to Date** more than the **Current Approved #** stated for question 11?	☐ No **– go directly to Q#13** ☐ Yes
	If yes, Was an amendment submitted *prior to* recruiting over the approved number?	☐ Yes: date submitted: ☐ No: **submit an Unanticipated Problem Report**

13.	**What happened with the participants?** ☐ N/A—*record or specimen only study*	**Total # to Date**	**Activity of any participants within the last approval period***
	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? Some 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) Add-up the total numbers in **a - e**.	**Total of a-e:** This should equal the "*Total # to Date*" in Q #12(a)	

Section C: Study Events

14. Has any of the following, events occurred? ☐ Yes ☐ No **If yes, please address each applicable event below.**

Event		Date of Events	Summarize the Details of the Events and Reason Why:
(a) Audits (Internal/External) Who did the audit, why did they do the audit and what was the outcome? State audit participant safety and risk findings. If these were found, was a UP report was submitted?	☐ None ☐ Yes		
(b) Lapsed IRB Approval **If Q#8 was answered "yes", then select "yes" & state why**	☐ None ☐ Yes		*Why?*
(c) Participant Complaints	☐ None ☐ Yes		

	(**d**) Suspensions by the IRB	☐ None ☐ Yes		

Section D: Public Health Pandemic Study Status

15.	**(a)** Were research activities paused due to a Public Health Crisis (i.e. COVID-19)?	☐ Yes, complete item (15b) ☐ No, study activities were necessary to sustain life (go to question 16) ☐ No, study activities were remote with no in-person visits (go to question 16) ☐ No, study is a retrospective chart review (go to question 16) ☐ Other Describe and then (go to question 15b):

	(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 E: Study's Summary & Results

16.	Provide a brief summary of the study, listing the main purpose or goals and include the relevant findings: a) **Brief list of goals met *or* the overall purpose:** **b) Brief overall findings:**	
17.	Have any papers, abstracts, presentations, etc been generated as a result of the study?	☐ Yes, ***if yes,*** please **list** below—do not attach full articles ☐ Not at this point ☐ N/A

	List the reference(s):

Section F: Data Storage & Retention

18.	**Personal identifiable information or specimens**	
	Are any personal identifiable information or specimens being kept (master list, voice, photo, audio, etc.- see definition on instruction page)?	☐ Yes ☐ No – ***If no,*** go to Q #19 ☐ No identifiers were ever collected – go to Q #19
	a) ***If yes,*** for what reasons? Note: Sponsor queries cannot be answered after closure.	☐ For FDA auditing purposes ☐ Other:
	b) Will identifiable information or specimens continue to be studied or analyzed?	☐ Yes- **STOP- the study cannot be closed.** See the directions page. ☐ No. Prior to any future use, a new protocol will be submitted in order to gain IRB approval (including 2nd data analyses, re-contacting, etc.)
	c) Will you share the identifiable information/specimens with others not on your IRB approved study?	☐ Yes- **STOP- the study cannot be closed.** See the directions page. ☐ No, not without first submitting a new protocol and gaining IRB approval.

	d) How will sensitive information or specimens be ***protected* and *stored*** and at ***what locations*** will they be kept? Note: this info should not be kept **off** WSU, affiliate, sponsor, Iron Mountain site (don't keep at home, on jump drive, etc.).	☐ On secure server that is password protected and the file is also password protected. Server is at ☐ WSU ☐ KCI ☐ DMC ☐ VAMC ☐ Iron Mountain's encompassing security system. ☐ Other:
19.	***De-identified* Research Data and/or *De-identified* Specimens**	
	a) *How* and at *what location* will the de-identified data or specimens be *stored*? Note, Data must be stored in a WSU approved secure manner. Please review the IRB approved protocol for the storage mechanism indicated.	☐ Data has already been destroyed—You are done with this form ☐ No data was collected —You are done with this form ☐ Iron Mountain ☐ Other:
	b) How will the de-identified data/specimens be *protected*?	☐ Iron Mountain's encompassing security system. ☐ Other:
	c) How will the de-identified data/specimens be *destroyed*?	☐ By Iron Mountain ☐ Shredding ☐ De-identified data will not be destroyed ☐ Other: