**University of Wisconsin-Milwaukee IBC and Biosafety Program Protocol Registration Form- Blood Draws**

Version 1.0, 04/2018

This form is for PIs conducting blood draws on clients not known to be infected with any bloodborne pathogens. If the PI is working with blood known to be infected with any pathogens (i.e. HBV, HCV, HIV, CMV, etc.), this form cannot be used, and the IBC Registration Form that goes to full committee review must be used. The completed form can be e-mailed to the Biological Safety Officer, Danielle Rintala via e-mail at: rintala@uwm.edu for Biosafety Program and IBC review. The instructions carefully. PIs are required to complete the entire form and their Bloodborne Pathogens Exposure Control Plan. An approved protocol must be on file within 30 days of notification of request for filing and will require prior IRB approval.

# Principal Investigator Contact Information

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| Principal Investigator (PI):  | Click or tap here to enter text. |
| Position/ Title:  | Click or tap here to enter text. |
| E-mail:  | Click or tap here to enter text. |
| Department and Program:  | Click or tap here to enter text. |
| Phone:  | Click or tap here to enter text. |
| Campus/ Office Address:  | Click or tap here to enter text. |
|  |
| Alternate Contact (must be part of this protocol as a researcher) | Click or tap here to enter text. |
| E-mail:  | Click or tap here to enter text. |
| Phone:  | Click or tap here to enter text. |
|  |
| Emergency Contact Information- Cannot be personnel in study. |
| Name:  | Click or tap here to enter text. |
| E-mail:  | Click or tap here to enter text. |
| Phone:  | Click or tap here to enter text. |

# Section 1. General Information

## Section 1.1. Protocol Title

Title of Protocol: Click or tap here to enter text.

This submission is a (select one): Choose an item. If renewal, provide the IBC protocol #: Click or tap here to enter text.

## Section 1.2. Other Committee Protocols

**Supplement request: Attach IRB protocol to this form as needed.**

Protocol(s): [Protocol #(s)]

Most Recent Approval Date(s): Click or tap to enter a date.

## Section 1.3: Funding

Type of Funding: Choose an item. Specify Source: Click or tap here to enter text.

Grant Number: Click or tap here to enter text.

## Section 1.4. Training and Certifications

All personnel must have a current record of OSHA Bloodborne Pathogens Training (completed within the last 365 calendar days), record of training to conduct blood draws, record of training for safe needle practices, and, if working with blood in the laboratory after doing draws, must have laboratory safety training and biosafety training on record.

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| --- | --- | --- |
| **Name (include all personnel involved in protocol)** | **Title/ Job Description** | **Training Records**  |
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## Section 1.5. Research Location(s)

Current lab inspections for laboratory safety, biosafety, and, if applicable, radiation safety, need to be completed within the last year by the Department of University Safety and Assurances for IBC approval.

|  |  |  |  |
| --- | --- | --- | --- |
| **Building and Room Number**  | **Research Activity/ies** | **Highest BSL** | **Most Recent Inspections and Dates** |
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# Section 2. Research Description

**Supplement Request: Must attach Bloodborne Pathogens Plan.**

## Section 2.1. New Research Studies Only

Summarize the rationale for this research study and the overall goal of this study. Do not exceed 200 words

Click or tap here to enter text.

Describe the origin of the blood samples (i.e. patient population(s) to be sampled).

Click or tap here to enter text.

Provide the research question (hypothesis/ hypotheses) to be tested.

Click or tap here to enter text.

Provide a brief description of the procedures employed in this protocol.

Click or tap here to enter text.

## Section 2.2. Renewals Only

Summarize the rationale for this research study and the overall goal of this study. Do not exceed 200 words

Click or tap here to enter text.

Summarize the progress and accomplishments of this study since its start date:

Click or tap here to enter text.

Summarize procedures, and describe any proposed modifications that are included in this proposal that were not in the previous submission(s)- attach supplemental information as needed.

Click or tap here to enter text.

Identify any changes to the protocol since the previous submission to IBC.

Click or tap here to enter text.

# Section 3. Biocontainment, Decontamination, and Disposal of Waste

All research personnel involved in blood draws are required to wear gloves, protective clothing, and practice universal precautions in accordance with the Bloodborne Pathogens Exposure Control Plan when handling blood samples, conducting draws, or disposing of waste. Identify the types of PPE being used below.

|  |  |  |  |
| --- | --- | --- | --- |
| Type of PPE | Type of PPE (i.e. brand, material) | When PPE will be worn/ used | Decontamination/ Disposal Method |
| Gloves |  |  |  |
| Eye Protection |  |  |  |
| Protective Clothing |  |  |  |
| Other (specify): |  |  |  |

All disposal of needles must be done in an approved sharps container. Describe below how the needles are collected for safe disposal.

Click or tap here to enter text.

How will any other waste be disposed of after completing the blood draws (i.e. glassware, used test strips, etc.)?

Click or tap here to enter text.

If any equipment (i.e. centrifuge, vortexer, etc.) is used, how will it be decontaminated after use?

Click or tap here to enter text.

# Section 4. Occupational Health

All personnel should be offered the Hepatitis B Vaccine Series and complete the request for vaccination or declination form in the Bloodborne Pathogens Exposure Control Plan. The Hepatitis B vaccine series must be paid for by the department if it is requested. No one can be required to receive vaccines at UWM, but the Hepatitis B vaccine is strongly recommended for personnel conducting blood draws.

1. Is there a vaccine recommendation for working in your research facility?

[ ] No- should recommend Hepatitis B vaccine series.

[ ] Yes- specify if there are additional recommendations besides Hepatitis B vaccine series: Click or tap here to enter text.

1. Have all personnel completed a consent/ declination form for the Hepatitis B vaccination series?

[ ] No- complete before commencing research

[ ] Yes- PIs should store these in a confidential location (preferably by giving to their HR rep for safekeeping in their personnel file).

# Section 5. Reporting

I, **Click or tap here to enter text.** , the principal investigator of this study, agree to abide by all university, local, state, and federal guidelines and regulations regarding the safe handling of needles and human blood samples. I am additionally responsible for the following:

* Ensuring my personnel are trained in the safe handling of needles and sharps prior to collecting blood draws and review best practices with my personnel regularly to minimize accidental needlestick injury;
* Ensure that myself and my staff have completed Bloodborne Pathogens Training within the last calendar year.
* Safely dispose of needles and any other materials used in the research study;
* Follow all procedures and guidelines in the approved Bloodborne Pathogens Exposure Control Plan and in my approved protocol; and
* Reporting of any accidental needlestick injuries or blood exposure events following University policies, ensuring any work-related injury is reported to the University as soon as possible and exposed personnel are sent to their primary care physician for screening for Bloodborne Pathogens.

I will be responsible for correcting work errors and unsafe laboratory conditions. I will maintain a biological inventory and a laboratory biosafety manual outlining policies, procedures, and approved protocols, and will require all personnel to review it and sign that they have reviewed it. If there are any changes to personnel or the protocol, I will submit the appropriate request for changes to the protocol. I understand that the approval of this protocol expires in 3 years, at which time I will be expected to submit a renewal form or a new protocol form if I am changing my protocol.

Click or tap here to enter text. Click or tap to enter a date.

Principal Investigator E-signature (Type Name) Date

|  |
| --- |
| ***Office Use Only***IBC Protocol Number: **Click or tap here to enter text.**Date Approved: **Click or tap here to enter text.**Approval By: **Click or tap here to enter text.**Renewal Date: **Click or tap here to enter text.** |
| Biological Safety Officer Signature:  |
| PI Signature:  |