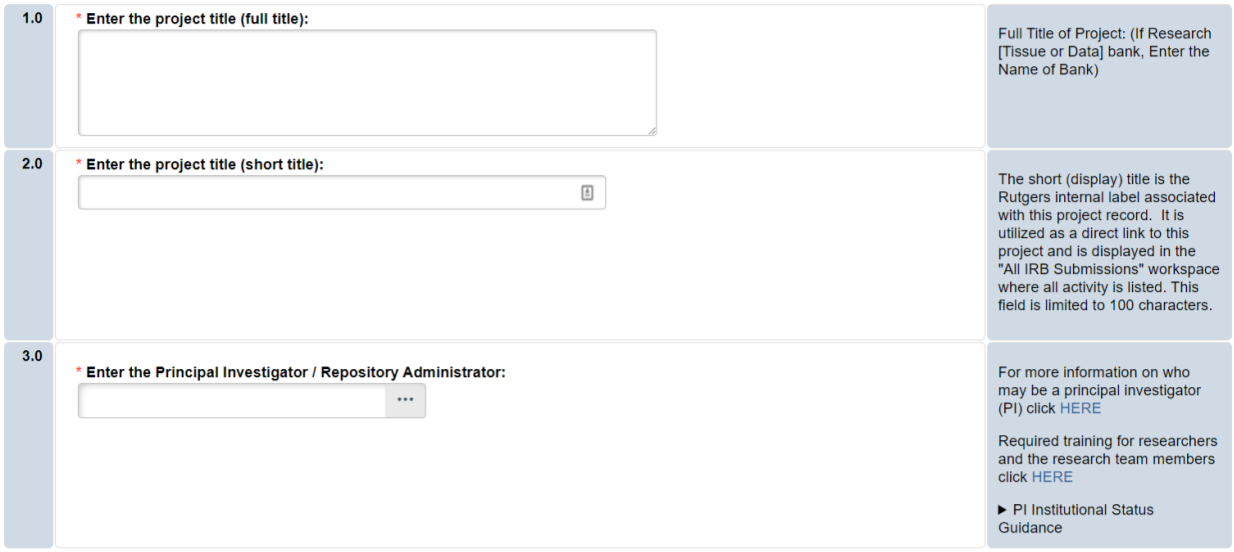
eIRB+ Application Guide

for Quality Improvement / Quality Assurance Projects

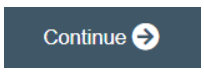
Please remember that not all sections below will apply to your application/research study. Some sections might NOT appear. The sections that appear as you complete your eIRB+ application are contingent upon your responses in previous sections. If you encounter difficulty in completing a section that does not appear below but DOES appear in your application, kindly contact the IRB office at irboffice@research.rutgers.edu for assistance.

Section 1.0 - General Project Information



- **ENTER** the study's Full Title (Q 1.0) and Short Title (Q 2.0). The Short Title entered will display in the eIRB+ dashboard.

- **ENTER** the Principal Investigator (Q 3.0) of the study by clicking the 3 dots (right side) or by typing the person's name in the open field.
    - **VISIT** our page to see who can and cannot serve as Principal Investigator (PI).
    - **RU graduate** students serving as the PI must **ADD** a faculty advisor as a Co-Investigator
- **ADD** a study coordinator in Q 4.0, the person entered here will receive all correspondence and notifications regarding this study along with the Principal Investigator.
- **ADD** any Rutgers-affiliated study team members in Q 5.0 Co-Investigators to Q 6.0 Other Study Staff.
    - **IRB Tip**: Ensure all members completed Rutgers CITI requirements

Once all information is provided, click 

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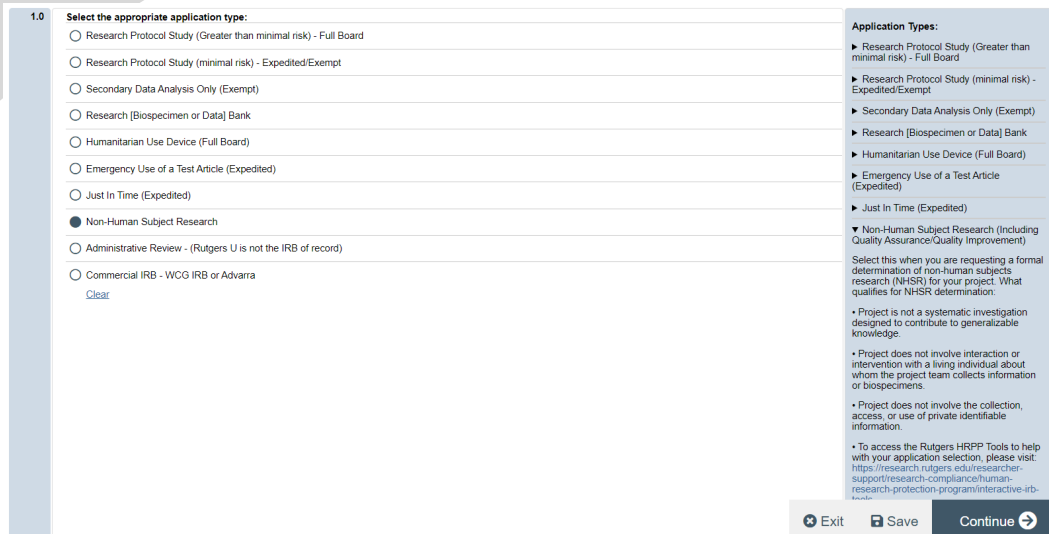
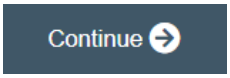
Section 1.1 - Submission Type



- For Non-Human Subject Research or Quality Assurance/Quality, **SELECT** 'Non-Human Subject Research.'

Once all information is provided, click 

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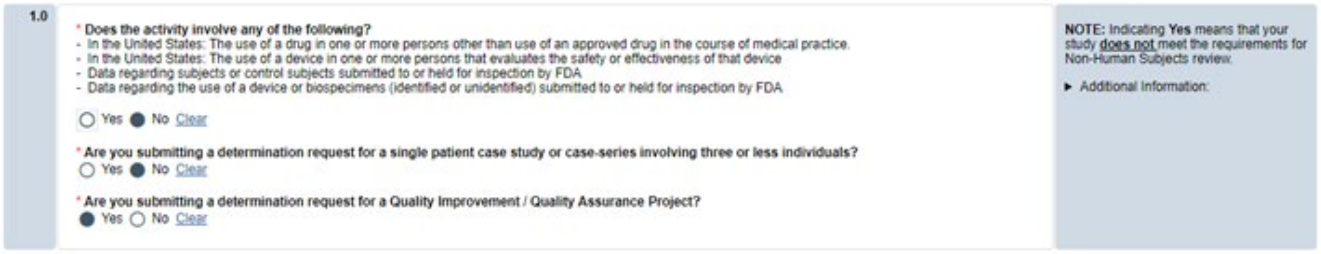
Section 2.0 Non-Human Subjects Research

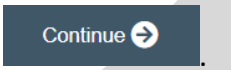
For **Quality Assurance/Quality Improvement** projects:

- **SELECT** 'No' to Q 1.0 and 2.0.
- **SELECT** 'Yes' to Q 3.0.



A case report is an unsystematic clinical observation that states the outcome or response of a single patient to a diagnostic strategy or treatment. Case reports serve to document and share novel cases amongst the medical community for educational purposes.

Quality Assurance, Quality Improvement, Program Evaluation, Evidence-Based Practice and Benchmarking are quality activities used to evaluate and/or (continuously) improve the effectiveness of organizational processes and practices, products, programs or services, as well as, to develop the appropriate benchmarks. The purpose of quality activities, and their conclusions, are local and specific, aiming to improve organizational efficiencies and effectiveness and ensuring educational, clinical or program decisions rest on sound evidence.

Once all information is provided, click 

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Section 2.4 - Quality Activities

RESPOND to all 10 TRUE/FALSE questions. Please note, **Q 8.0** requires a brief typed description. The guidance bar on the right provides additional context.

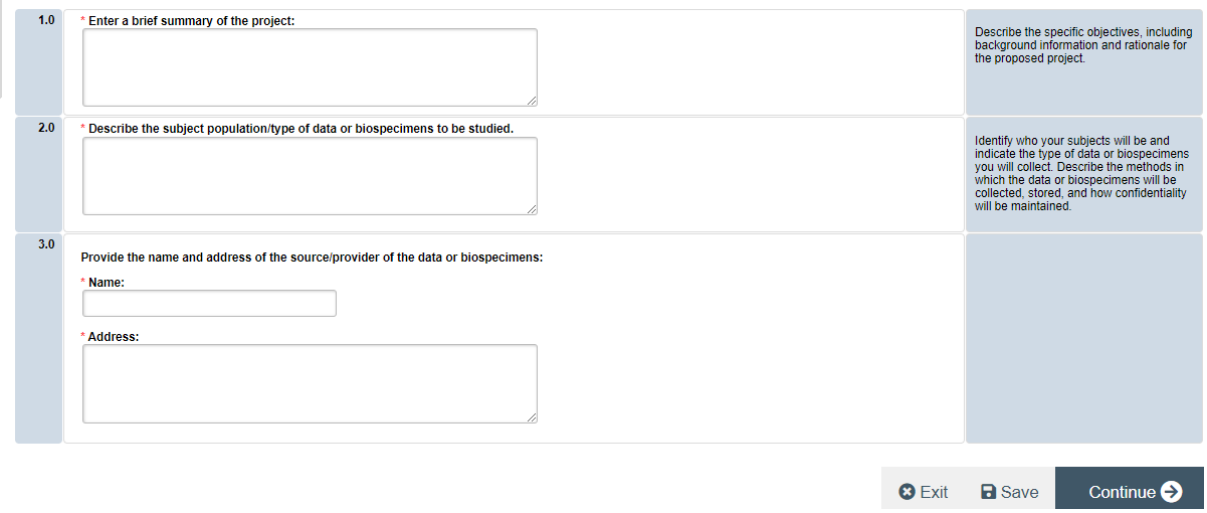
For a proposed project to be classified as containing only quality activities—which do not require IRB review—the answers to all of the questions in this page must be '**TRUE**' for each activity proposed in the project. If one or more answers is '**FALSE**', the project requires IRB review.

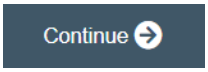
1.0	* The intent of the proposed activity is to assess and/or improve the quality of a practice, product or program to ensure established educational, clinical or program service standards are met or best evidentiary practices attained. ● True ○ False Clear	In order to qualify for NHSR/QA-QI determination: The intent of the proposed activity must be to assess and/or improve the quality of an existing practice, product, or program to ensure established educational, clinical or program service standards are met or best evidentiary practices attained
2.0	* No activity proposed provides less than standard of care, services or instruction to participants. ● True ○ False Clear	Quality Assurance (QA) and Quality Improvement (QI) consist of activities that are undertaken to measure the effectiveness of standard accepted processes, programs, or services, the results of which are intended to be shared only with individuals associated with the process, program or service being evaluated. QA/QI projects cannot expose individuals to any additional risks. More information can be found HERE:
3.0	* No practice, product or program changes proposed are experimental and no test interventions or research questions are added that go beyond established or evidentiary best practice. ● True ○ False Clear	In order to qualify for NHSR/QA-QI determination: The practice, product or program changes proposed: * MUST NOT be experimental; * MUST NOT involve test interventions; * MUST NOT involve research questions that go beyond established or evidentiary best practice.
4.0	* The proposed activity does not: (1) include a 'control group' in whom care, products, services or educational instruction are intentionally withheld to allow an assessment of its efficacy or (2) assign participants to receive different procedures, therapies or educational instruction based on a pre-determined plan such as randomization. ● True ○ False Clear	Control group is the group of subject that receive no treatment or a standardized treatment. The control group is compared to the treatment/intervention group.
5.0	* The proposed activity does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including "off-label" indications). ● True ○ False Clear	
6.0	* The proposed activity does not test an intervention or add research questions that go beyond established evidentiary best practice and/or are intended to generate generalizable knowledge. ● True ○ False Clear	
7.0	* The proposed activity would not increase harm—physical, psychological, social or economic—than would normally be encountered by the individual if s/he was not participating in this activity. ● True ○ False Clear	
8.0	* The lead person on the project has organizational responsibility and authority to recommend or impose a corrective action plan based on the outcome(s) of the activity, as applicable. ● True ○ False Clear * Describe how the findings from this activity will be utilized by appropriate stakeholders with organizational responsibility/authority to recommend or impose a corrective action plan:	
9.0	* Interpretation of the data or any feedback to those who would benefit from the findings will not be deliberately delayed. ● True ○ False Clear	
10.0	* The proposed activity has merit and will likely be conducted regardless of any possibility of publication or presentation that may result from it. ● True ○ False Clear	

Exit Save Continue

Once all information is provided, click Continue .

Section 2.5 Non-Human Subjects Research Study Summary



Once all information is provided, then click 

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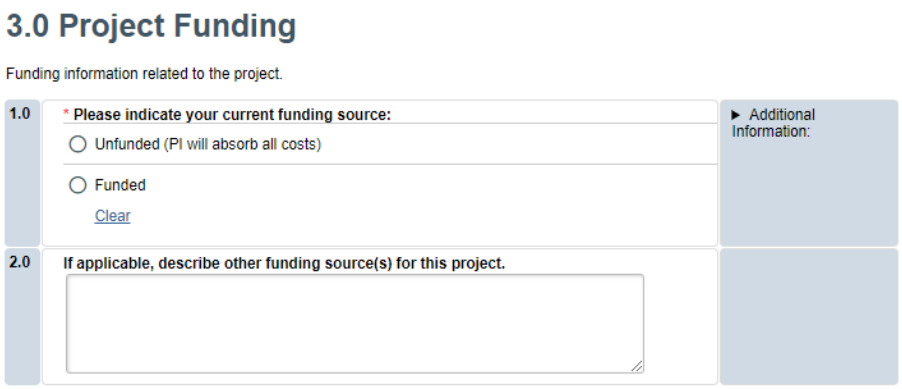
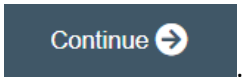
Section 3.0 Project Funding



- **SELECT** whether the study is **funded** or **unfunded** in Q 1.0.
    - Select **unfunded** only if the PI of the study will absorb all costs.
    - If funded externally or by department, select **funded** and fill out the following section 3.1 Funding Sponsor Information.

Once all information is provided, then click 

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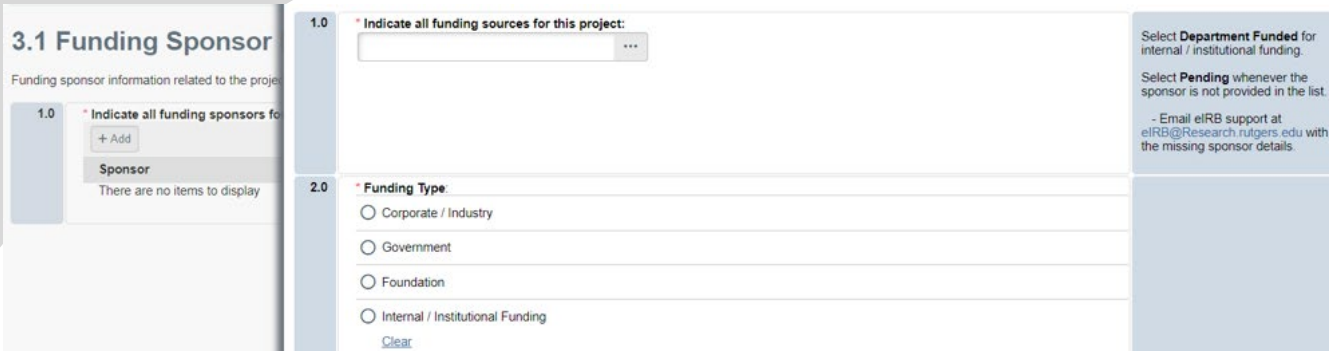
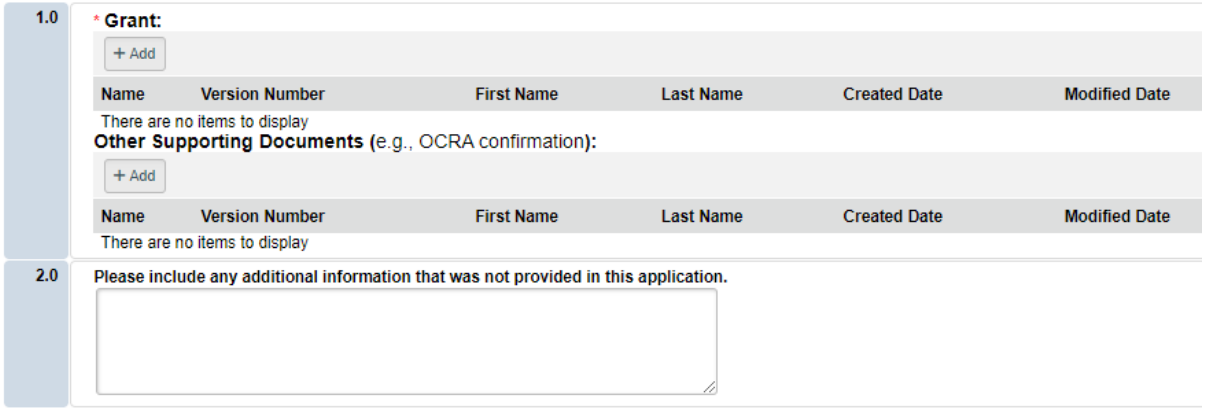
Section 3.1 Funding Sponsor Information



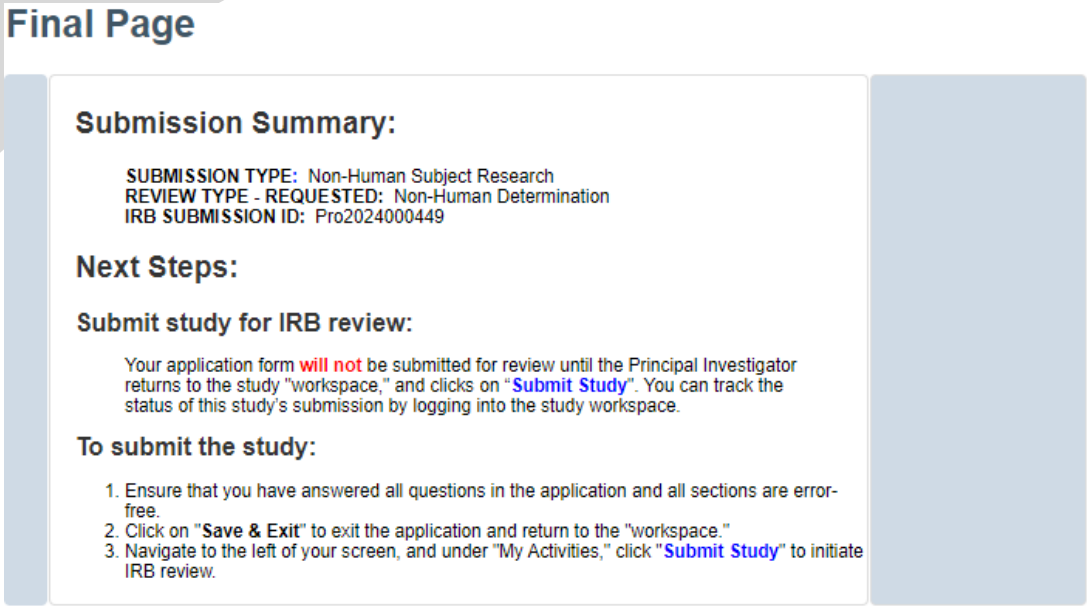
- **ADD** funding source by selecting the + Add
- **TYPE** the name of funding source or type 'Department Funded' for internal/institutional funding.
- **SELECT** funding type and select OK to save.
- **DELETE** a sponsor you've listed by accident by hovering over the sponsor entry and selecting the 'X' that appears on the right side of the highlighted row.

Once all information is provided, click Continue .

Section 10.0 - Attachments

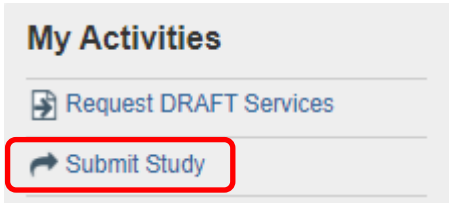


- **UPLOAD** any other supporting documents: Site agreements, surveys, data collection tools, certifications, etc.
- **SELECT** Continue .



- **REMEMBER** to select 

which will take you to the study main page. Selecting this will **NOT** submit your application to the IRB. You must navigate to **MY ACTIVITIES** and select 'Submit Study' if you are ready to submit to the IRB.



Related Links and Interactive Tools

I do not know if my research is considered human subject research or if I need to submit to the IRB?

Who can serve as the Principal Investigator on a research study?

What are the CITI requirements for the study personnel on my application?

What application type should I choose?

Are my research sites engaged in research? Use the Engagement in research tool.

I will be using a site for recruitment only, where can I find the performance site approval form?

Where can I read more information about international research and sites?

Who can I contact regarding Institutional Biosafety Committee (IBC) approval?

Who can I contact for questions about Scientific Review Board and obtaining SRB approval?

What consent template should I use? Use IRB Review Type and Template Recommendation Tool.

Where can I find the most recent consent form templates?

I will be using a site for recruitment only, where can I find the performance site approval form?

If you have any other questions, please contact the IRB inbox at irboffice@research.rutgers.edu.