Wayne State University
Institutional Review Board (IRB)

WSU IRB Administration Office
87 East Canfield, Second Floor
Detroit, MI, 48201
313-577-1628
irb.wayne.edu

IRB eProtocol

Continuation Submissions

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Continuation Session Outline

- **WSU IRB Continuation**
  - Overview of requirements & Continuation submission reminders
- **Submitting an eProtocol Continuation**
- **Completing the continuation form**
  - Attaching documents
- **Making modifications at the time of Continuation**
- **Questions**

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Continuation to IRB applications

(Overview)

The WSU IRB is responsible for continuing review of research at intervals appropriate to the degree of risk.

The IRB conducts an in-depth review of the all pertinent documents to determine whether the research continues to meet the criteria for approval.

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Continuation Key Terms

(overview)

Expiration Date: date in which an approved research protocol terminates unless a request for continuation/renewal is reviewed and approved

Protocol Approval Period: approval interval specified by the IRB. (6 months, 364 days, 36 months etc.). The WSU approval period begins from the initial date of IRB approval and ends at midnight on the day of expiration. Approval periods are specified on IRB approval memo.

Full Board submissions expiration date is based on the date last reviewed at a convened IRB Meeting.

Expedited submissions expiration date is based on the date approved by the expedited reviewer.

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Continuation Key Terms

(overview)

Lapse of IRB Approval: continuation/renewal not granted prior to the expiration date.

No research activities can be conducted

Research Activities Include:

- Recruitment and Informed Consent Procedures
- Collection of data/information from or about living individuals
- All research-interventions or interactions with currently enrolled participants (unless the IRB finds that it is in the best interest of the participants to continue interventions or interactions)
- Analysis involving human participant data

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eProtocol Continuation Reminders

90 days

60 days

30 days

90 days from the date of expiration. The Continuation Form is available. The continuation form is not available before this date in eProtocol.

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eProtocol Continuation Reminders

60 days before Expiration

Submit to the IRB at least **60 days** before to deter a lapse in approval.

Minimum Recommendation:

Submit at least 6 weeks before expiration

Single IRB studies 8 to 10 weeks

However remember any administrative approvals (PRMC, VA-CIC)

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eProtocol Continuation Reminders

60 days AFTER

Expiration

Continuation Submission

is not allowed

Study will need to be submitted as new protocol

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Submitting an eProtocol Continuation

System Requirements Reminder

- WSU Access ID & Password is required for log in
- Supported by Firefox & Safari web browsers



- CITI Training is required for all personnel.

CITI Training must remain up to date for all key personnel
The Basic Refresher course must be completed before submission

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Submission Method Comparison

Traditional Paper Method	eProtocol
Continuation Form Available on IRB website	Continuation Form Available in eProtocol 90 days before expiration
CITI Training Checked Manually	CITI Training is checked electronically (WSU Access ID must be included for CITI profile)
Modifications not made during continuation submission	Modifications/Amendments can be made during the continuation submission

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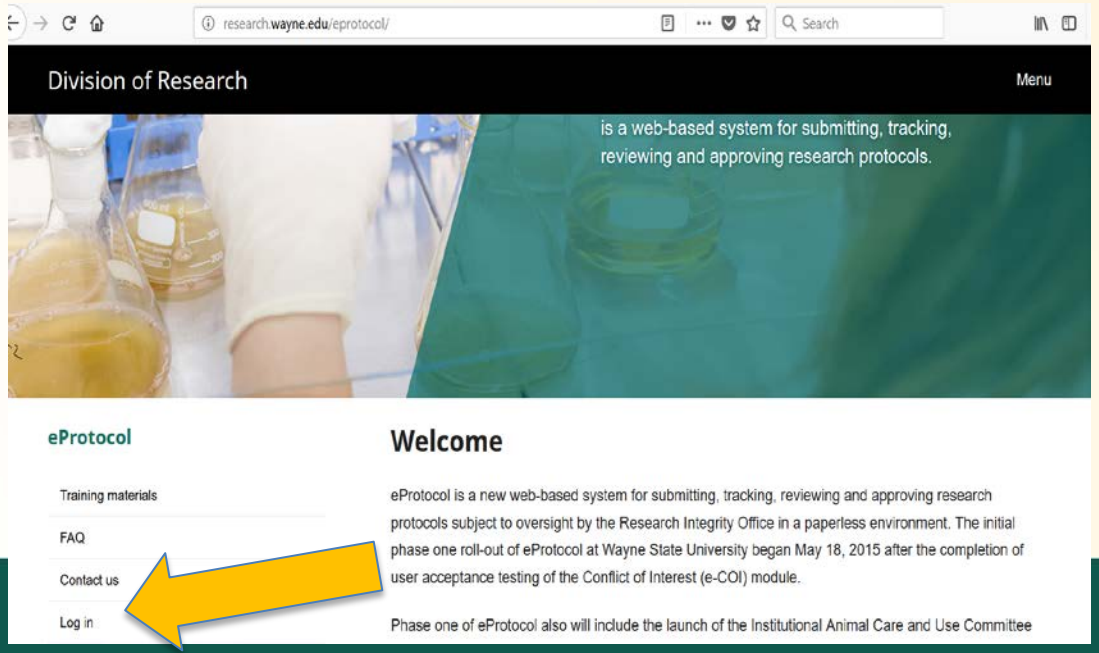
Submit an eProtocol Continuation

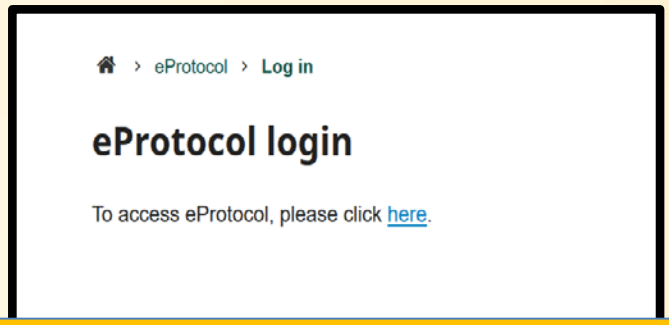
Log on to eProtocol

WSU Access ID & Password is required

eProtocol link on the IRB's website

This link will take you to the Division of Research eProtocol's website





https://ksprodweb.ovpr.wayne.edu/

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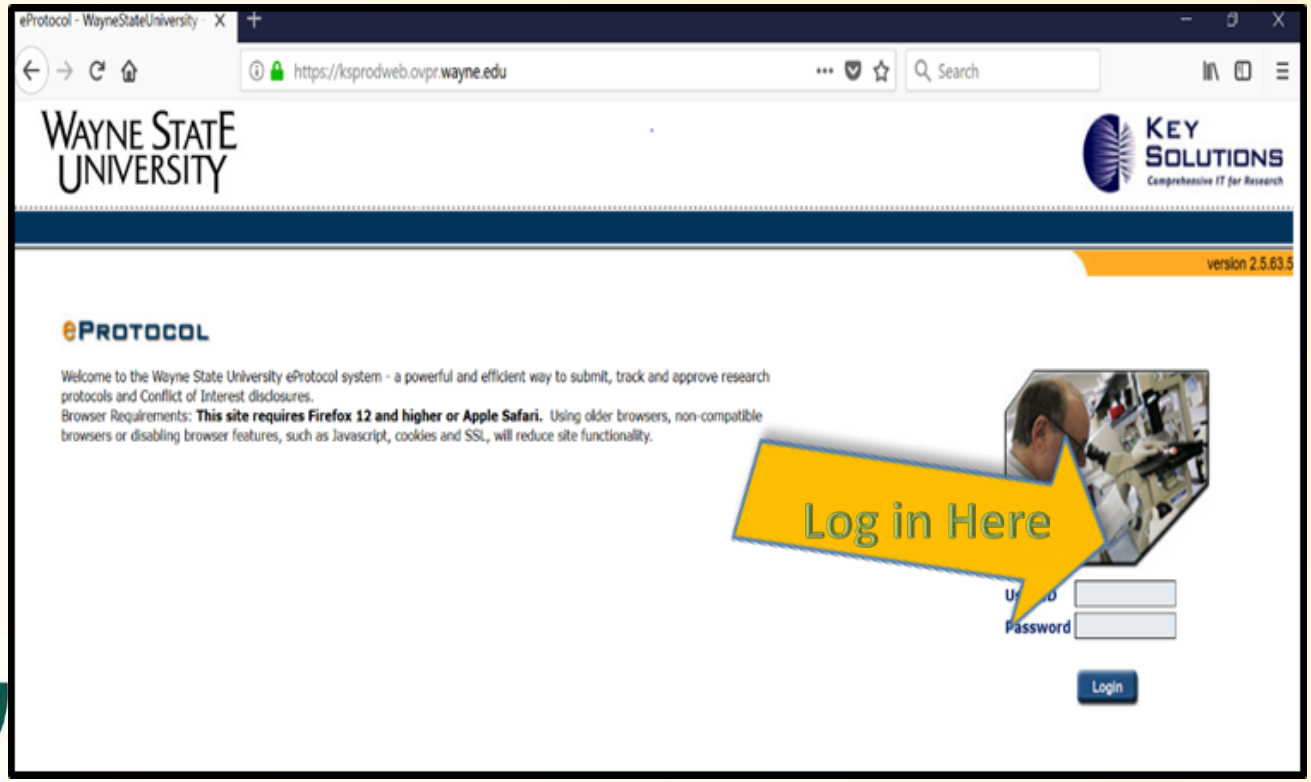
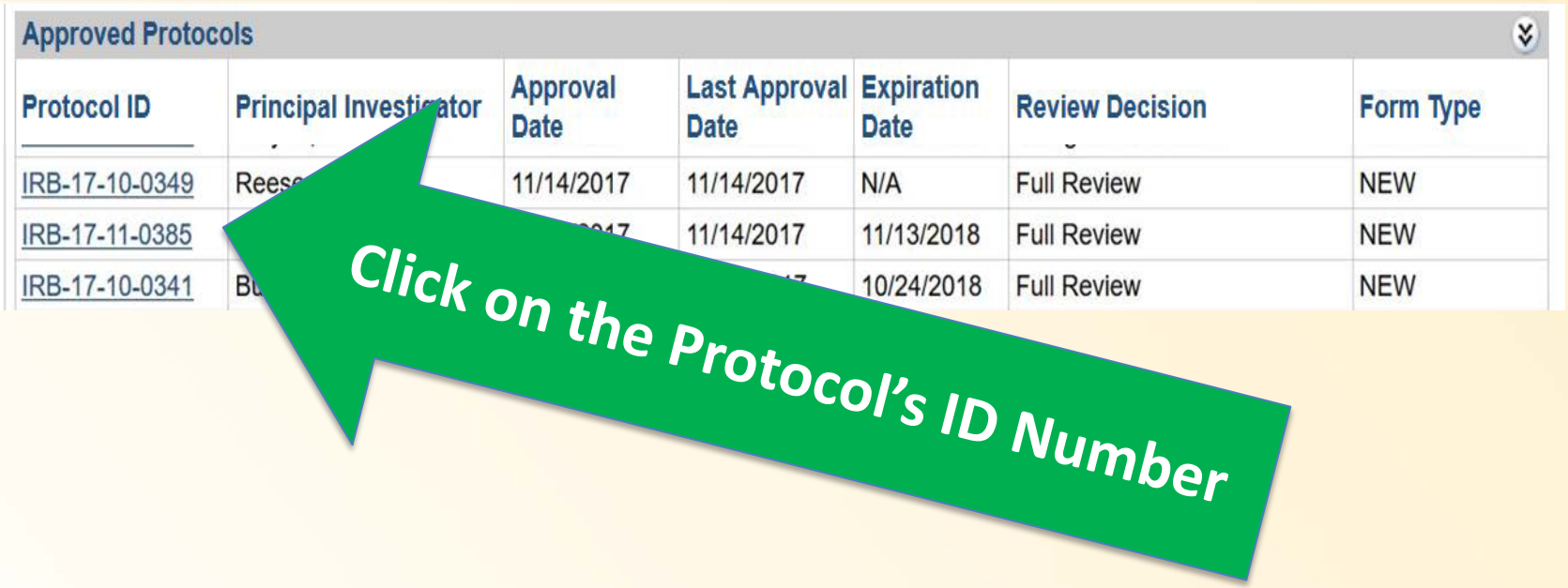
Submitting an eProtocol Continuation

Log on to eProtocol



Starting a Continuation

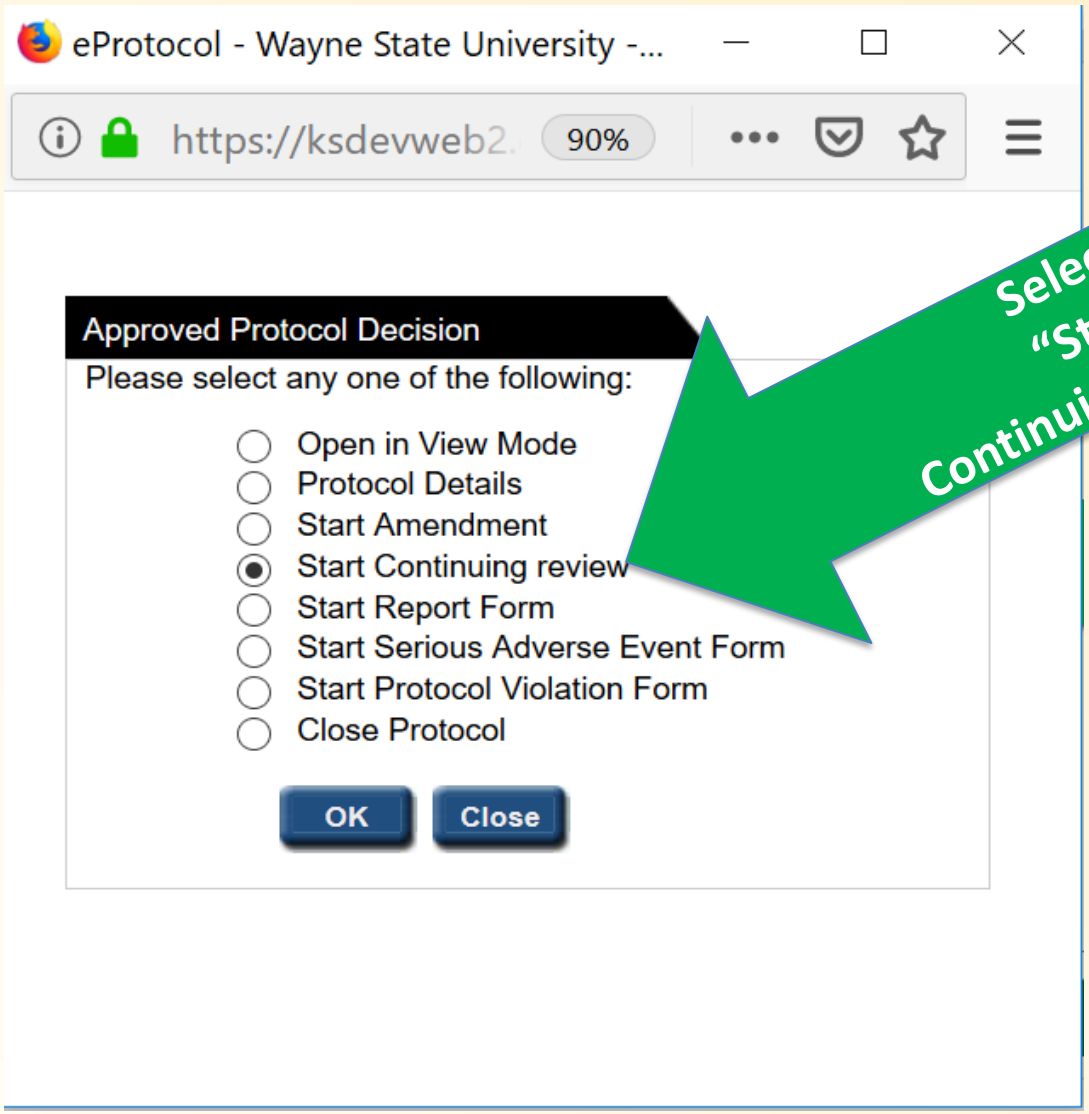
Scroll down to the **Approved Protocols** section on your IRB Dashboard



Key Personnel that have edit capability for a submission can start and submit a continuation.

- Those listed under **Personnel Information** as: PI, Co-Investigator, Study Coordinator, Administrative Contact have edit capability.
- Key personnel listed as "Other Personnel" **do not** have edit capability

Starting a Continuation



eProtocol Continuation Form

Complete all sections/questions of the form

REVIEW TYPE

☐ **FULL BOARD** ☐ **EXPEDITED**

Note: Expedited Continuation Review is allowed for a full board protocol when: (a) has no participants enrolled at any site subject to WSU IRB Oversight, (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 applicable, select one of the following:

- ☐ Eligible for Flexible Review (see IRB Website for Flexible Review Policy http://research.wayne.edu/irb/policies-human-research.php)
- ☐ Eligible for Transition to the Revised Common Rule (see IRB Forms site for Transition Appendix) Attach Transition Appendix to Protocol Information-Attachments Tab
- ☐ *Status Update Report
- ☐ N/A

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eProtocol Continuation Form

CONFLICT OF INTEREST REMINDER

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:

(I) 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.

(II) The PI must update the COI section of this Form and attach the FCOI management plan to the Protocol information-Attachments section.

STUDY STATUS: PARTICIPANT ENROLLMENT

Has this project accrued participants (consented) and/or collected data/specimens since last IRB Approval? Yes ✓ No N/A

If No, please select reasons for not accruing participants/data/specimens.

- ☐ Insufficient Staff
- ☐ Insufficient Funding
- ☑ Lack of eligible participants
- ☐ Other

If Other, please explain:

Carefully responding to the requested information

eProtocol Continuation Form

STUDY STATUS: PROGRESS TO DATE

Provide a brief summary of study's progress to date.

EVENT REPORTING

Has approval for this study expired? Yes ✓ No

Please explain the reason(s) that the approval lapsed

Please describe the corrective action plan to prevent a lapse in the future

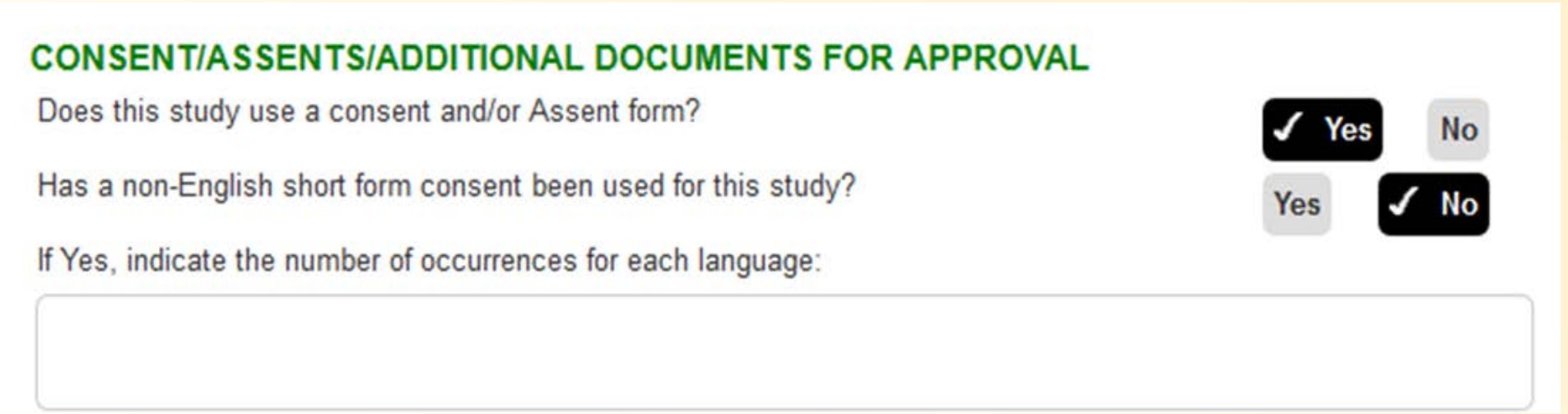
Were additional research participants enrolled, or data collected, after the expiration date? Yes ✓ No

Describe all activities that continued after expiration of approval

The various sections request information that is vital to determining if the submission still meets the criteria for approval

eProtocol Continuation Form

Provide current consent and/or assent documents



ePROTOCOL CONTINUATION SUBMISSION

Attach clean copies of:

- Consent/Assent Forms
- Participant Materials
- Recruitment Materials/Advertisements/Flyers

Attach publications and presentations

eProtocol Continuation Submission

Attachment	Add | Delete
Click the 'Add' button to add 'Attachment'	

Please attach a 'clean' of all Consent/Assent/Participant document(s)
A "clean" unstamped copy of all documents that are due to expire should be included: Consents/Assents /Recruitment/Participant Materials

Attachment	Add | Delete
Click the 'Add' button to add 'Attachment'	

Attach any publications, abstracts, and/or presentations that have resulted from the study.

Attachment	Add | Delete
Click the 'Add' button to add 'Attachment'	

Please attach most recent Data Safety and Monitoring Report

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- An amendment can not be submitted when a continuation is pending.

- The Continuation must be approved before another submission type is allowed.

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eProtocol Continuation Submission

Making Modifications

However, **modifications** are allowed during submission of the continuation.

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eProtocol Continuation Submission

If modifying the submission:

- Indicate modifications are being made on the continuation form.
- Provide a summary of the modifications requested
- Attach the modification summary to the continuation application

eProtocol Continuation Form

Making Modifications

PROTOCOL MODIFICATIONS

Are you making changes to this study?

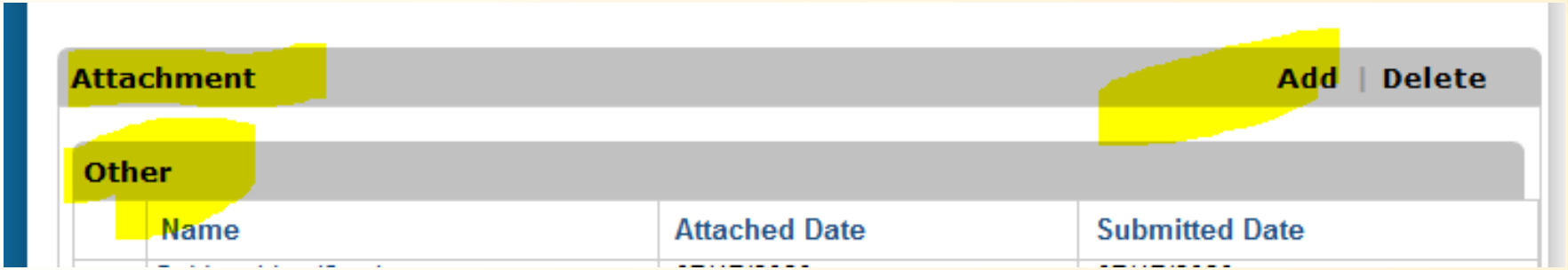
✓ Yes No

☐ Please provide a summary of the changes being made. Please update all applicable sections of eProtocol form. Note, If changes are being made to the study's goals, aims, or hypothesis this must be updated for the background rational section of eProtocol.

eProtocol Continuation Form

Making Modifications

- Towards the bottom of the continuation form, attach the modifications summary under “Other” Attachments.



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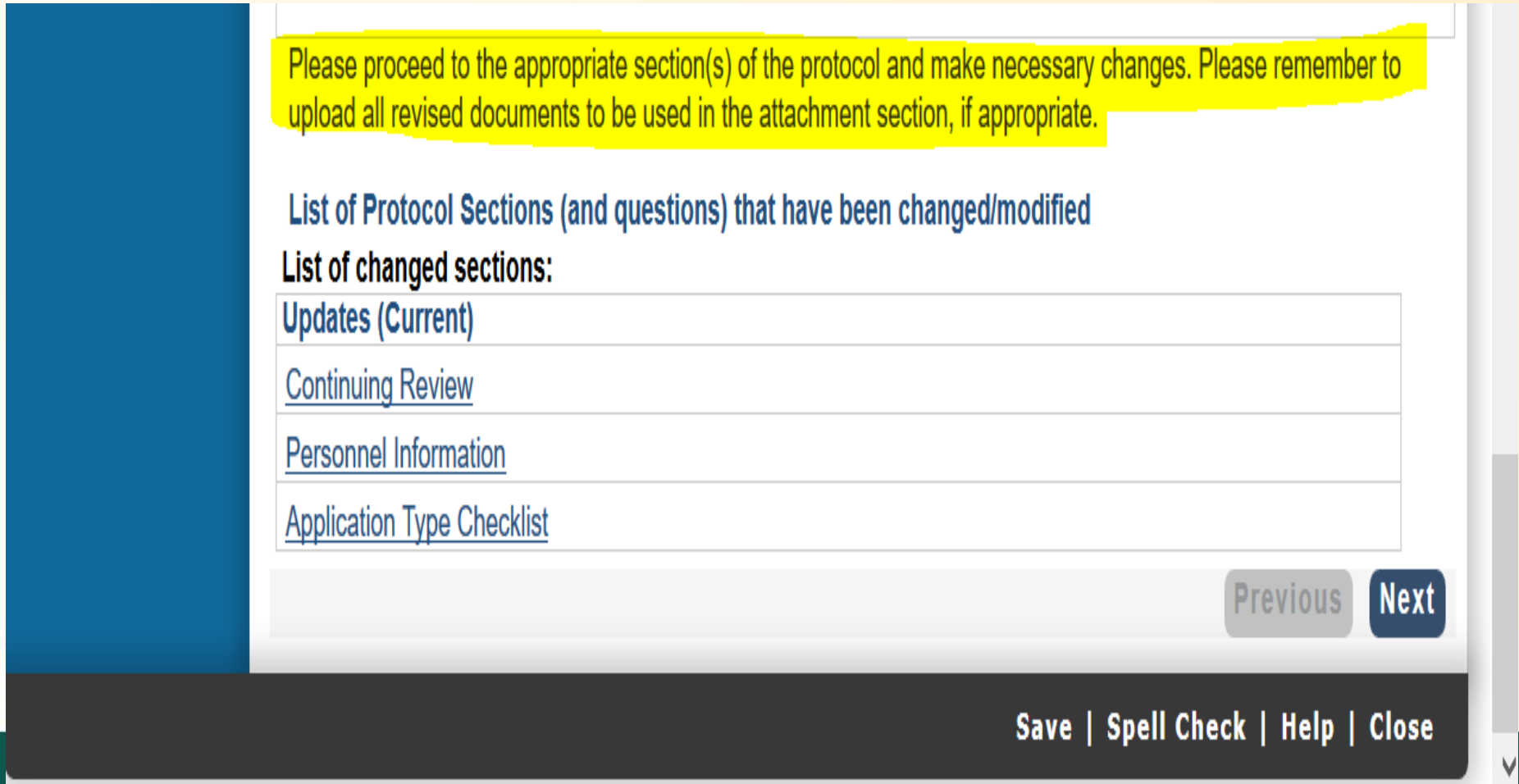
eProtocol Continuation Form

As you make changes the sections revised will appear at the end of the form



Questions ?

Need Assistance contact the IRB Administration Office

WSUIRBinfo@wayne.edu

Tel# 313-577-1628

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