Creating a New Protocol in BPMS

Please Read This Notice

Research with biological materials, such as recombinant DNA and/or biological pathogens, is required to be approved through an Institutional Biosafety Committee (IBC). A biosafety protocol is generated by a Principal Investigator to describe such research to provide the IBC with information to:

1. **accurately assess risks associated with the research**
2. **recommend an appropriate biosafety level for conducting the research**
3. **approve the protocol to allow research to continue**

Please be aware that all grants must be congruent with the biosafety protocol. If there is proposed work in a grant that is not in the biosafety protocol (but is required to be), the grant will be held.

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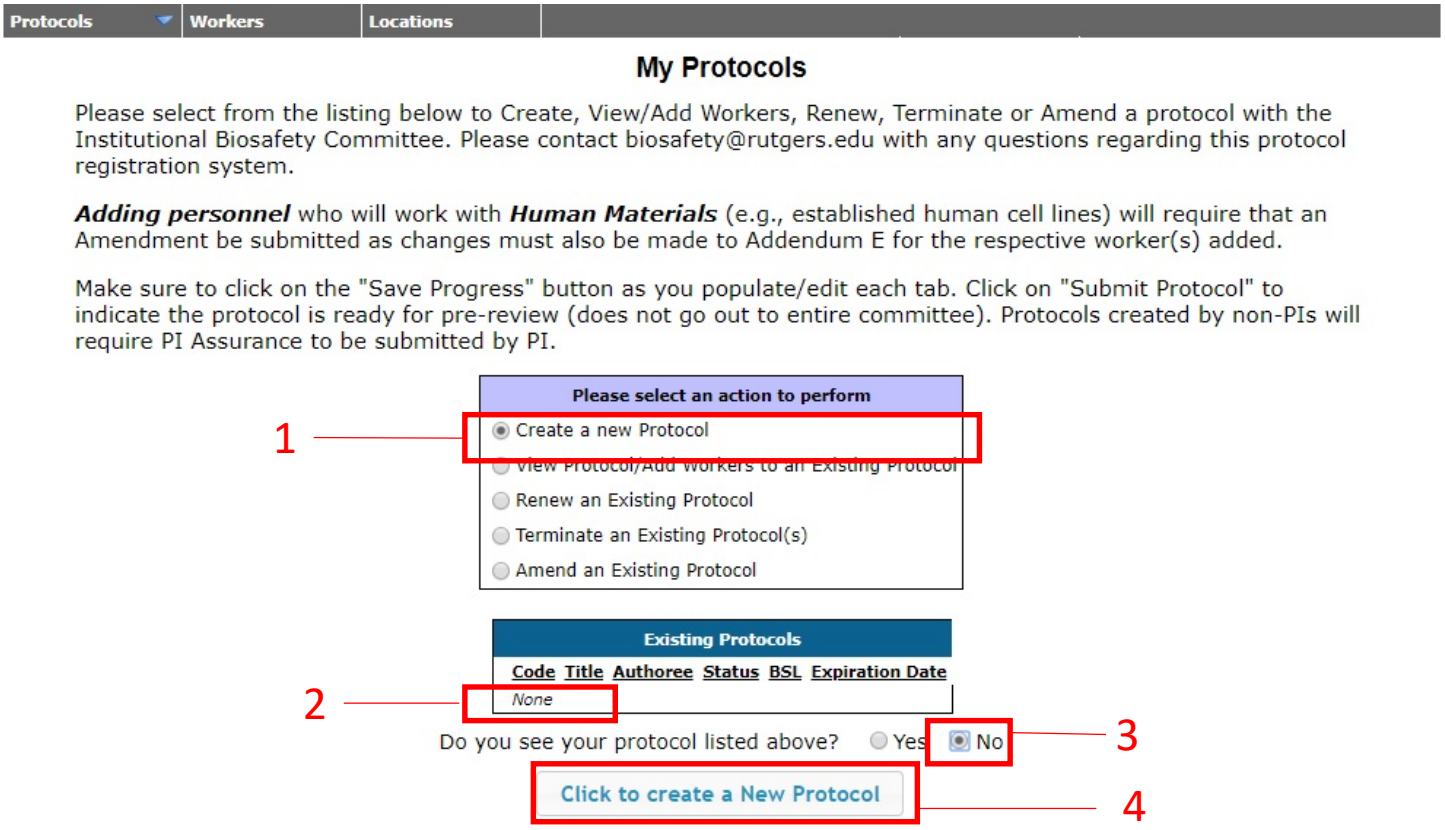
1. To create a new registration:

1. In “My Protocols”, click on “Create a new Protocol”
2. Verify that a similar protocol does not already exist in the “Existing Protocols” panel
3. Click “no” if there is no similar existing protocols
4. Click on “Click to create a New Protocol” button



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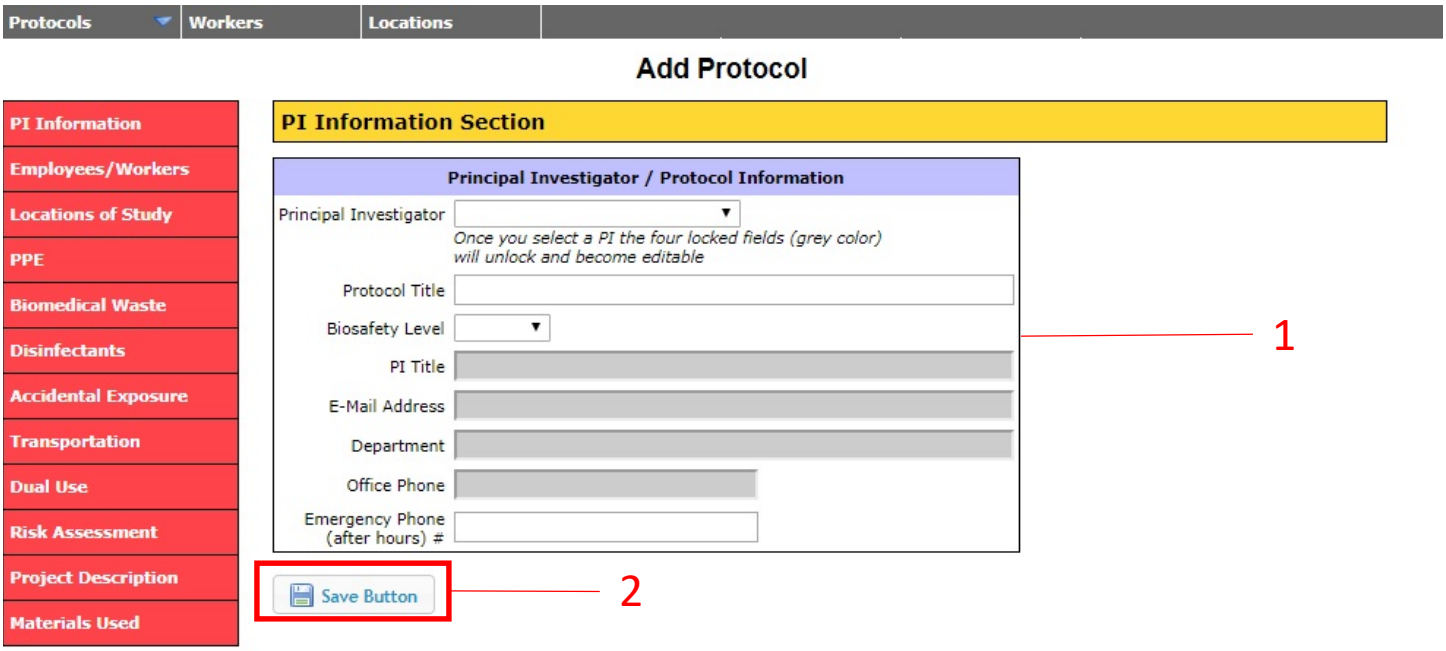
2. Initial PI Information:

1. Fill out Principal Investigator Information
   - *i. Information should be up-to-date*
   - *ii. Biosafety Level is the projected biosafety level of the laboratory for this protocol*
2. Click “Save Button”



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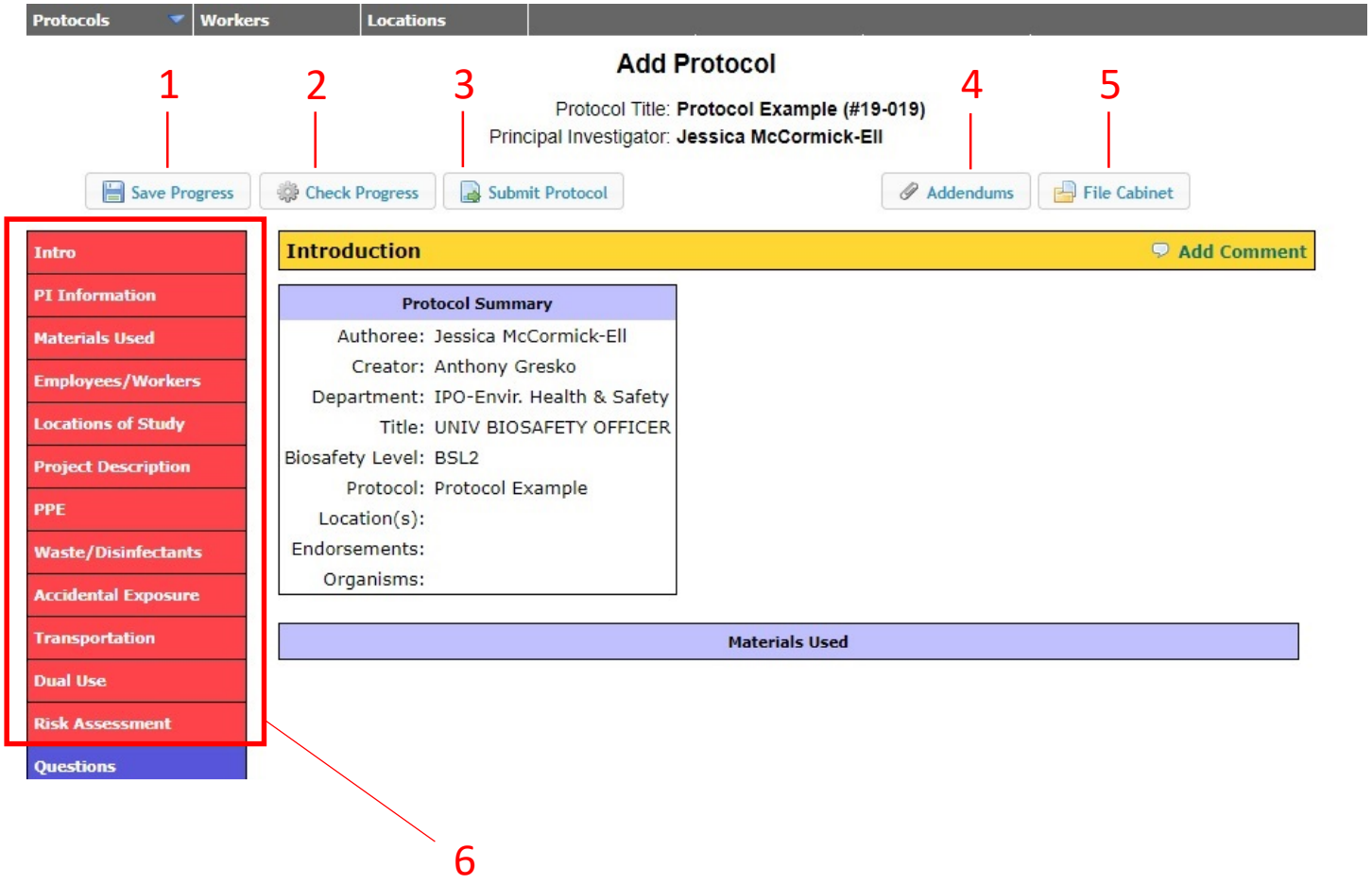
3. Home Screen:

1. "Save Progress" button – *allows progress to be saved.* ***This should be clicked often to continually save your progress.***
2. "Check Progress" button – *provides indications of sections yet to be completed*
3. "Submit Protocol" button – *will submit protocol upon completion of ALL sections*
4. Addendums – *Additional sections of the protocol to describe materials used. Each addendum will be created only after you complete the "Materials Used" section of the Protocol*
5. File Cabinet – *allows uploads of additional documents (i.e. laboratory SOPs, plasmid/vector maps, permits, etc.)*
6. Protocol Sections – *must be completed (see next pages of this guide)*



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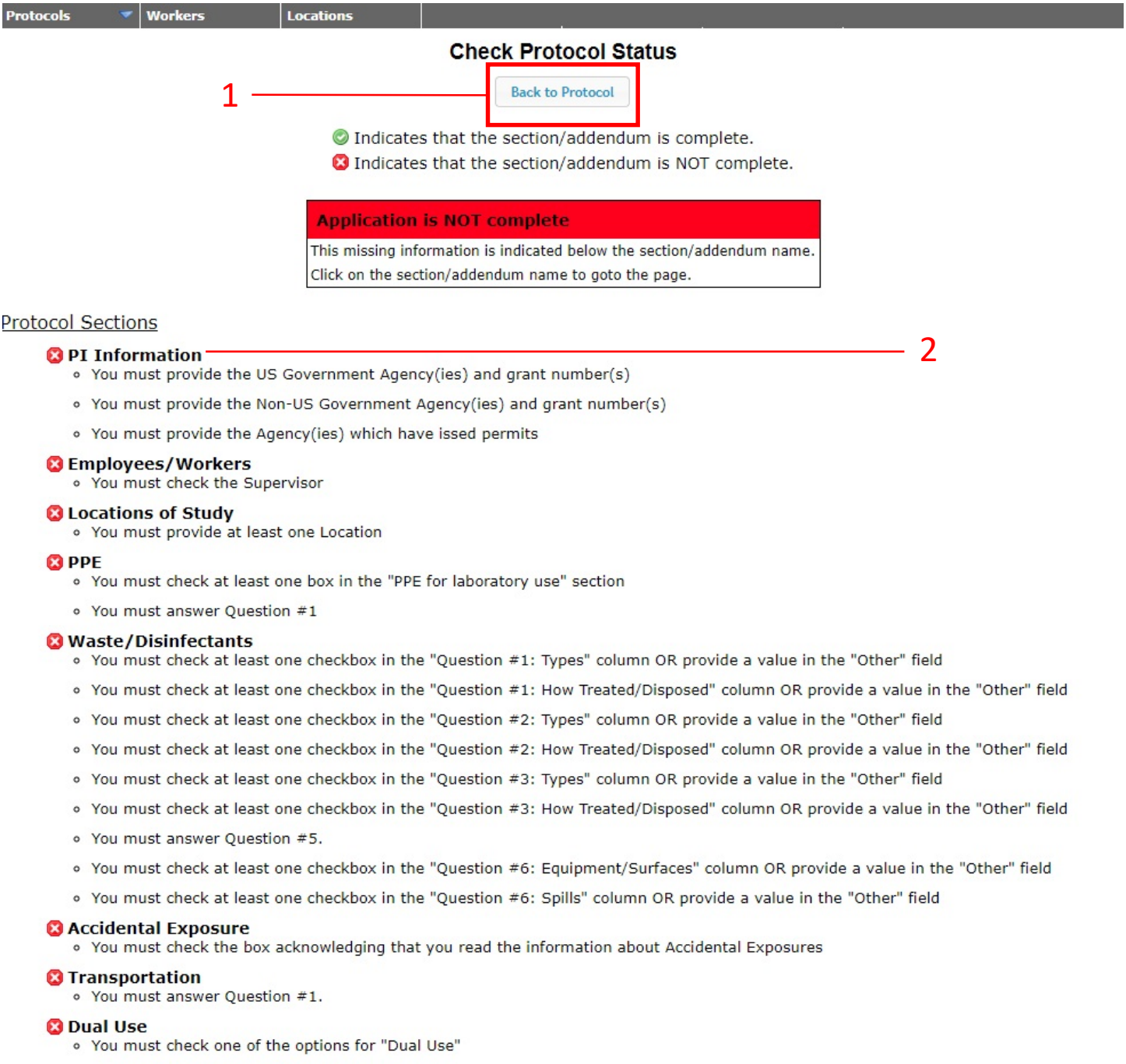
4. Check Protocol Status:
This section provides notifications of sections that are incomplete and must be completed prior to submission of protocol.

1. "Back to Protocol" – allows return to home page of protocol
2. Clicking on the Bold Section Header will bring you to that section to edit/view it



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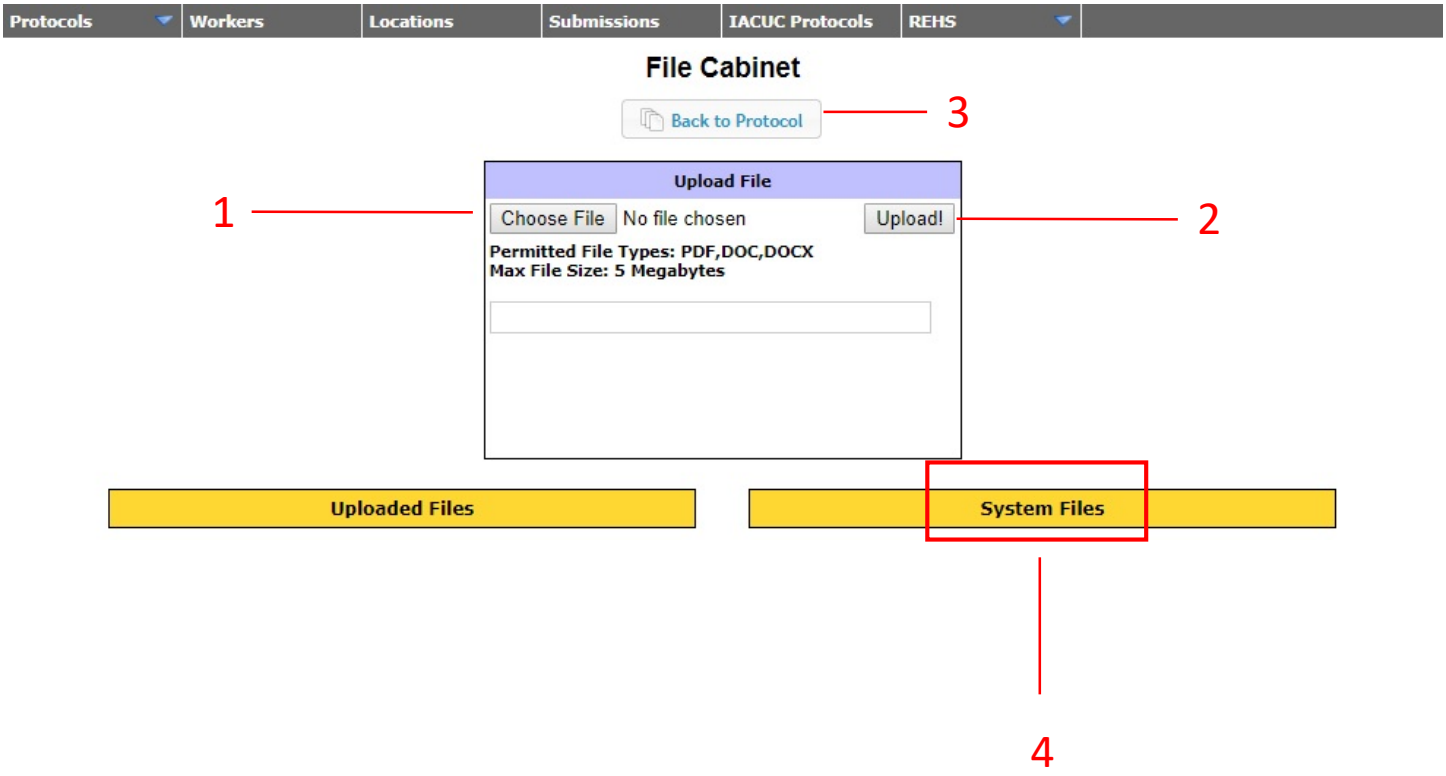
5. File Cabinet:
This section allows uploads of additional documents (i.e. laboratory SOPs, plasmid/vector maps, permits, etc.)

1. Click “Choose File” to choose a file from computer
2. Once file displays next to “Choose File” button, click “Upload!” button
3. Click “Back to Protocol” to return to protocol
4. System files will show approval letters and PDFs once submitted/approved.



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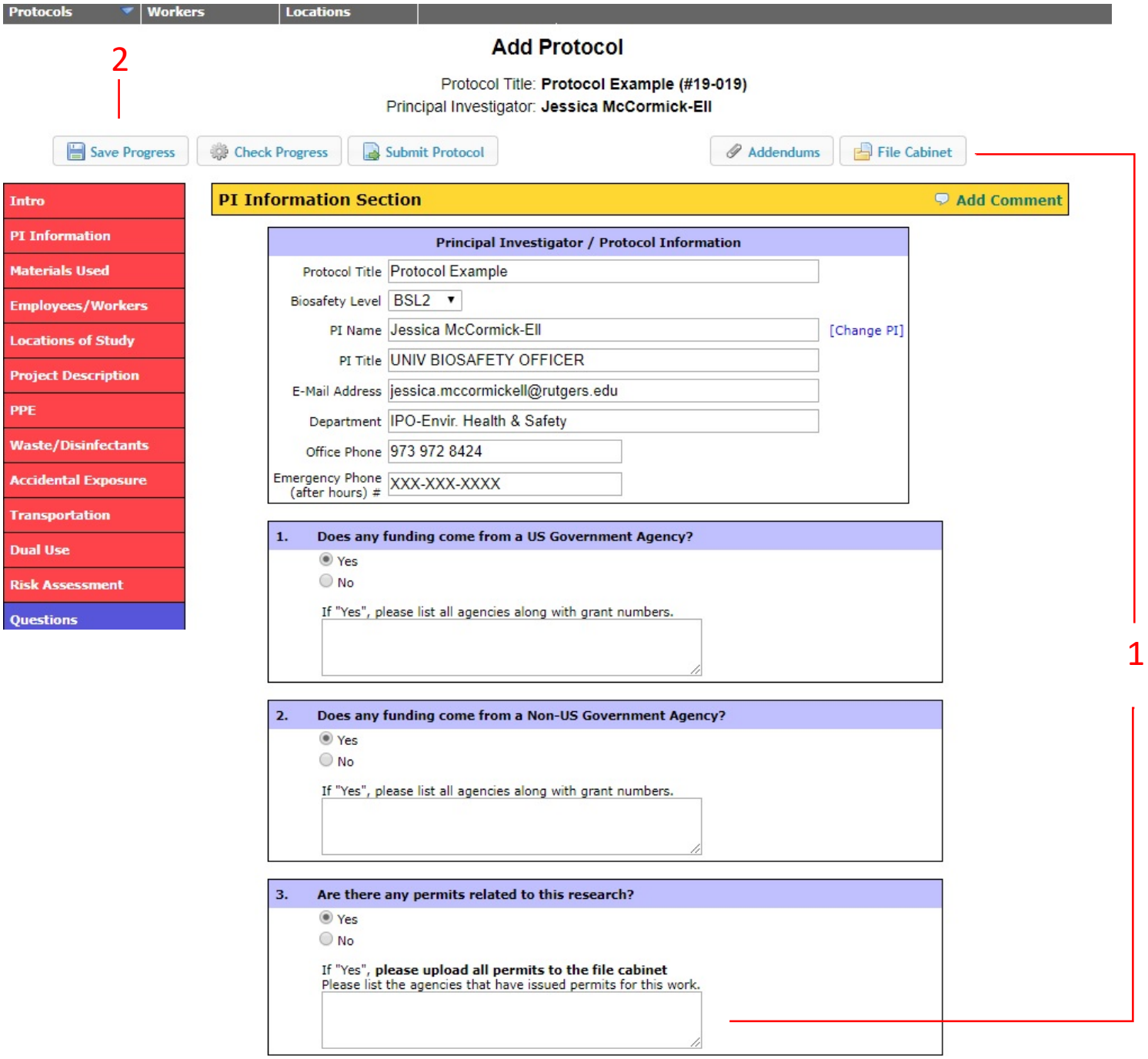
6. PI Information Tab:

This section requires information surrounding funding sources and permits related to the research. Each question must be answered. If "yes" is answered, additional information is required to be input into the text box.

1. Question 3 requires PDF versions of permits to be uploaded to the File Cabinet tab.
2. Another reminder, it is good practice to click the "Save Progress" button as you complete each tab.



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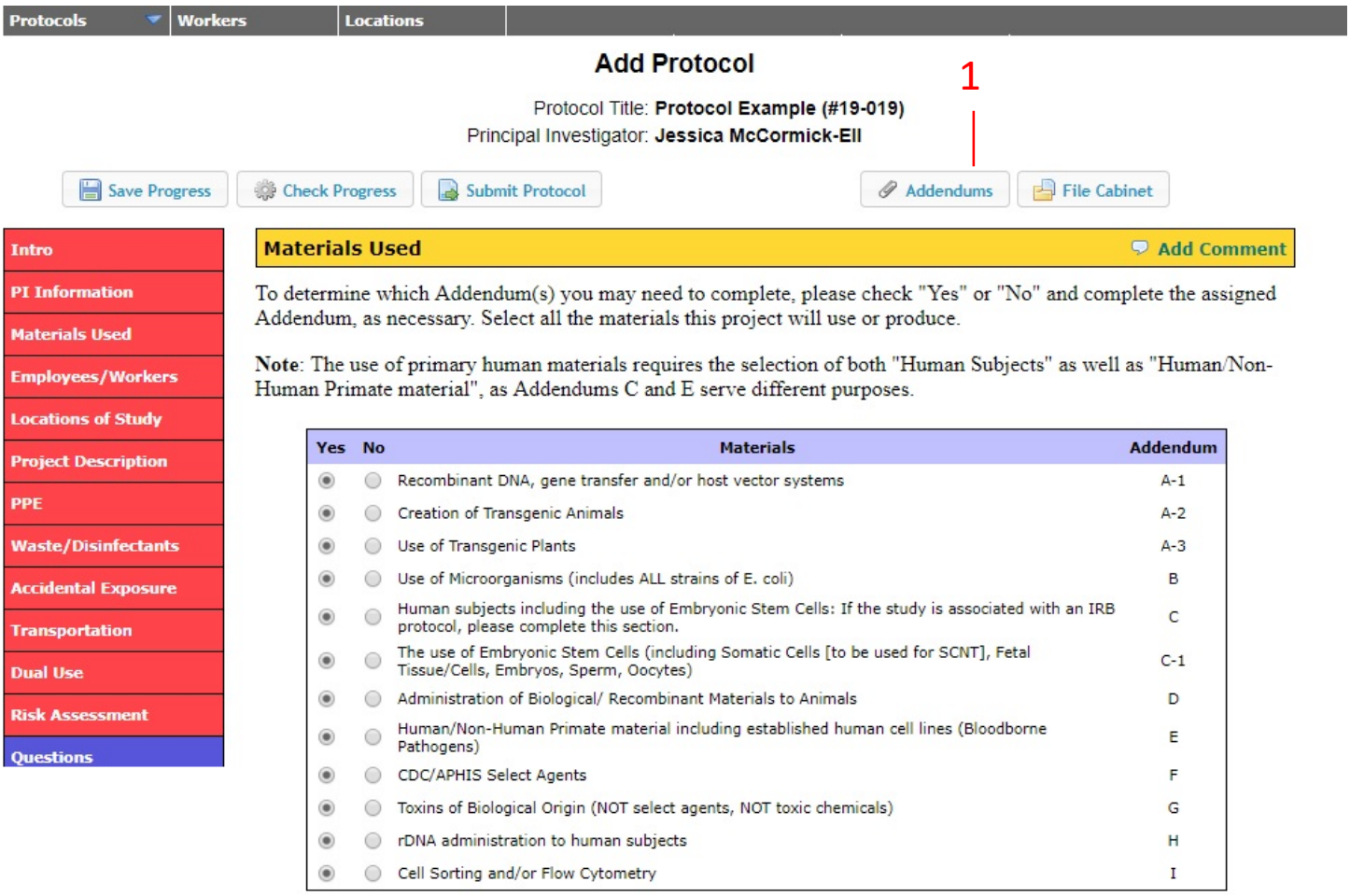
7. Materials Used:

Each question must be answered with either “Yes” or “No”. Each time a “Yes” is checked, another Addendum tab (named A-1, A-2, A-3, B, C, etc.) is added in the Addendum section.

1. Once all questions in this section have been answered, Addendum tabs will be created in the Addendum section, which is described later in this guide.



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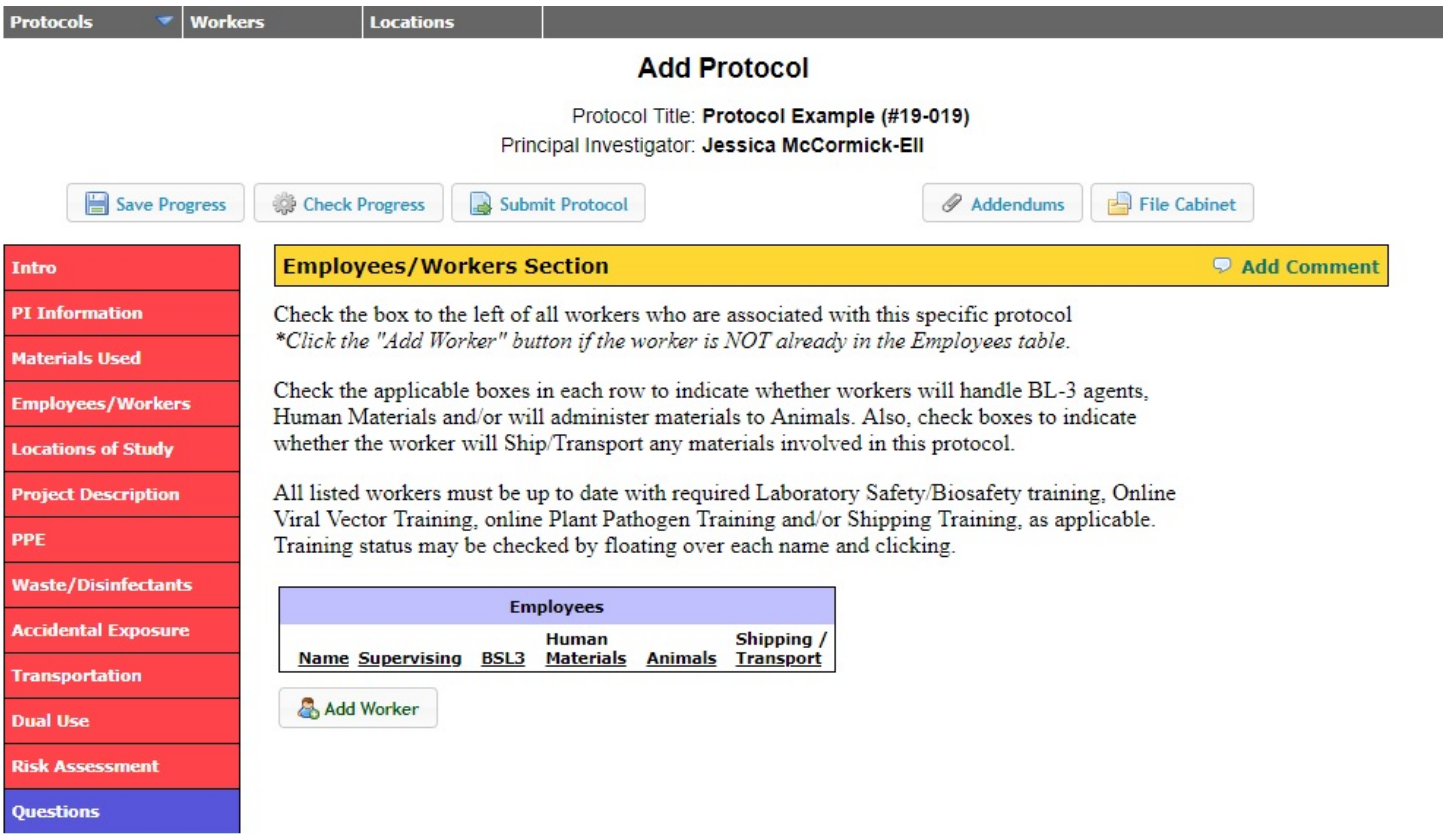
8. Employees/Workers:

Follow the directions displayed to Add Workers to the protocol.
** Adding new workers to an existing protocol can be done at this page and does NOT need to be submitted in an amendment.

- You must mark what role the worker has in the laboratory. Working with human cell lines (established cell lines) is working with Human materials
- Shipping/Transport should only be marked if someone is transporting materials on a road or by air (not hand carrying)



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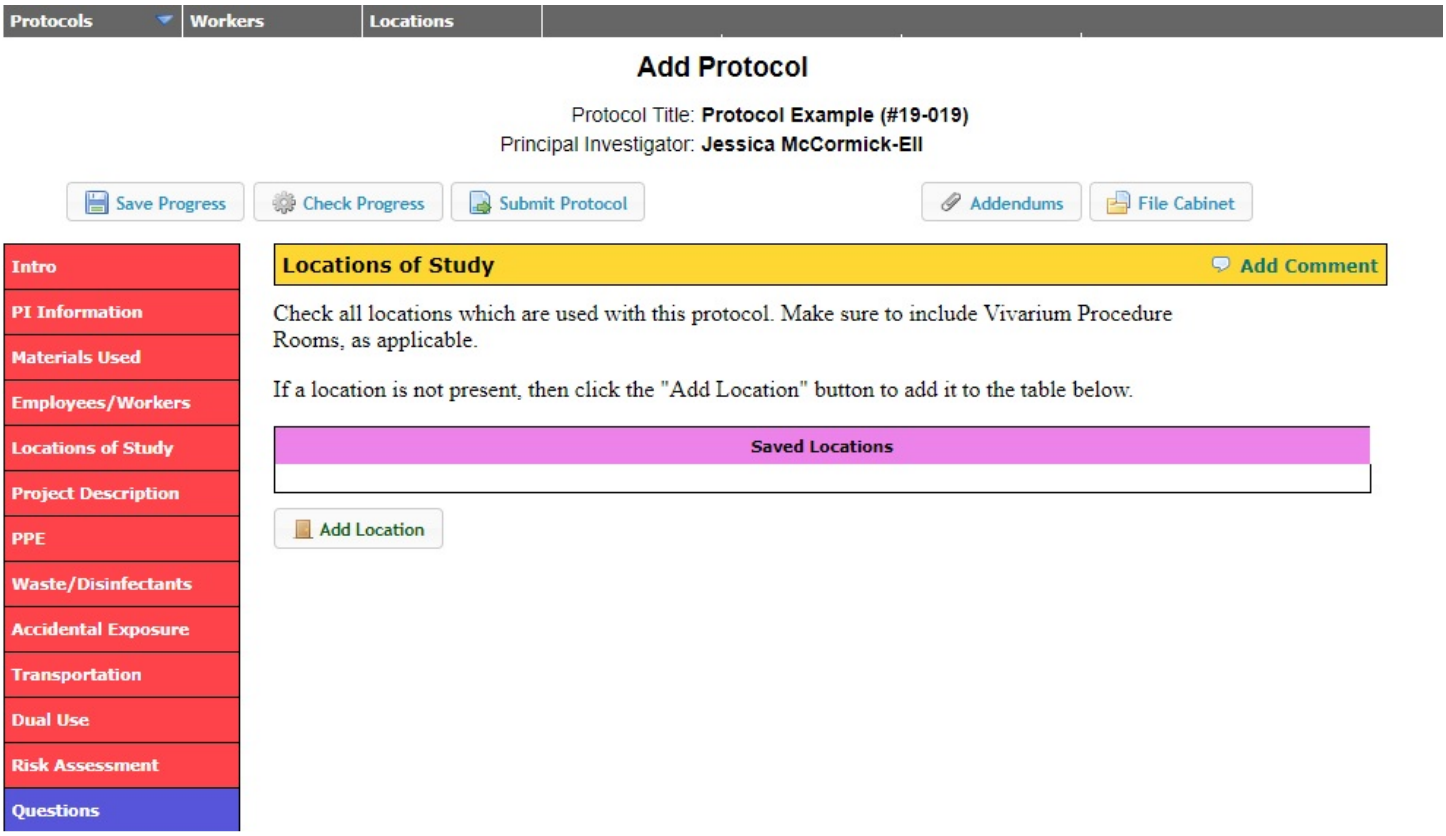
9. Locations of Study:

Add each room that workers will be utilizing for any work involved in this protocol, **including autoclave rooms**. Describe the function and containment controls utilized in each room.



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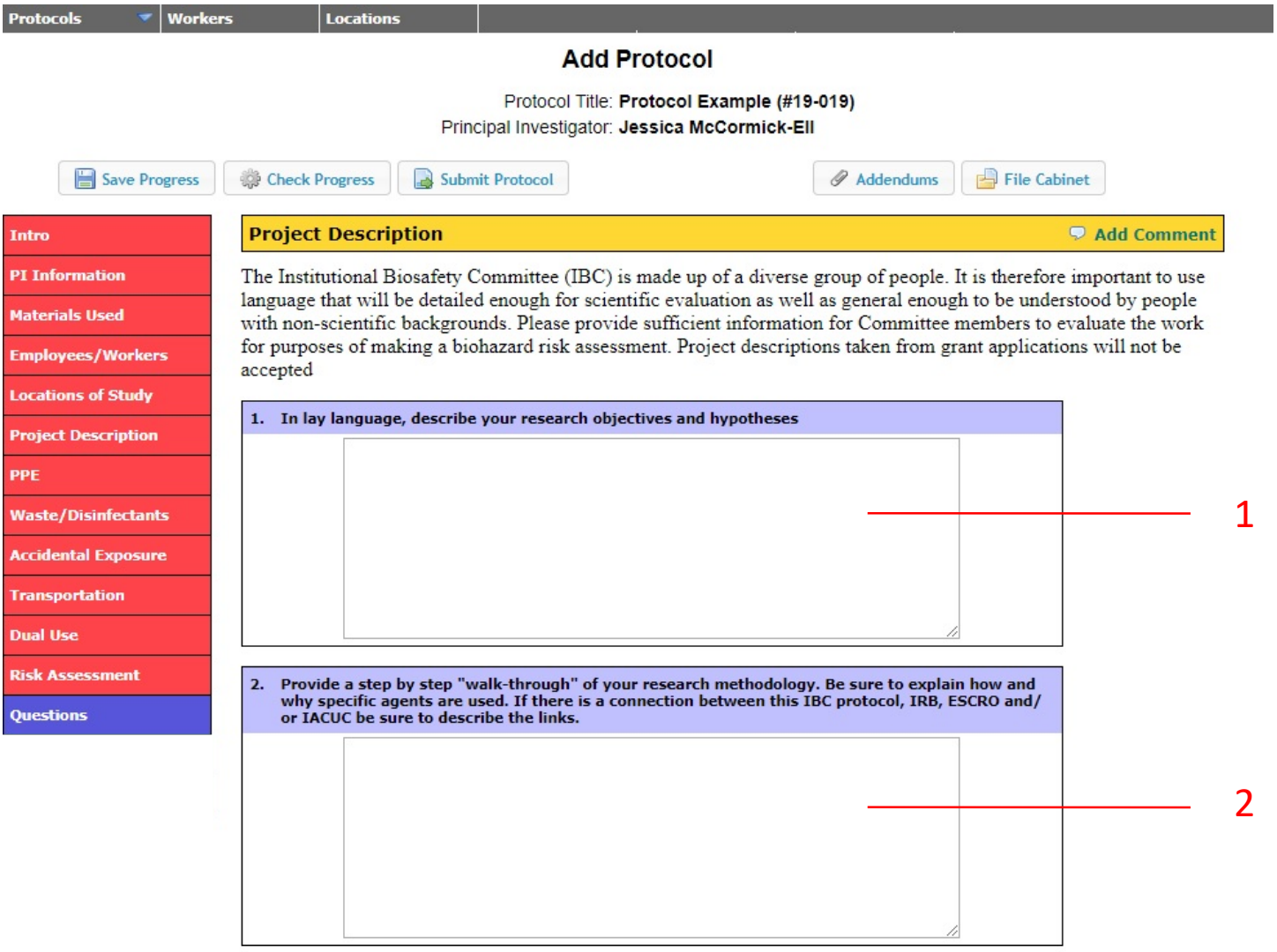
10. Project Description:

1. Please describe your research in terms that a lay person can understand. Do NOT copy and paste from a grant what the specific aims are.
2. This question asks to describe experiments that you will be performing and why specific biological material is needed for those experiments. For each experiment, describe what precautions will be used to minimize risk (engineering controls, work practices, etc.). This is NOT a recreation of your grant but instead is a section to describe how you will perform each of your experiments safely. Please include work with animals, human subjects, and analysis of infected tissues.

SEE NEXT PAGE FOR VERY HELPFUL HINTS



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10. Project Description

HELPFUL HINT 1: This section is NOT a copy/paste from the specific aims section of a grant. If the grant is selling how impactful the research will be, the project description is selling how safe the research will be.

- **Grant Example**: “Performing our vaccine challenge into mice will determine the efficacy of the vaccine in inducing both cellular and humoral immunity against infection which will determine possibility of a platform to prevent human disease”
- **Project Description Example**: “Performing our vaccine challenge into mice will be done inside a Class II biosafety cabinet to protect against potential aerosols. Injection will be performed with safe sharps to reduce the chance of needle stick exposure.

This is going to a Biosafety Officer and IBC reviewer, not a funding committee. They are not checking for the validity and/or reasoning for doing your science, but instead are reviewing for the safety of your science.

HELPFUL HINT 2: The **Project Description** section should describe how each experiment is done TO A CERTAIN EXTENT. This means that each experiment should be described as to what they are doing and how, but specific SOPs are not to be written here. Example below.

Good: Cells will be transfected with RNAi molecules against XYZ gene and are then infected with example virus. Cell monolayer is harvested for total nucleic acid or protein purification to determine gene expression using SOP 1(uploaded to file cabinet)

Bad: 1. Open flask. 2. Remove media. 3. Wash with PBS. 4. Transfect cells with 50 nanograms/1 million cells of siRNA targeting XYZ gene. (And continuing like this)

The bad example above is in SOP format. SOPs can be mentioned but should not be written out in the **Project Description**. They should be uploaded into the **File Cabinet**, which is a section to store all external files (SOPs, plasmid maps, permits, publications showing data).

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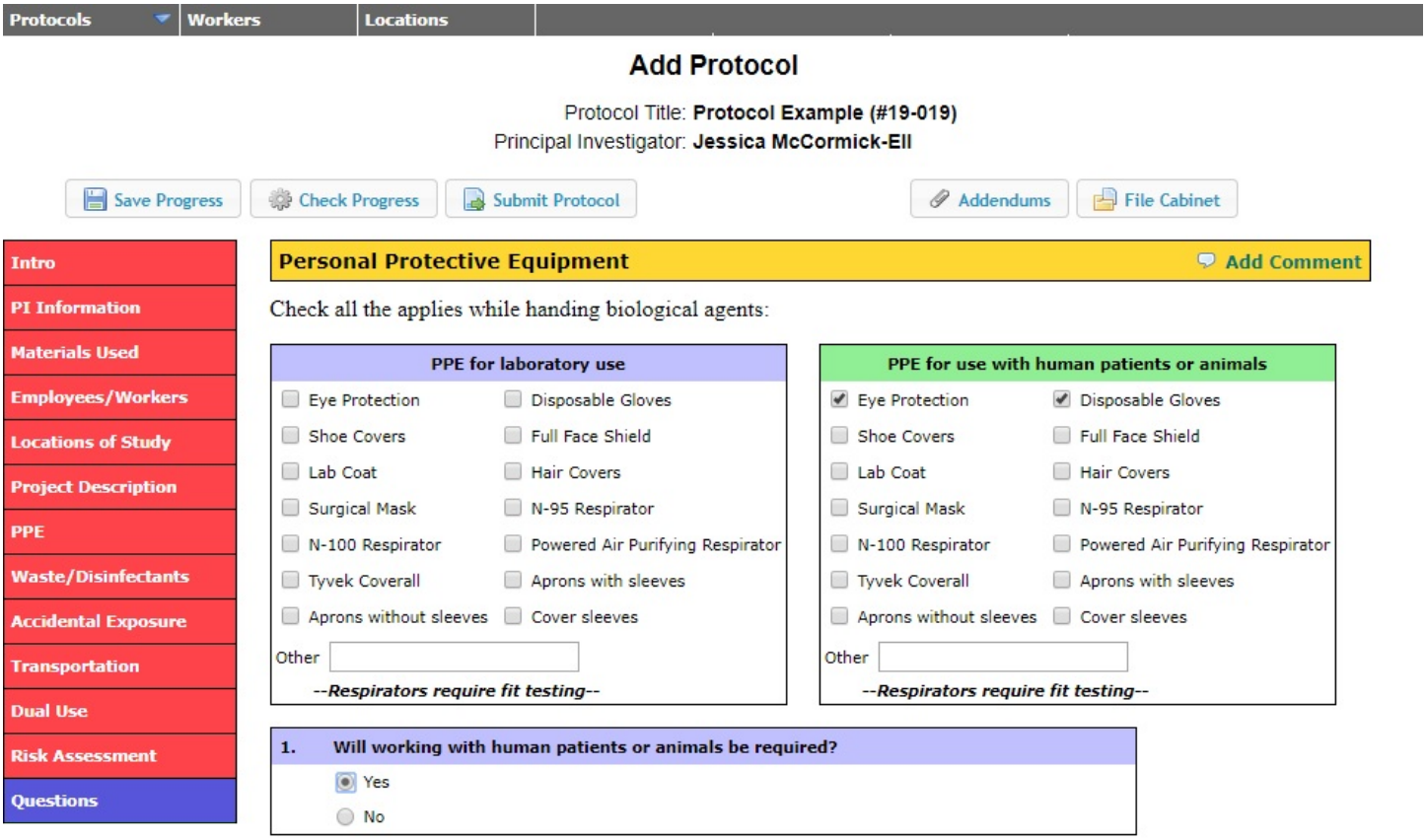
11. PPE:

Check all boxes that would apply to PPE that would be required to work with the biological hazards in your laboratory.



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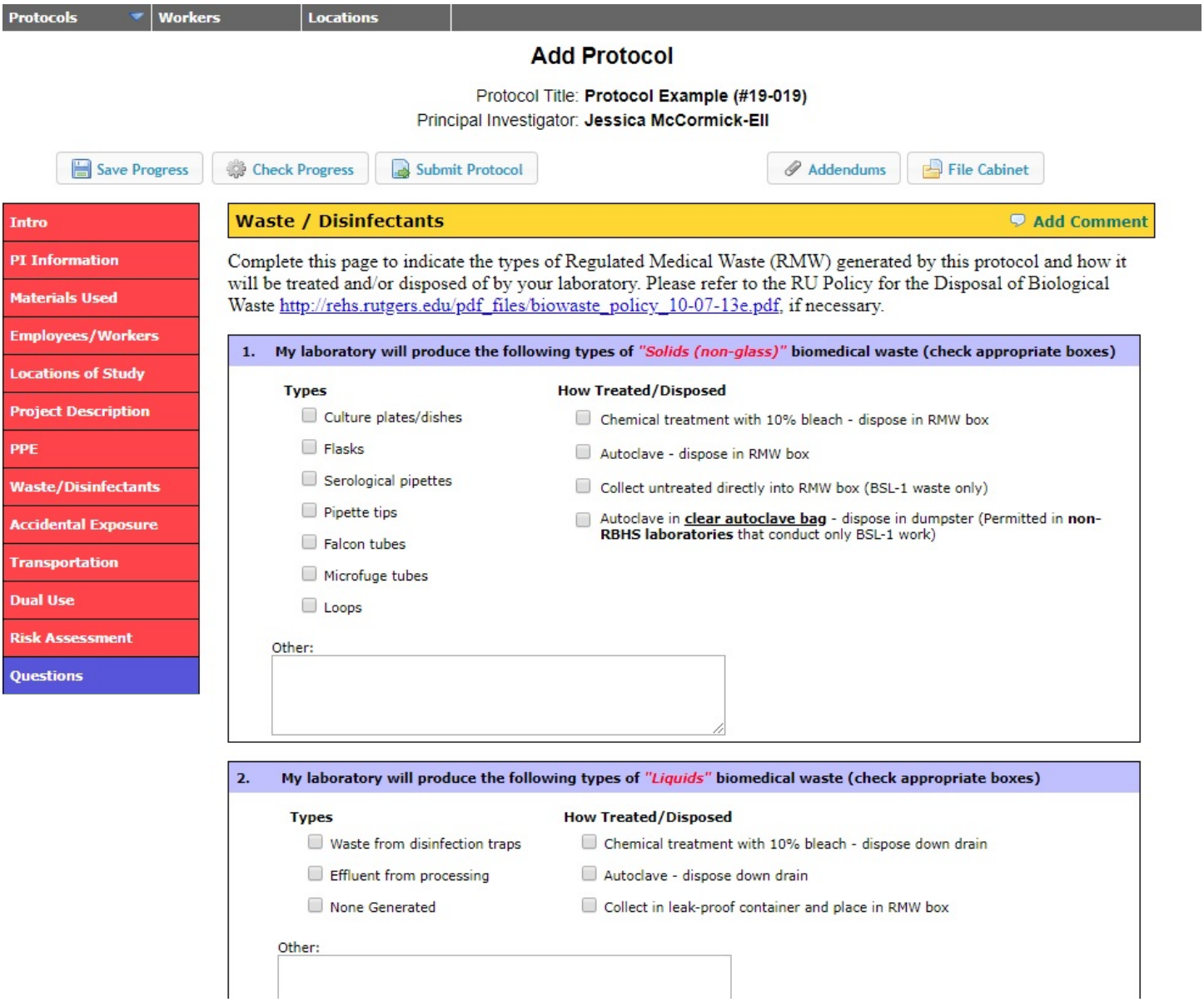
12. Waste/Disinfectants:

Describe how all types of waste will be treated. If you need more information, please refer to the RU bioguide for more information (see link below).
https://ipo.rutgers.edu/sites/default/files/RU%20Biosafety%20Guide.pdf
- 70% ethanol is never acceptable as a primary disinfectant



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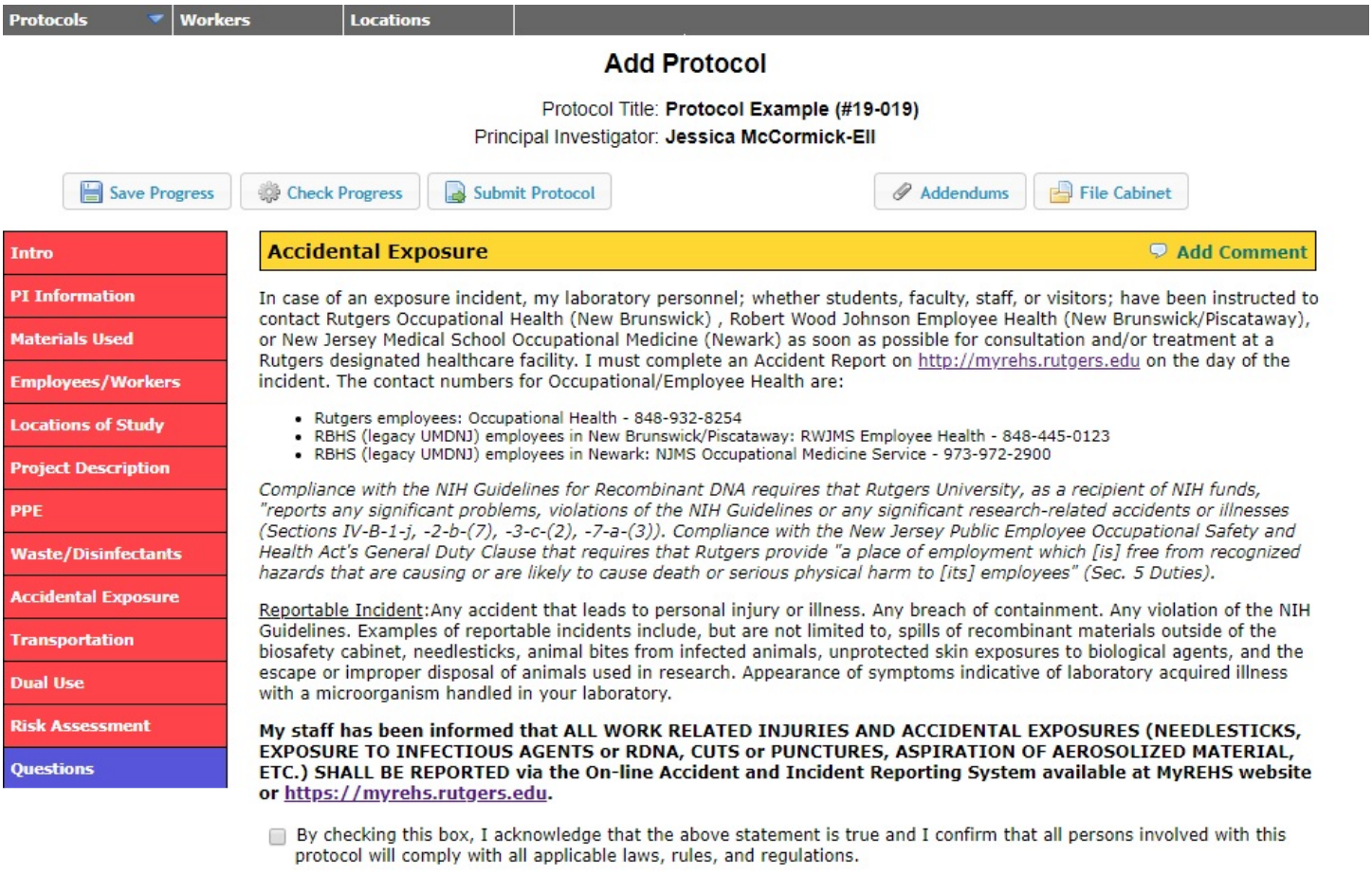
13. Accidental Exposure:

Read and acknowledge this disclaimer.



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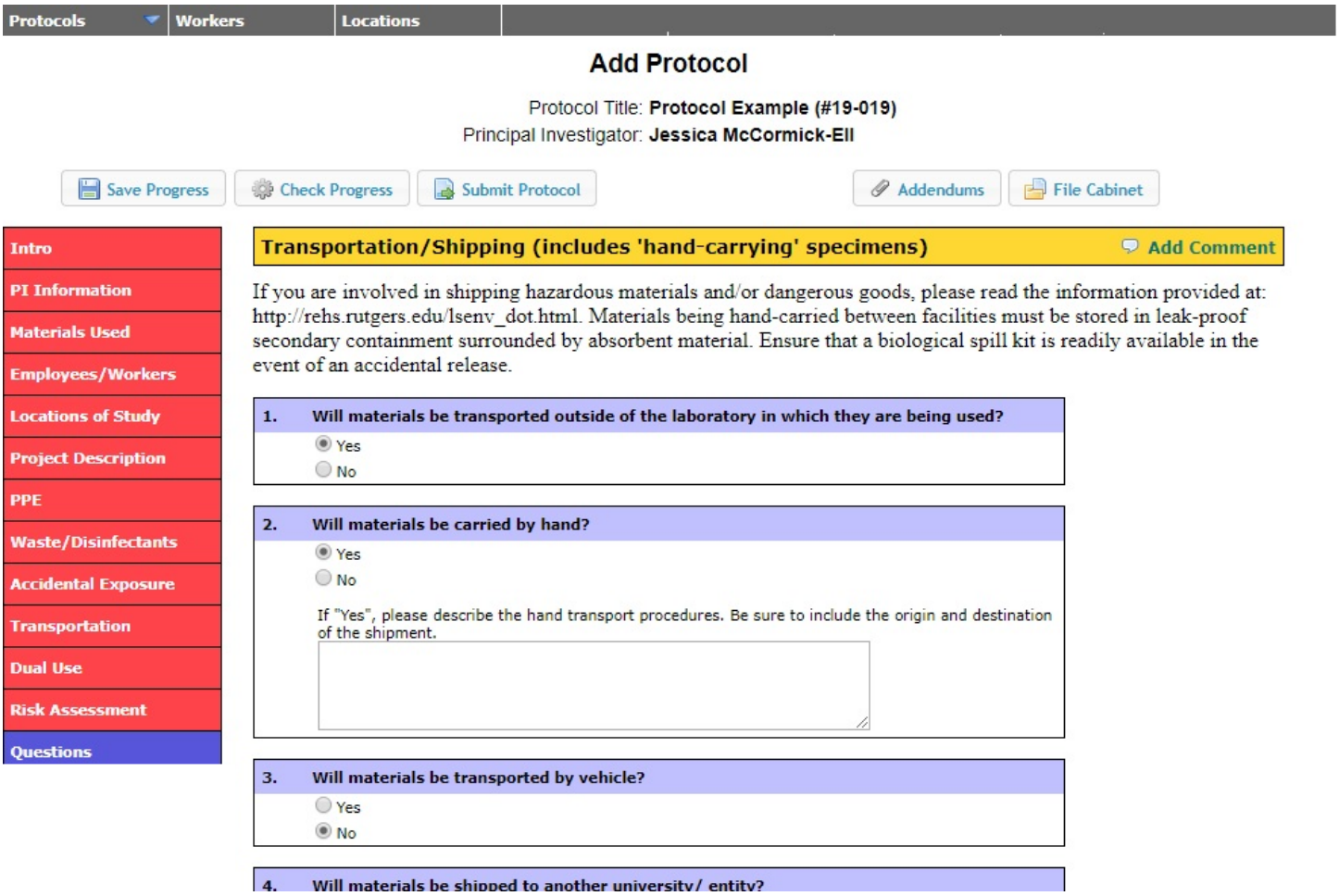
14. Transportation:

Describe how you will be transporting biological material. .



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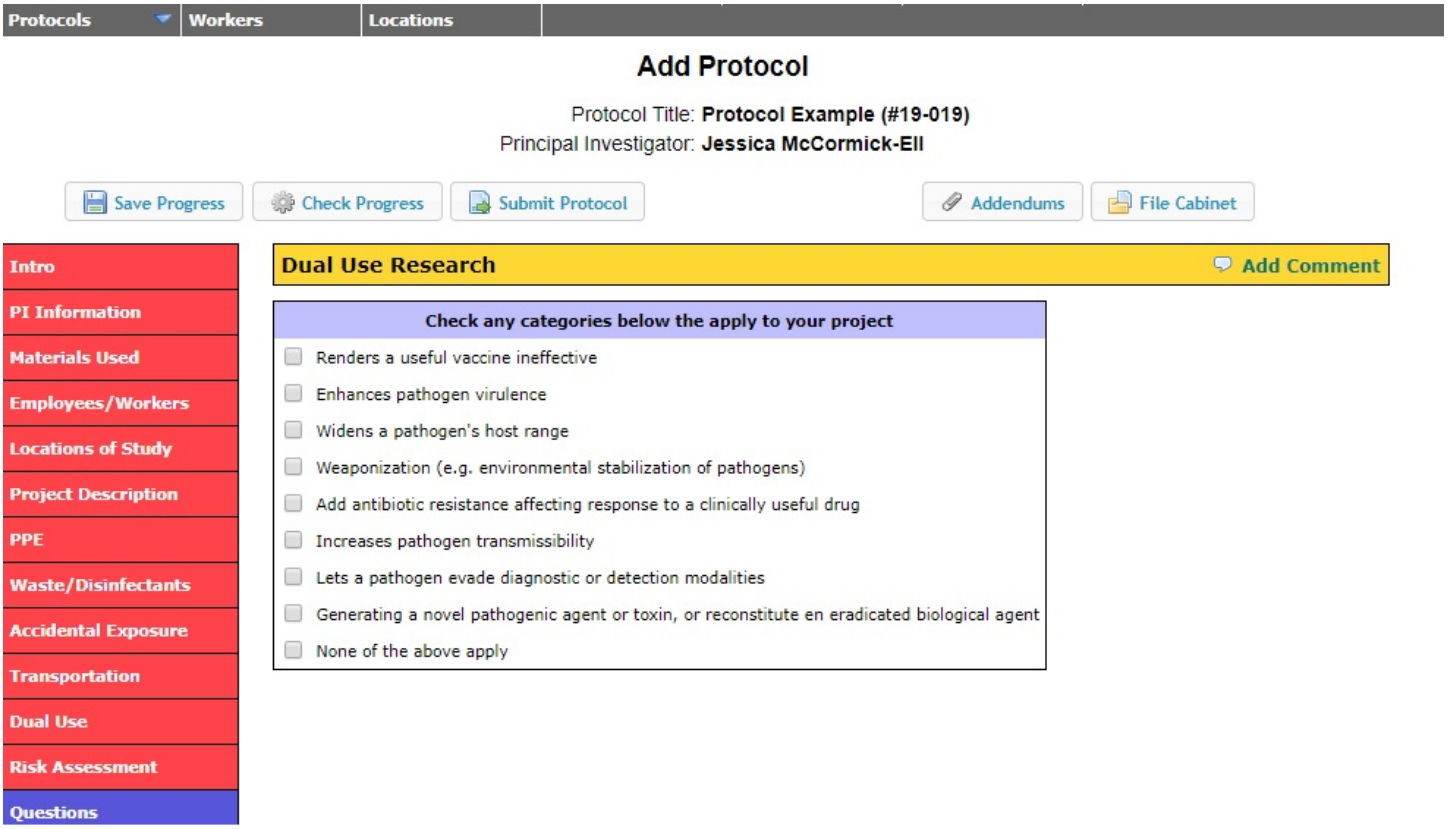
15. Dual Use:

Check any box that may apply to your research. If none apply, check "None of the above apply". Please contact Biosafety if you need help determining whether research could be Dual Use.



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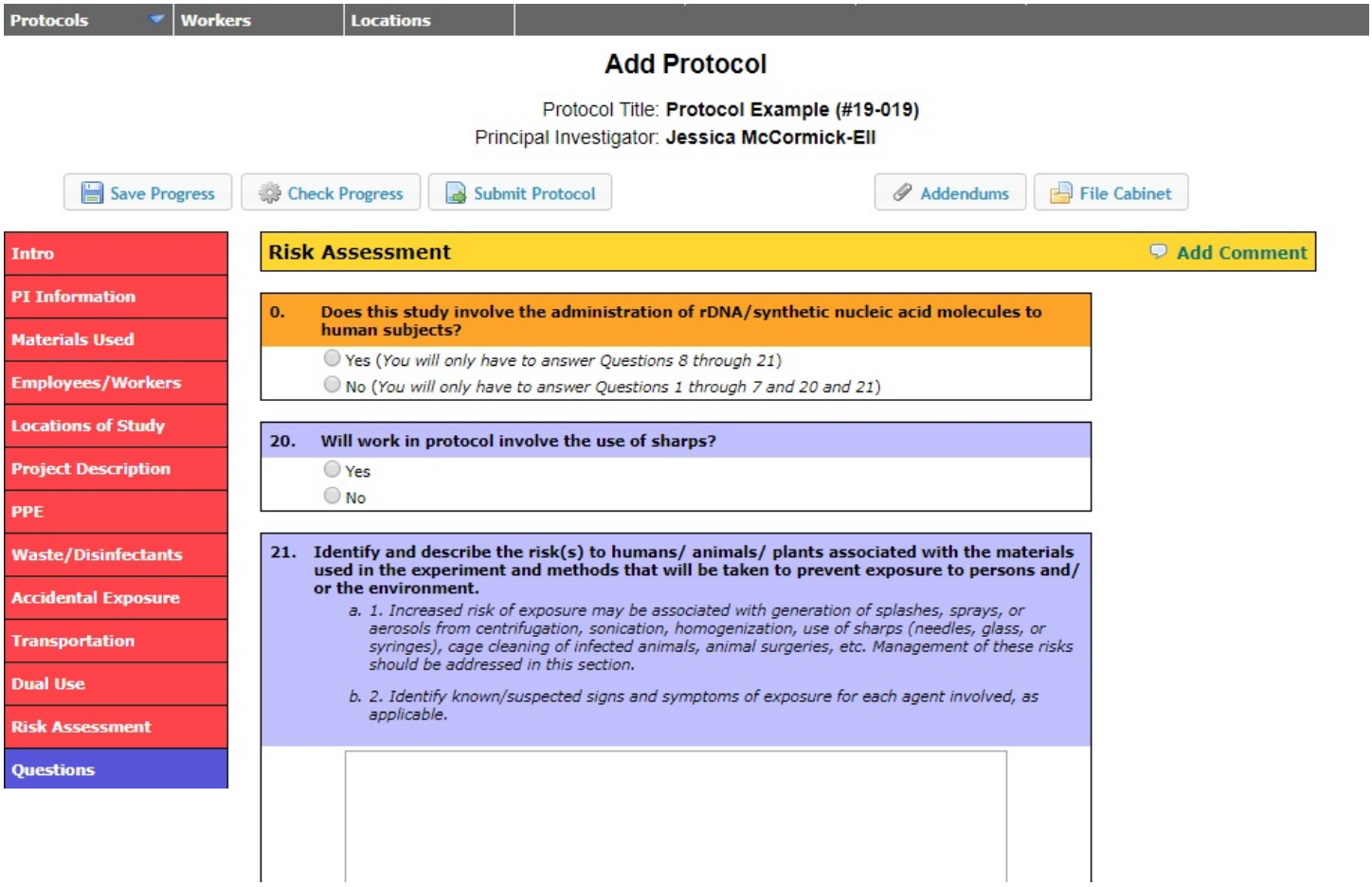
16. Risk Assessment:

Please describe in detail the hazards associated with the biological materials you will be working with.

- Please do not write “no risk” when working with human cells. Human cell lines always have a risk of blood borne pathogens (even established cell lines).
- Acknowledge the risk of gene expression in a lab worker that would be accidentally exposed to recombinant/gene editing technologies (viral vectors, CRISPR, etc)
- If you are working with Sharps, as would be mentioned in the Waste section, please describe the risks associated with Sharps in this section as well.



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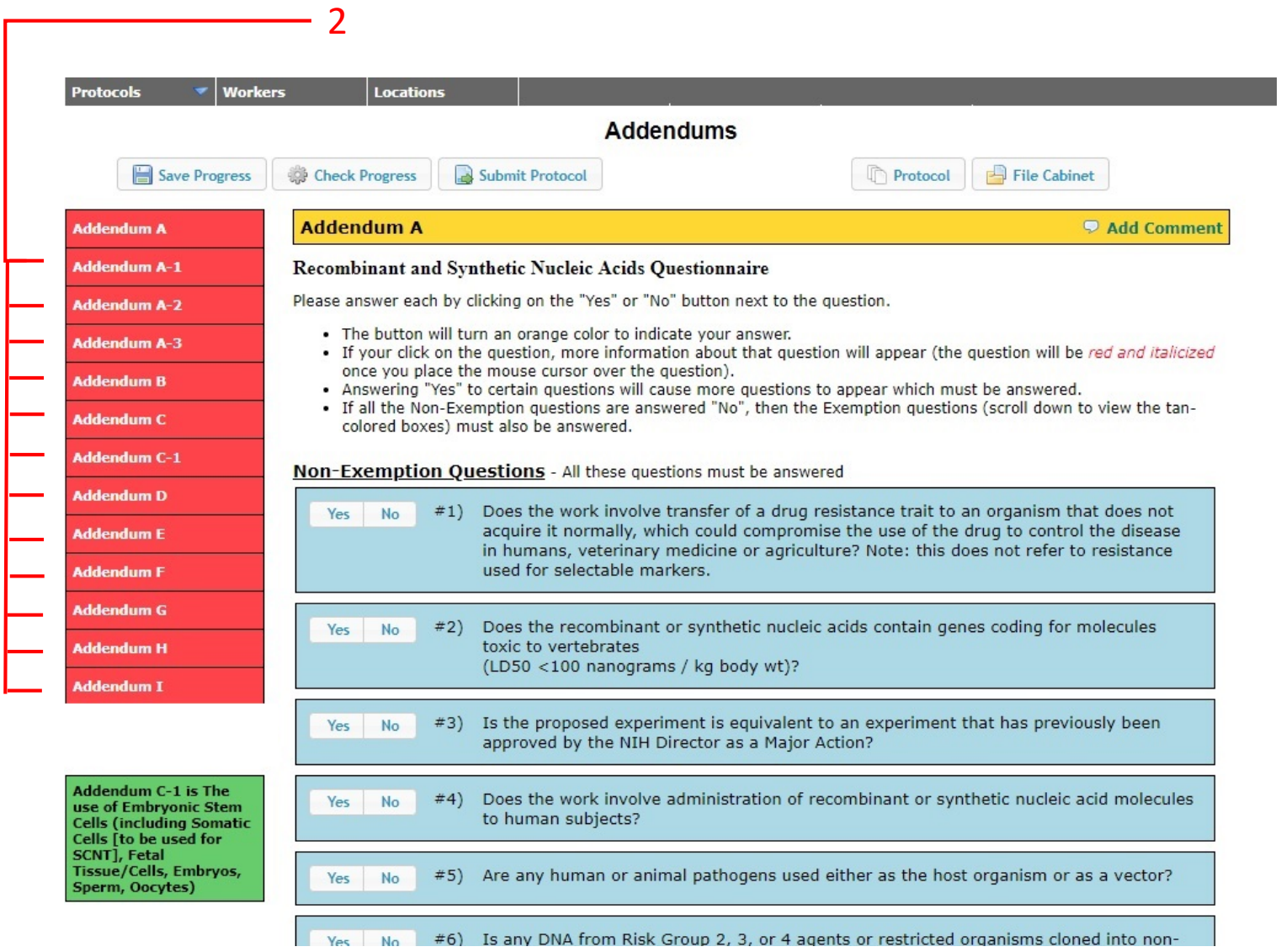
17. Addendums:

1. Follow the directions and answer each Yes/No question by clicking on either "Yes" or "No".
2. Once all questions for Addendum A have been answered, proceed to Addendum "A-1" by clicking on the red tab to the left of the screen entitled "Addendum A-1". Complete ALL Addendums that are present. Keep in mind, you only have Addendum tabs to which you checked "yes" to in the "Materials Used" tab from the Protocol.
3. For a sample response to these questions, please see the attached document "Biosafety Protocol Template"



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17. Addendum A and A-1 Helpful Hints:

Addendums A and A-1 are often a source of difficulty when creating a protocol. Here are some hints to think about when/if you are required to complete these addendums. Also, the IBC Protocol Example is a great resource to show you an example of responses to the questions in these addendums.

Addendum A

This section is to determine how rDNA will be used.

1. Where does the research fall under the NIH guidelines?
2. What/how rDNA is being used?
3. What/how viral vectors are being used?
4. Do genes of interest (rDNA) pose an increased risk? (oncogenic, immunosuppressive)
5. What are the viral vector concerns?
    a) Competent vs Incompetent
    b) Recombination potential
    c) Residual viral gene expression
    d) Method of vector construction/propagation
    e) Integration potential

If the research includes CRISPR or viral vectors, make sure you read/sign the CRISPR guidesheet or viral vector factsheets and upload to the **File Cabinet**.

Addendum A-1

This section is to further determine the risk of rDNA and vectors.

1. Do the vectors/strains/gene targets present any hazards?
    a) Are the gene targets oncogenic?
    b) Does putting the vector into the host present additional risks?
2. Is the viral vector contaminated with replication competent virus?

E.coli must be mentioned here. You also need to ensure all plasmids are listed, including the transfer **AND** packaging plasmids. Plasmid maps should be uploaded into the **File Cabinet**, and should relate to the vectors in the chart here.

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18. Submit Protocol:

1. Click on the “Submit Protocol” button to submit a finished protocol.
2. When the protocol is being reviewed by Biosafety, the PI will need to answer questions in the questions tab. When reviewers ask for more information through a question, please provide the information **in the requested sections of the protocol.**