

How to Create a Master Protocol Registration (MPR)

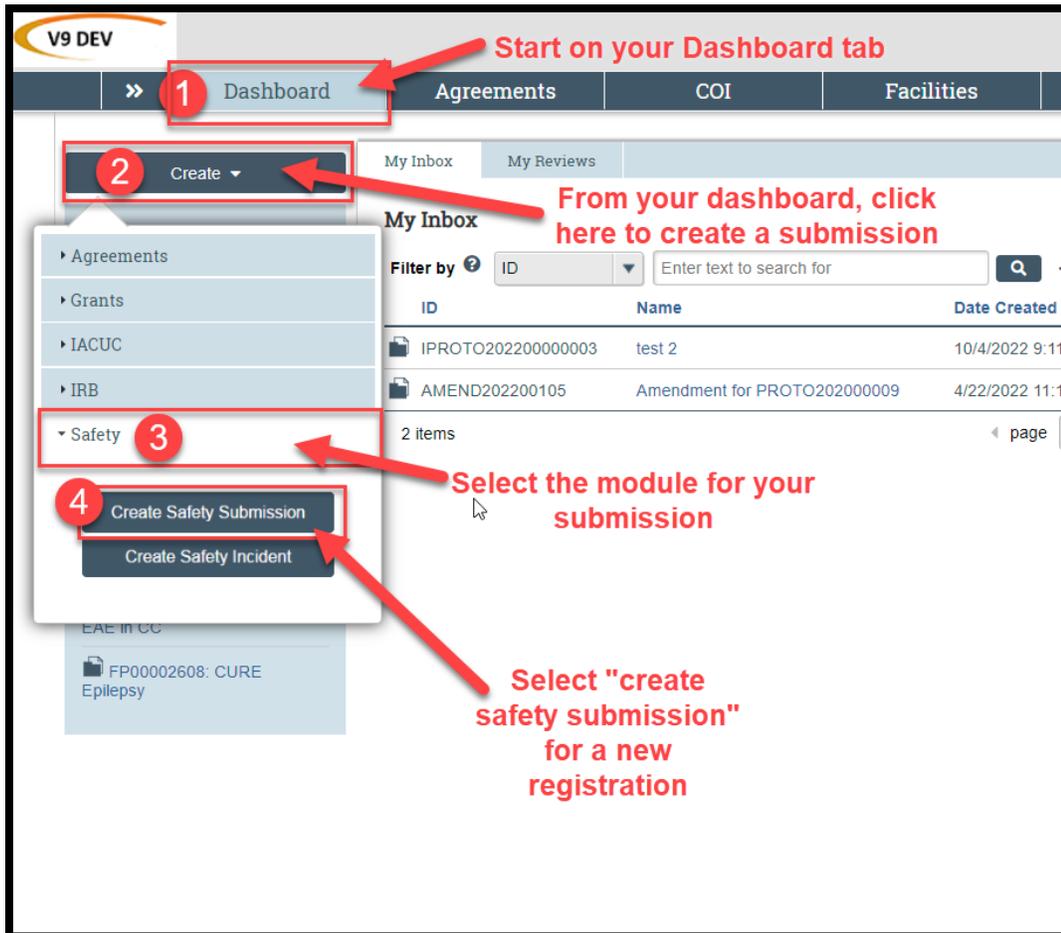
You prepare an MPR for IBC review by entering information into a series of on-line smartform pages. The number of smartform pages included may change based on the answers you provide. There is a "Supporting Document" page at the end of the registration where an SOP, BARD, or vector map can be attached.

Before you begin, gather files and information about your research such as:

- Supporting information files. See [Checklist of Information to Attach later in this document](#).
- Training Status and Role for each of your study team members

To Create an MPR for review:

From IBC>Submission Screen, Create Safety Submission.



V9 DEV

1 Dashboard

2 Create

3 Safety

4 Create Safety Submission

Start on your Dashboard tab

From your dashboard, click here to create a submission

Select the module for your submission

Select "create safety submission" for a new registration

ID	Name	Date Created
IPROTO20220000003	test 2	10/4/2022 9:11
AMEND202200105	Amendment for PROTO202000009	4/22/2022 11:1

2 items

page

FP00002608: CURE Epilepsy

A new registration form will pop up. Fill in the applicable boxes and answer the questions on the forms.
Please note: New UVMClick registrations will have a new numbering scheme. Example: "IREG202200001"

Helpful Hints:

The menu on the left side is an index of the pages. As you fill out the protocol additional pages may be added. You can skip from page to page by clicking "continue" in the corner or by clicking the different section headings here.

The add button will be in various places in the registration and will allow you to add different line items to tables.

Clicking "continue" will save and advance the page.

TIP: A red asterisk (*) precedes each mandatory question. If you cannot answer a question at this time or want to continue on a later page, use the menu on the left side or click "save" and come back to your protocol at a later time. All mandatory questions must be answered before the registration can be submitted.

Note: Questions that are not preceded by a red asterisk must still be filled out if the question applies to your work.

Supporting Documentation:

The following items may be required for your registration submission:

- SOP - Standard Operating procedure
- BARD - Biological Agent Reference Document
- Grant/Contract - Sponsor and ID#
- Grant Document(s)
- Vector maps

A page-by-page guide:

Basic Information page:

Editing: REG202200013

Basic Information

1. * Select admin office:

- Safety
- [Clear](#)

2. * Title of lab registration: (enter name of DEA registrant, if applicable)

New Registration

3. * Short title: (enter name of DEA registrant, if applicable) ?

New Registration

4. * Summary of research under this lab registration (The summary should describe the central question(s) the research is intended to achieve, the objectives of each project and the core methods or approach used in each project. If this is a DEA Registration then please enter '...')

Summary

Please provide a complete summary

5. * Select appropriate safety review: ?

- Biosafety
- Stem Cell Research Oversight
- Chemical Safety
- Radiation Safety
- [Clear](#)

6. * Principal Investigator or DEA Registration Holder (If this is an IBC Registration choose the PI. If this is a DEA Registration choose the Registration holder.)

Margaret Vizzard ...

[Exit](#) [Save](#)

Basic Information Page Cont.

7. * What is the activity?
 DEA Registration Documentation
 Research ← **Select your research activity**
 Teaching
[Clear](#)

8. * Are you using Core Facilities?
 Yes No [Clear](#) ← **If any Core Facilities will be used, indicate here**

9. * Select the core facility(ies):

- Animal Care** ← **Select all Core Facilities from the list**
- Biobank
- BSL3 Lab
- Cancer Translational Research
- Flow Cytometry and Cell Sorting**
- Inhalation Facility
- Microscopy
- Proteomics Facility
- The Neuroscience COBRE: Cell and Molecular Core Facility
- Vermont Integrative Genomics Resource

* Please include details of specific materials that will be used in each core facility checked above:
 Animals will be treated with virus and kept in a BSL2 facility until the end of the study.
 Treated cells will be brought to the flow cytometry facility once virus has been inactivated. ← **Provide a clear and detailed description of what materials will be brought to each facility.**

Note: All Core Facilities selected from this list will review your registration and may request additional information.

Exit Save Continue →

Protocol Team Members page:

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Validating Compare

Basic Information & Funding

Basic Information

Protocol Team Members

Funding Sources

Biosafety Summary

Biosafety Summary

Agents, Toxins, & Microorganisms

Tissues, Blood, or Body Fluids

Biohazards

Risk Management

Risk Group and Containment Practices

Exposure Assessment and Protective Equipment

Dual Use Research of Concern

Waste Management

Custom Pages

Protocols/Registrations

Supporting Documents

Supporting

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Protocol Team Members

1. Identify each additional person involved

[+ Add](#)

Name	Roles
Update Aubrie Clas	Key Person
Update Linda Mei	Key Person
Update Margaret Vizzard	Principal Investigator

2. Team member training: ?

Filter by: First Name [v] Enter text

First Name	Last Name	Training
Margaret	Vizzard	<input type="text"/> Course <input type="text"/> Occup Health

3. External team member information: ?

[+ Add](#)

Document

There are no items to display

Add Study Team Member

1. * Select the protocol team member:
 Melanie Locher [v]

2. Role in research: (check all that apply)

- Faculty Sponsor
- Key Personnel**
- Key Personnel-animal handler
- Principal Investigator

3. Additional roles performed by team member:

4. Is this team member involved with procedures?
 Yes No [Clear](#)

Click "add" to add new personnel to the roster

Funding sources page:

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Funding Sources

1. * Identify each organization

+ Add

Funding Source Funding Source

There are no items to display

Add Funding Source

Add your funding source. If UVM based funding, use "Internal Funding".

1. * Select the funding organization. If your project is departmentally funded, select "Internal Funding" from the list. If your funding source does not appear in the list, contact IBC staff so they can add it.

2. Sponsor's funding ID: (assigned by external sponsor)

3. Grants office ID: (SPA Funding Proposal #)

4. Attach files (ex. Grant application excluding the budget):

+ Add

Document Date Modified

There are no items to display

The Grants Office ID# only applies for external funding sources and is required to link the funding source. Your contact in SPA can help you find this number.

Your Grant document is required. If there is no grant (internal funding) you must upload a research description or specific aims.

* Required

OK OK and Add

Biosafety Summary page:

Validate Compare

Editing: REG202200013 Go to forms menu

Basic Information & Funding

- Basic Information
- Protocol Team Members
- Funding Sources

Biosafety Summary

Biosafety Summary

Risk Management

- Risk Group and Containment Practices
- Exposure Assessment and Protective Equipment
- Dual Use Research of Concern
- Waste Management

Custom Pages

- Protocols/Registrations

Supporting Documents

- Supporting Documents

Biosafety Summary

1. * Select any items involved in the lab registration. Note, unchecking any items will cause you to lose data associated with the page(s).

Please choose "Human Research Participants" if your research involves Gene Therapy.
Please choose "Select Agents or Toxins" only if your research involves those Select Agents or Select Toxins listed on the CDC Federal Select Agents List.
Please choose "Other" if your research involves Toxins that are not on the CDC list, and then describe in the box below.

- Tissues, Blood, or Body Fluids
- Primary Cells or Cell Lines
- Bacteria, Yeasts, Fungi, or Parasites
- Viruses or Prions
- Select Agents or Toxins
- Recombinant or Synthetic Nucleic Acids
- Human Research Participants
- Animals
- Genetically Modified Animals
- Plant Pathogens
- Other

2. If other, describe items:

Each box that is checked will add a new page to the registration.

Exit Save

Agents, Toxins, and Microorganisms pages (all are similar):

V9 DEV

Validating | Compare

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Tissues, Blood, or Body Fluids

1. * List type and source of agent

2. Describe any tissues trans

3. Describe the quantity of tis

Agents, Toxins, & Microorganisms

Tissues, Blood, or Body Fluids

Biohazards

Risk Management

Risk Group and Containment Practices

Exposure Assessment and Protective Equipment

Dual Use Research of Concern

Waste Management

Custom Pages

Protocols/Registrations

Supporting Documents

Supporting Documents

Add Biological Agent Information

1. * Agent: ...

2. * Biocontainment level:
 BSL-1
 BSL-2
 BSL-3
[Clear](#) **Select one**

3. * Describe the use of the agent:

Provide a clear description here

4. * Where are you obtaining the material from?

5. * Storage Locations: ?
 ...

Facility	Building	Usage
There are no items to display		

6. * Usage Locations: ?
 ...

Facility	Building	Usage
There are no items to display		

7. * Supplier:

8. * Quantity:

9. * Experimental concentration: (page continued)

10. * Is agent used in animals?
 Yes No [Clear](#)

11. * Is agent used in humans?
 Yes No [Clear](#)

12. * Is agent recombinant or synthetic?
 Yes No [Clear](#)

* Required

OK OK and Add Another Cancel

Click "add" to add information about each agent

Enter the name of the agent. You can either start typing in the box or click the "..." to open the search function. If you agent isn't listed, Please contact RPO to have it added.

Enter the storage and usage location. Locations might be different.

Complete both fields

(scroll down for more questions)

9. * Experimental concentration: (page continued)

10. * Is agent used in animals?
 Yes No [Clear](#)

11. * Is agent used in humans?
 Yes No [Clear](#)

12. * Is agent recombinant or synthetic?
 Yes No [Clear](#)

* Required

OK OK and Add Another Cancel

If agent is used in animals, please be sure that the "animals" on the biosafety page was checked

Risk Group and Containment Practices page:

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Fill out this page as applicable

Risk Group and Containment Practices

1. * What is the highest risk group level of the biological agents and materials you will use in the proposed research? (If you are unsure designation of an agent and/or material please refer to the [NIH Guidelines Appendix B](#))

RG-1
 RG-2
 RG-3
 RG-4
[Clear](#)

2. What are the highest biosafety containment practices required for the research activities covered by this registration? (If you are unsure containment practices for your research activities refer to the BMBL or NIH links in each category below.)

BMBL:

Biological Research Standards

* **Biological Research Involving Small Animals**

ABSL-1
 ABSL-2
 ABSL-3
[Clear](#)

Biological Research Involving Arthropods

ACL-1
 ACL-2
 ACL-3
[Clear](#)

NIH Guidelines rDNA or synthetic nucleic acids:

Physical Containment	Research Involving Large Animals	Research Involving Plants	Large-scale Uses of Organisms
<input type="radio"/> BL-1 <input type="radio"/> BL-2 <input type="radio"/> BL-3 Clear	<input type="radio"/> BL1-N <input type="radio"/> BL2-N <input type="radio"/> BL3-N Clear	<input type="radio"/> BL1-P <input type="radio"/> BL2-P <input type="radio"/> BL3-P Clear	<input type="radio"/> BL1-LG <input type="radio"/> BL2-LG <input type="radio"/> BL3-LG Clear

If animals are used, this section needs to be completed

Exposure Assessment and Protective Equipment page:

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Exposure Assessment and Protective Equipment

1. * Describe consequences of exposure or release of agents used to humans, animals, and plants: ?

Be specific here

2. * Indicate the personal protective equipment that will be used:

Lab Coats
 Eye Protection
 Gloves
 Gowns
 Shoe Covers
 Respirators
 Other

3. If other, specify:

This page should provide details of PPE and safety measures to be used

4. * Indicate the engineering controls that will be used (e.g., biological safety cabinet, gasketed centrifuge cups/tubes, sealed containers, etc.):

Be specific here

Dual Use Research of Concern page:

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Dual Use Research of Concern

1. * Dual use experiment categories used in this research: (select all that apply)

- Enhances the harmful consequences of the agent or toxin
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical or agricultural justification
- Confers to the agent or toxin resistance to clinically or agriculturally useful prophylactic or therapeutic interventions, or facilitates the agent or toxin's ability to evade detection methodologies
- Increases the stability, transmissibility, or capability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstructs an eradicated or extinct agent or toxin
- None of the above

Note: If you checked any dual use categories above and use agents or toxins in the research, the protocol is likely to be dual use research of concern.

2. * Explain why you believe this registration is or is not dual use research of concern:

3. Check all that apply:

Description
<input type="checkbox"/> View Avian influenza virus (highly pathogenic)
<input type="checkbox"/> View Bacillus anthracis
<input type="checkbox"/> View Botulinum neurotoxin
<input type="checkbox"/> View Burkholderia mallei
<input type="checkbox"/> View Burkholderia pseudomallei
<input type="checkbox"/> View Ebola virus
<input type="checkbox"/> View Foot-and-mouth disease virus
<input type="checkbox"/> View Francisella tularensis
<input type="checkbox"/> View Marburg virus
<input type="checkbox"/> View Reconstructed 1918 influenza virus
<input type="checkbox"/> View Smallpox virus

Annotations:

- Red arrow pointing to "None of the above" with text: "Most UVM Registrations will check 'none of the above'"
- Red arrow pointing to the list of agents with text: "If you are unsure whether your registration applies here, check the list of agents listed in question #3"

Waste Management page:

Editing: REG202200011

Waste Management

1. * Describe the process for decontaminating solid waste (i.e. autoclave, boxed waste system):

2. Describe the process for liquid waste decontamination:

3. Autoclave Location:

4. * Describe the plans for decontamination:

Annotation: Red text: "Please be specific with your answers."

Protocols/Registrations page:

Editing: REG202200013

Protocols/Registrations

- Please enter any IRB protocols that are related to this IBC registration:**

Protocol Number

There are no items to display
- Please enter any IACUC protocols that are related to this IBC registration:**

Protocol Number

There are no items to display
- Please enter any IBC registrations that are related to this IBC registration:**

Protocol Number

There are no items to display

Click "Add" to enter any protocols that are associated with this registration.

Supporting Documents page:

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Supporting Documents

Thank you for completing the information required to submit this registration to the appropriate Safety Committee.

- Attach additional supporting documents including BARs/SOPs: ?**

Document	Date Modified
There are no items to display	

 - Take this opportunity to review the information you have provided. It is very important that the responses in this registration be thorough and specific. Failure to provide complete information will result in a delay in the review of this registration and may result in the registration being returned to the team for correction or completion.
 - Note that this registration has not yet been submitted for review. Upon completing the information in this registration and clicking the "Finish" button below, forward this submission for review.

Add all SOPs, BARs, and any other related documents here

SUBMISSION:

When the registration is completed, you will need to click “submit” to send it to RPO to begin the review process. On the main protocol page:

REG202200013

New Registration

Principal Investigator: Margaret Vizzard
Specialist:
Primary Contact:
Admin office: Safety
PI proxies: There are no items to display
Submitting Department:

Submission Type:
Safety Review Type:
Letter:
Last day of continuing:
Approval Date:
Biocontainment Level:
Exempt from NIH Guide:

Next Steps

- Edit Registration
- Printer Version
- Submit**
- Assign PI Proxy
- Assign Primary Contact
- Manage Guest List
- Manage Ancillary Reviews
- Add Comment
- Copy Submission
- Discard

Click here to submit your registration for review

History Documents Reviews Contacts CITI Training Snapshots

The system will show an error message with a list of required fields you have left blank.

Error/Warning Messages **If any information is missing, the system will give you an error message. You can click the link to the pages here** Refresh

Message	Field Name	Jump To
⊖ This is a required field; therefore, you must provide the required information.	Funding Sources	Funding Sources
⊖ This is a required field; therefore, you must provide the required information.	Agent Information	Tissues, Blood, or Body Fluids
⊖ This is a required field; therefore, you must provide the required information.	Highest Risk Group	Risk Group and Containment Practices
⊖ This is a required field; therefore, you must provide the required information.	Highest BMBL Standard	Risk Group and Containment Practices
⊖ This is a required field; therefore, you must provide the required information.	Exposure Assessment	Exposure Assessment and Protective Equipment

Once all errors are addressed, when clicking the submit activity, certification text will appear.

1. Read the text.
2. Click the “I agree to the assurances above” checkbox (required).

3. Click “OK”

Submit

REGISTRATION HOLDER
As the registration holder, I assure that the information provided is accurate and that I will follow all federal, state and UVM regulatory requirements.

REGISTRATION HOLDER PROXY

- As the proxy assigned by the registration holder to submit materials for this registration, I assure the Research Protections Office that the information that I have provided is accurate.

* I agree to the assurances above:

OK **Cancel**

Your MPR has been submitted and has started the review process!

Next steps:

- 1. BSO Review/Risk Assessment (if applicable)**
- 2. Pre-review by RPO**
- 3. Committee Review by either the full committee or designated member(s) depending on the submission type.**