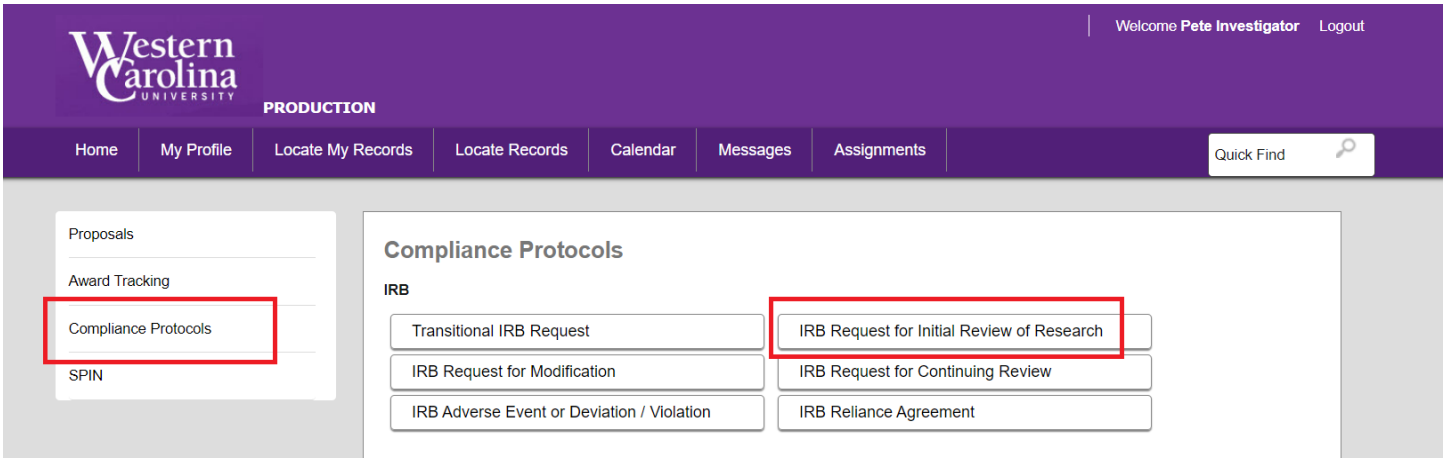
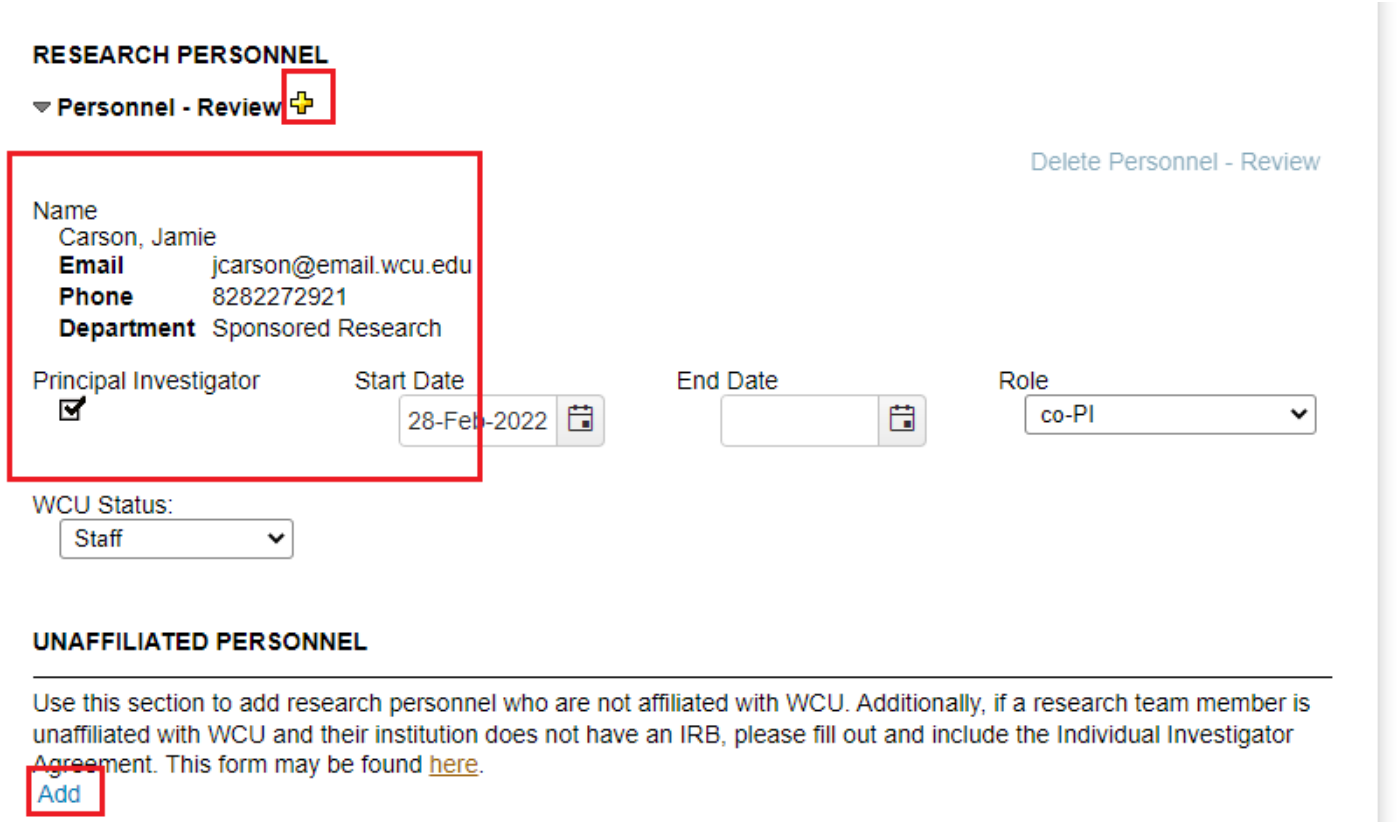
## Creating a New IRB Application

Login to InfoEd using your WCU credentials. You will be taken to your home screen in InfoEd. Click on “Compliance Protocols” in the menu on the left. IRB submissions may be found at the top of the screen. Click on “IRB Request for Initial Review of Research.” A new window will open.




The first part of the application is Research Personnel. The individual who creates the application is automatically named Principal Investigator. To change this, or add or more members to the research team, click the yellow plus sign. Any researcher not affiliated with WCU can be added by clicking “Add” under the Unaffiliated Personnel section.

Please note, **you should save your work continually by clicking “Save” in the top right corner**. When you save your application, you may come back to it at any time to complete it.



The next section will be the Project Summary section. Give your project a title and description. If the research is funded, click the pencil, begin typing, and locate your sponsor on the list. Continue answering the application questions.

**PROJECT SUMMARY**

Protocol Number
2021-11-01-02

Submission Number
2021-11-01-02-01

*1. Project Title:
Give your project a Title

*Principal Investigator
Investigator, Pete

Submission Type
IRB Request for Initial Review of Research

Protocol Type
IRB

2. Funding Source, if applicable. For internal grants and/or awards please select, Western Carolina University.

*3. Project Description: provide a concise (3-5 sentences) summary of the purpose and rationale of the activity using lay language.

*4. Does data collection involve the use of a survey?
☐ Yes ☐ No

*5. Does your research **only** involve using an existing data set where no recruitment is necessary?
☐ Yes ☐ No

The next section is for conflicts and dual relationships.

**CONFLICT OF INTEREST/DUAL RELATIONSHIPS**

*1. Are there any known or potential conflicts of interests (financial or other personal considerations that may compromise or potentially appear to compromise an investigator's objectivity, see University Policy 54) between the researchers and the participants or other entities related to this research?
☐ Yes ☐ No

*2. Do any of the research team members have an authority relationship (ex. Instructor/student, supervisor/employee, physician/patient, or other) with the potential participants?
☑ Yes ☐ No

Describe the nature of the relationship and how the research will be conducted to avoid undue influence on participants:
Disclose any authority relationships

Continue to the Study Procedures section. Click “Add” to upload your data collection instrument. Describe the data to be collected, name the instrument, and click the upload icon to upload the instrument. You may add as many instruments as needed.

**STUDY PROCEDURES**

1. Projected recruitment, data collection, and data analysis dates:
From: date of IRB approval

*To:

*2. List and describe the data that will be collected from participants. Upload a copy of each data collection instrument. If you are using an existing data set, please describe the data points already collected; you are not required to upload the existing data set.

Add

*3. Provide a sequential description of the activities in which participants will engage, including length of participation (if there are multiple sessions include frequency and length of each session), nature of intervention (if applicable), and indicate the timepoints of each data collection type listed above. If you are using an existing data set, please explain how you will be using the data in your research.

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Add

Remove

| | |
|---|---|
| Describe type of Data | Name, Email, DOB |
| Name of Data Collection Instrument | Survey |
| File Upload | |

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Proceed to the Benefits and Risk section of the application. Explain the benefits of the research.

**RISK AND BENEFITS SECTION**

1. Provide a description of the anticipated benefits from this study
The benefits listed in this section should also be included in the Benefits section of the informed consent.

☑ Participants of the study may directly benefit. Please note, compensation for participation is not considered to be a benefit.

Explain

Explain the benefits

☑ Society may benefit from the study:

Explain

Explain the benefits

Use the dropdowns to select the level of risk and complete any follow-up questions.

The risks listed in this section should also be included in the Risk section of the informed consent. Please also consider whether the disclosure of participants' responses outside the research team would place the subject at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, educational advancement or reputation.

Minimal risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

a. Indicate the appropriate level of risk for each category below.

| Type of Risk | Risk Level |
|---|---|
| Legal | * No foreseeable risk |
| Psychological | * No more than minimal risk |
| Social | * |
| Economic | * |
| Physical | * |

No foreseeable risk
More than minimal risk
No more than minimal risk

*b. Explain the nature of the risk, its likelihood of occurring, and its potential impact on participants:

The next section will be the Privacy and Confidentiality Section. Complete the section.

**PROTECTION OF PARTICIPANT PRIVACY AND CONFIDENTIALITY**

1. Confidentiality and Anonymity

a. Will the data from your study be:

☑ Confidential (The researcher can directly or indirectly match the data to the participant but participant identity is not disclosed.)

☐ Anonymous (Not even the researcher can match the data to the participant.)

☐ Neither (The researcher can match the data to the participant and participant identity will be disclosed.)

*b. List the types of identifying information to be collected (name, birthdate, email address, audio/visual recording, etc) and provide a rationale for why collection of each identifier is necessary for completion of the study:

email address in order to send interview link

Click "Add" to upload any Data Use Agreements. If your research requires Site Permission, click "Add" to upload the site permission letter. Add as many permission letters as needed. You may also upload any other relevant document in the Additional Documentation Section.

Submit copies of data use agreements if applicable. All data use agreements between WCU and external agencies should be reviewed by WCU Legal Counsel prior to signing.

Add

**EXTERNAL SITES**

*Are you recruiting participants, collecting data or obtaining records at any off-campus location?

☑ Yes ☐ No

*Sites may include K-12 schools, churches, business, public agencies, universities etc. List each site and briefly describe site involvement. **A dated permission letter on agency letterhead must be uploaded for each site. If the external site is requesting WCU IRB approval prior to providing permission, the PI must include dated correspondence showing the external site is aware of the research and will approve of it, once IRB approval is received.**

Add

Remove

| | |
|---|---|
| External Site Name | |
| List activities conducted at site (recruitment, data collection, record source) | |
| Permission Letter | |

**ADDITIONAL DOCUMENTATION**

Use this section to upload any additional documents. Please name the document accordingly.

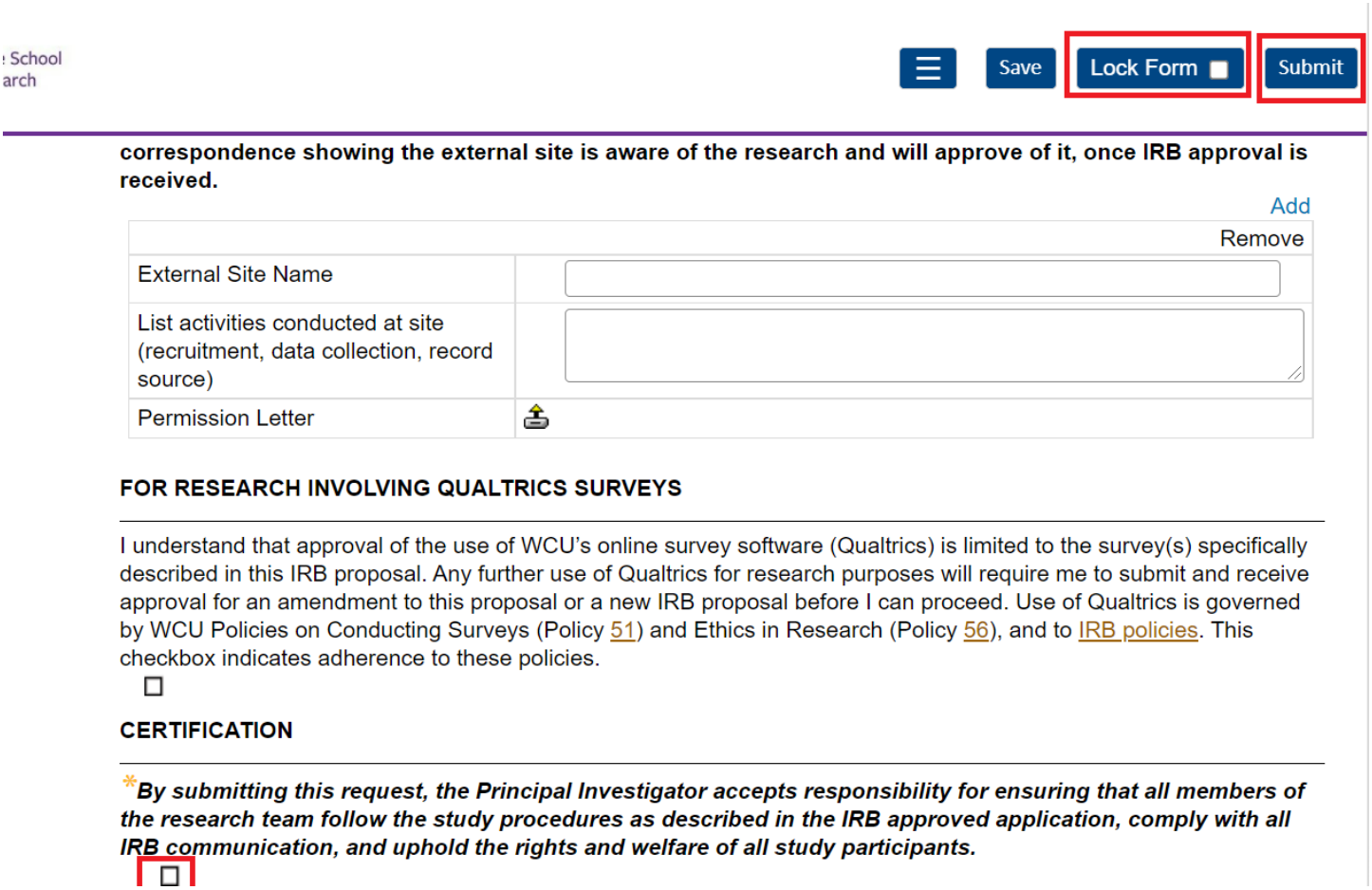
Add

**EXTERNAL SITES**

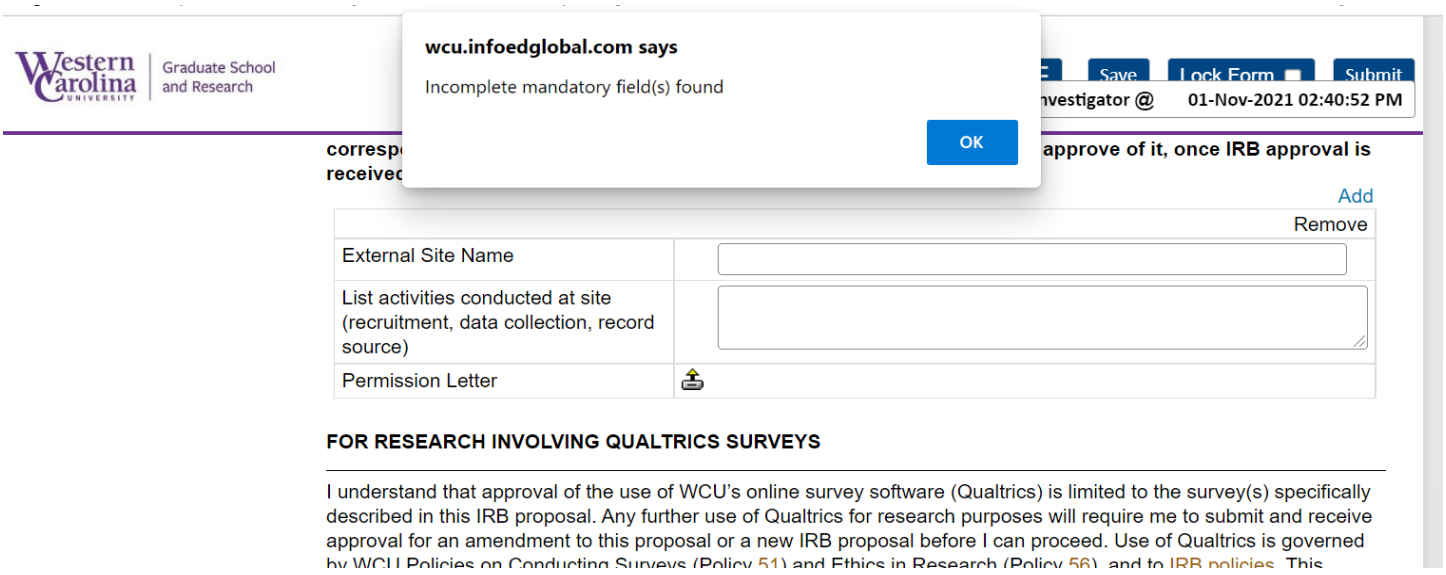
*Are you recruiting participants, collecting data or obtaining records at any off-campus location?

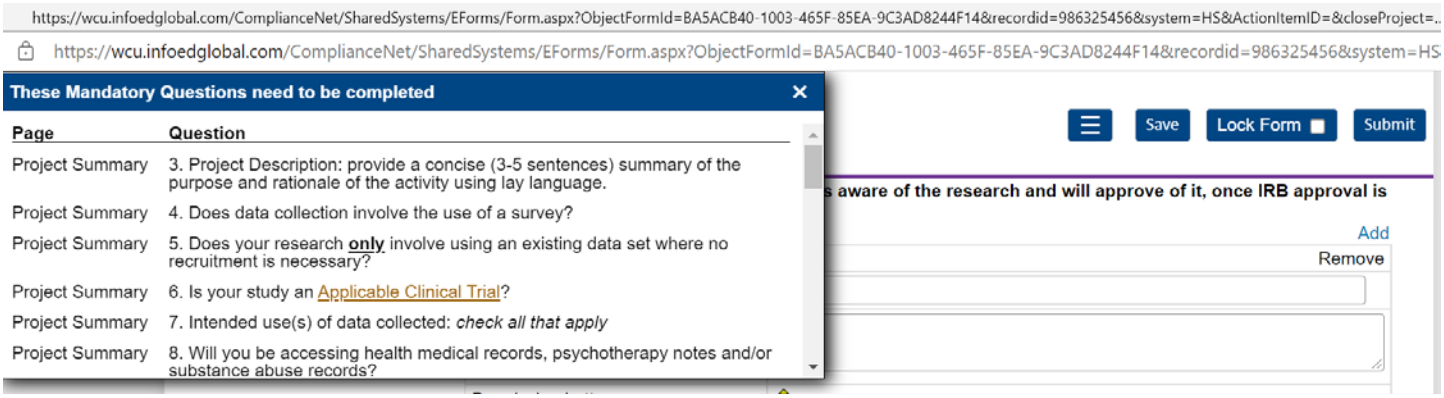
☐ Yes ☐ No

When you are finished filling out the application, check the certification box at the bottom of the application. Check the box next to “Lock Form.” Then click “Submit.”




If there are required questions that have not been answered, the system will notify you with a popup. Click ‘Ok.’ Another popup will appear to show which questions were missed.






Once all questions are answered, click “Lock Form” and then click “Submit”. Once the screen closes, your application has been submitted to the Research Compliance Office. You will receive an email notification.