Institutional Biosafety Committee

Standard Operating Procedures

Rev. October 2023

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Introduction

Eastern Virginia Medical School (EVMS) is dedicated to ensuring the safety and security of our staff, faculty, students, and community. To that end, the mission of the EVMS Institutional Biosafety Committee (*IBC*) is to:

- Ensure that registrations involving human and animal pathogens, tissues, and toxins are reviewed and found to comply with all federal, state, and local requirements
- Ensure that all recombinant or synthetic nucleic acid molecule registrations and research are in compliance with the National Institute of Health's *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines)*
- Establish policies and procedures ensuring biological materials are handled and disposed of safely and in the proper manner

The IBC executes its function in accordance with the principles and guidelines established by the U.S. Department of Health and Human Services (*HHS*), National Institutes of Health/Office of Science Policy (OSP*)*, Centers for Disease Control/NIH Biosafety in Microbiological and Biomedical Laboratories (*BMBL, 6th edition*), EVMS Biosafety Procedures Manual, and the EVMS Exposure Control Plan. Copies of the EVMS materials will be provided to new faculty and are available on the EVMS MyPortal site or from EVMS Research (OR).

The IBC conducts business through SciShield (formally BioRAFT), a modular software platform for research management and compliance oversight. IBC members, Principal Investigators (*PI*), and laboratory personnel can access SciShield at https://evms.bioraft.com/. Lab submissions, agent forms, biosafety-related training, and each laboratory's status are contained in SciShield.

This document encompasses the procedures and individual responsibilities related to the operation of the IBC. Each **IBC member** and **Principal Investigator** should be familiar with these procedures and their incorporated responsibilities.

Included in these SOPs are:

- Composition of the IBC
- List of reviewable registrations
- SciShield and registration submission procedures
- Required trainings

Committee Information

Membership Composition

Voting Members

The IBC shall have at least six (6) voting members, including the Chair(s). These voting members are appointed because they collectively have the experience and expertise to evaluate

and identify any potential risk to public health and/or the environment. Voting members include the EVMS Biological Safety Officer (BSO), the IBC Chair (or Co-Chairs), Principal Investigators, Faculty and a minimum of two (2) members external to EVMS (community members). Voting members are charged with discussing all safety aspects and risk assessments of submitted registrations. The voting members are to vote on an action for the submitted registration.

Alternate Members

There may be alternate members as part of the committee who are able to fill in for a voting member when that voting member is unable to attend, or if that member has a conflict of interest and is required to leave the meeting.

Alternate members shall fulfill a similar role as the voting member they are replacing for the meeting (e.g., if they are filling in for the laboratory animal expert, the alternate voting in his/her place must also be a laboratory animal expert). Only vote on a submission when the member they are replacing is not present in the meeting. Alternate members are always permitted to join the IBC meetings to participate in deliberations, but cannot vote unless the conditions stated above are satisfied.

Non-voting Members

Staff or faculty of EVMS may be appointed to serve on the IBC in a non-voting role should it be decided that such person(s) would be of assistance to the IBC in conducting their duties. Non-voting members cannot vote, but can participate in discussions and deliberations.

IBC Chair or Co-Chairs

The IBC Chair(s) will be chosen from the membership of the IBC. Such person(s) is/are to be knowledgeable in biological safety, including regulations, school policies, and ethics relevant to such research. The Chair (or Co-Chair(s)s) is/are responsible for conducting all meetings of the IBC.

The Chair(s), in his/her absence, will designate an appointee to serve as Chair during the period of absence.

IBC Administrator (IBCA)

The IBCA is a non-voting, support staff from EVMS Research. The IBCA sends all correspondence from the IBC to the Investigators. The IBCA is charged with the responsibility of IBC records (meeting minutes, training, registration and PI files, etc.) and is also responsible for reviews, delegating reviewers for registrations, distributing supplemental information to IBC members and initial reviews of adverse event reports.

All form submissions, attachments and other materials requested by the IBC are to be sent to the IBCA. SciShield registrations are prescreened by the IBCA prior to being sent to the IBC. The IBCA can administratively approve changes in personnel or room number in the SciShield registration.

Institutional Official

The *Institutional Official (IO)* serves as the *Ex-Officio* of the IBC. The *Ex-Officio* is a non-voting member of the IBC with the following exception:

- The *Ex-Officio* will be allowed to vote if said person creates a voting majority at a scheduled meeting.

Term

In general, IBC membership is by appointment for a three-year term. If a member is chosen to become Chair, the term of said member may be extended as required. Terms are renewed at the discretion of the EVMS Vice Dean of Research.

Appointments

Appointments to the IBC are made by the Vice Dean or Dean of Research, on the recommendation of the EVMS Committee on Committees.

Meetings

Schedule

The IBC meets on the second (2^{nd}) Monday of each month. The IBCA will contact committee members prior to the scheduled meeting in order to establish whether a quorum will be present.

A 5-day electronic review for Annual Reviews, Exempt, Modified/Requested Revisions Registrations can be granted by the IBC Chairs and approved by the full IBC. The review period is set at 5-business days. After 5 business days, if there is no call for full committee review, the Registration will be designated as Approved.

A quorum is the minimum number of committee members required to be present or available for discussion in order for the committee to conduct business. For the IBC, the quorum is defined as fifty percent (50%) of the voting membership plus one.

Reviewable Registrations

The IBC is charged with review of all registrations utilizing the following:

- Recombinant or synthetic nucleic acids, including all methodologies that involve the isolation, amplification, hybridization, and other uses of biologicals and/or nucleic acid molecules from any organism
- Culture of human or animal pathogen(s)
- Laboratory-induced infection of a human or animal with any human or animal pathogen(s)
- All human tissues and cells
- All other tissues and cells
- Studies referred to the IBC from the Institutional Animal Care and Use

Committee (IACUC) or the Institutional Review Board (IRB)

Non-member Attendance

Principal Investigator

A Principal Investigator (PI) may be requested to attend an IBC meeting when the committee deems attendance will aid in the clarification of a registration. A request of attendance from the IBCA or IBC Chair(s)(s) will be given to the PI before the scheduled IBC meeting.

General Public

The *NIH Guidelines* Section IV-B-2-a- (6) state:

- When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its Institutional Biosafety Committee meetings to the public.

In accordance with the *Guidelines*, the general public is permitted to attend formal IBC meetings. In order to attend, arrangements with EVMS Research must be made in advance. Requests of attendance will be answered by EVMS Research prior to the scheduled meeting.

Before a member of the public is granted approval for attendance, the following documentation must be provided to the EVMS Research:

1. A formal, written request for attendance must be submitted to the Office of Research.
2. A personal background information sheet must be completed by each attendee. This information sheet should have, but is not limited to
    a. Legal name
    b. Contact information
    c. Relevant company or organizational affiliations
3. A signed Participation/Confidential Non-Disclosure agreement

EVMS Research reserves the right to refuse a request of attendance for any reason.

While members of the general public may be given permission to attend IBC meetings, the IBC Chair(s)(s) have the discretion to end official meetings at any time and to bar individuals from attending future meetings.

Proceedings

Procedure

All IBC members are to review each new registration and registrations with changes in materials and/or methodologies. Only one member of the committee will be assigned the responsibility of reviewing a registration at the meeting. After a registration review and discussion, the Committee may vote to:

- Approve the registration as submitted
- Approve the registration pending receipt of clarifying/additional information
- Disapprove or table (postpone consideration of the registration) as submitted

A majority vote carries a motion. PIs will be informed in writing (fax, email and/or mail) of the committee's decision and of any additional information the committee is requesting.

Registration Records

Records of laboratory registrations, biological safety training documentation, laboratory status, and email correspondences are maintained on the SciShield system. A supplemental record will be kept by EVMS Research, in either electronic or hard copy format. The supplemental record for each lab contains the following information:

- Research registration – all versions are retained
- Approval documents from other committees or agencies
- Notifications of IBC decisions
- Records of registration renewal activities
- Reports on amendments and adverse events
- Correspondence between the IBC and investigators of the project

The files on each laboratory will be retained for at least 3 years after termination of the research has been documented.

Meeting Records

Agendas and minutes of IBC meetings are stored by EVMS Research either on digital media or by hard copy and are kept indefinitely. Meeting records are available to the general public upon written request.

Requests for information regarding the IBC or its records are to be forwarded to EVMS Research. In accordance with Section IV-B-2-a-(6) of the *NIH Guidelines*, EVMS reserves the right to redact any information it deems private or proprietary. This information includes, but is not limited to

- Confidential commercial information
- Names, home telephone numbers and addresses
- Specific information whose disclosure would directly compromise

institutional or national security

Member Records

Curriculum vitae of active members of the IBC are maintained by the Office of Research and will be updated as necessary. Each member's membership term will be monitored and updated as necessary.

IBC Business in the Event of a Pandemic or Other Emergency

The IBC will meet as often as necessary to fulfill its responsibilities to EVMS and the community. In the event of a pandemic or other emergency that prevents quorum of voting members to be in-person, IBC meetings will be held via the use of telephone or video conferencing.

Emergency Review

This process will be conducted on an **emergency basis only, usually in cases where the release of grant money requires an accelerated decision**. The Chair(s) reserves the right to defer consideration to a regular IBC meeting.

In order to request an emergency review, the Principal Investigator will notify the IBCA of their request for emergency review in writing (fax, email and/or mail). The PI will then certify their laboratory registration through SciShield.

If the request for emergency review is granted, the IBC Chair(s) will call an emergency IBC meeting to review the registration. In the event of a called emergency meeting, full quorum must be met in order to render a decision. The PI will then be notified of the decision.

If the request for emergency review is denied, the PI will be notified of the decision and the registration will proceed to the IBC as is customary.

Approval Period

A newly approved registration receives an initial approval period of one year, and may be renewed for four (4) consecutive years by annual review. At the time of a laboratory's annual review, the PI is to add a statement to the bottom of each project identifying the review year and changes (if any) made. The IBC will then review these changes and impart a decision.

However, the total span of the registration is five (5) years. After four annual reviews, the PI must submit their Registration as an Initial Review and the IBC will review the entire registration. This will start a new 5 year span.

Conflict of Interest

In accordance with Section IV-B-2-a-(4) of the *NIH Guidelines*

- If any IBC member is a PI, co-investigator, or a subordinate to a Principal or co-investigator on a registration that is being reviewed by the IBC, the member must inform the Chair(s) of the conflict of interest (*COI*), leave the

room during the review and abstain from voting on the registration.
- If an IBC member neglects to inform the Chair(s) of any COI and a registration is reviewed and approved, the registration must undergo re-review by the Committee. If a registration is re-reviewed, the COI member must leave the room while the review is in progress and must abstain from any votes involving the registration.
- All COIs will be noted in the minutes of the meeting.

Extension

A 30-day deadline extension may be granted for original registration submissions or annual registration reviews. The PI must submit a written letter to the Chair(s) requesting the extension no later than ***one week*** before the SciShield Submission Deadline. **The granting of an extension request is on an individual basis and is at the discretion of the Chair(s).**

- Extensions are limited to one (1) 30-day extension per registration

Reviewer's Responsibilities

IBC Members are delegated the responsibility of reviewing a registration by the IBCA. While only one (1) IBC member, the Reviewer, is responsible for the official review of a registration, all members should review each registration in order for the committee to have a complete risk assessment of the proposed research.

In reviewing a registration, the Reviewer should focus on the ***biological risk*** associated with the projects. A summary of the research should be given in language that is understandable to everyone, including those outside the scientific community. Particular attention should be paid to:

- Relevant techniques involved (recombinant or synthetic nucleic acid molecule transfer, centrifugation, aerosolization, etc.)
- Biohazardous agents and materials (microbes, plasmids, tissues, cell lines, etc.)
- Agent handling and biological equipment (biological safety cabinets, personal protective equipment used, danger to surrounding environment, etc.)
- Training dates for all laboratory personnel

Once a summary of the laboratory's work has been completed, the Reviewer should point out the major and minor issues with the registration.

After a complete risk assessment by the committee, the Reviewer should make one of the following recommendations for the registration:

- Approve
- Approve pending changes/clarifications/modifications

- Disapprove or Table

Registration

Laboratory registrations are entered and maintained in the SciShield system. A hard copy of the submission should be in each lab and be readily accessible to all personnel. The following procedures should be followed for submitting registrations for review to the EVMS Institutional Biosafety Committee (IBC).

Laboratory (Lab) - For the purpose of IBC reviews, a *Lab* is defined as a place equipped for experimental study in a science or for testing and analysis. Those investigators with independent funding, projects and/or protocols that are sharing lab space must have an independent biosafety registration. Generally, one lab is associated with a single principal investigator (PI).

Initial Registration Review

Schedule

Initial registrations,are certified in SciShield by 5:00pm on the Monday **two weeks** prior to the next scheduled IBC meeting. The registration is then prescreened by the IBCA and the BSO. Any requested modifications to the registration must be completed and the registration re-certified by 12:00 pm the following Friday (*Requested Modification Deadline*).

- Example: Submission due in July 2022. submission date is 5:00 pm Monday June 27, 2022. The requested modifications are to be completed and the submission re-certified by 12:00 pm Friday July 1, 2022. The IBC meeting is held Monday July 11, 2022.

Registration

All laboratory registrations are to be completed on the SciShield website. Once in the SciShield system, the PI must complete several components in order to certify the registration.

1. Enter background laboratory information including the laboratory focus, project titles and personnel.
2. Complete the project information section detailing funding sources, materials and methods used, specific aims of the research, and lab techniques employed. All information should be addressed with respect to biological safety and risk assessment of the laboratory.
3. Complete each survey as required by the SciShield system.
4. Complete Viral Vector and/or Human Pathogen Registration Forms (as necessary).

All registrations must be certified in the system ***two weeks*** before the scheduled IBC meeting. Unacceptable submissions will be returned to the PI for correction and resubmission.

Collaborating Investigators

Collaborating PIs are defined as investigators of independent laboratories that are conducting scientific experiments for a common research project. Often detailed descriptions of these projects will not require separate registration by both PIs' laboratories and approval by the IBC. However, if the involved research occurs across both/all the laboratories, then the project(s) must be registered into SciShield *both* by the Investigator and the Collaborators.

- Co-registration must occur if the PIs:
  - Have the **intention** to be "hands-on" in the manipulation of the biological materials involved in the project.
    - If it *is not* the intention of the collaborator to be physically involved in the project, but occasionally assists in physically manipulating biological materials, then they are not considered to be a Collaborating Investigator.

-OR-

  - Have **scientific interest** in the research being conducted.
    - If the collaborator is only providing a laboratory service or technical support (such as occasionally conducting RT-PCR for a peer or assisting in the research design of a project), then they are not considered to be a Collaborating Investigator.

- In the case of collaborating PIs and/or Shared Research Space:
  - The Principal Investigator is responsible for writing the project description. Co-investigators must write the project title and IACUC/IRB protocol numbers associated with it, no description necessary.
  - IACUC and IRB numbers - In the Human or Animal Source Materials Survey section, investigators should write all protocol numbers associated with their research. If their research is covered under a different person's protocol, they should write the protocol number followed, in parenthesis, by the PI's name. Example: 10-008 (Smith).
  - In the event of multiple independent researchers using a shared laboratory space that involves special procedures (ex., biohazards, agents, human/animal specimens, BSL2/2+), the individual PIs will need to seek IBC approval as determined on a case-by-case basis by the IBC. Each PI should be aware of other groups sharing the laboratory space and follow the highest biosafety level within the shared space(s).

Exempt Registrations

Some registrations do not fall under the *NIH Guidelines* Section III A-E or under the EVMS "Reviewable Registrations" criteria. These registrations can be granted Exempt Status. It is the responsibility of the IBC, not the PI, to determine if the research qualifies for exempt status. **Designation of Exempted status is determined on an individual basis and is at the discretion of the IBC.**

The application deadline to have a registration evaluated for exempt status is the same as that for a convened committee review. The PI must still submit a laboratory registration through SciShield. The Exempt Subcommittee, comprised of the IBC Chair(s)(s) and the BSO, will then determine whether a registration qualifies for exempt status.

If the Exempt subcommittee determines the research is exempt, the PI will be informed of the IBC's decision via written letter and email. The PI will still have the responsibility of notifying the IBCA (1) if there are any changes to the research that might deem it non-exempt, and (2) an annual communication to verify the exempt status of the research. Exempt registrations will be tracked by the IBC until completion, but formal annual reviews are not required from the PI.

Exempt labs will be sent an electronic copy of their SciShield registration at the time of requesting each annual update via e-mail. Labs that utilize recombinant or synthetic nucleic acids will not fall under "Exempt" category.

If the Exempt subcommittee determines the research is not exempt, the research registration will be included in the upcoming fully convened IBC meeting.

Amendment Procedure

An immediate notification to the IBCA is required when the Biosafety Level of a registration is changed.

The Principal Investigator is responsible for submitting all proposed methodology and/or technique changes to the registration, by modifying and recertifying the registration. The IBCA will send the recertified registration to the IBC Chair(s)(s) and the Chair(s)(s) will determine if the changes/modifications go before the committee either electronically or during a convened meeting. If presented with the amendment request in a convened meeting, the Committee will review and vote on the proposal. For amendments reviewed electronically, IBC members will leave their comments and/or give their approval through email directlyto the IBCA. The review period is set at 5-business days. The PI will then be informed of the IBC's decision.

An amendment may be required if a *congruency* is needed to release Internal and/or External awarded funding. The IBCA will send the recertified registration to the IBC Chair(s)(s) and BSO for review and determine if the modifications are approved or go before the Committee. As above, the Committee will review and vote on the proposal. The PI will then be informed of the IBC's decision.

The IBCA may administratively approve changes in personnel on a registration in between annual reviews. The PI must also ensure proper training for any additional personnel; this includes their Biosafety Training, Autoclave Training, Shipping Training (if applicable) and latest Bloodborne Pathogen Training date.

The Committee must be notified in writing (letter/email) when changing or transferring a registration to a new PI. The transfer of a registration to a new PI will require the submittal in writing (letter/email) from both the original and new PI for review and approval. The new PI must certify a new registration if they are new faculty, or amend their existing registration to include the new research. The original PI must submit a letter indicating the study is terminated and the disposition of materials (see *Completed/Terminated Registrations*).

Minor modifications via an amendment to a registration, may be approved by the IBC Chair(s)(s) and BSO.

Requested Revisions

The following are for modifications/clarifications requested by the IBC for approval of an IBC registration. Revisions can either be reviewed by the Chair(s)(s) (or designated IBC Committee member) to make a final approval, or the Committee as a whole can view modifications/clarifications and vote at the next scheduled IBC meeting. The Committee will decide on which method of resubmittal is needed on a case-by-case basis. Until the final approval is given for a registration, the registration will not be considered approved by the IBC or designated as "Approved" in the SciShield system.

Minor Revisions with Resubmission

Minor revisions can be made by submitting the modified and re-certified registration in SciShield. Some clarifications requested by the Committee in regards to the registration, may need to be addressed via an email for review. This will then be reviewed by the BSO or IBCA. If acceptable, the BSO or IBCA will send the registration to the Chair(s)(s) or a designated IBC member for final approval. Final approval is sent to the PI in the form of an email through SciShield stating their status has been marked as approved.

Resubmission

Revision(s) requiring the full Committee's re-evaluation must be certified in SciShield and the Committee will review the registration at the following IBC Meeting. The PI is notified in writing of the Committee's decision and requirement(s) for resubmission.

Omitted Information

When the IBC or PI discovers an instance of omitted or absent registration information, the following procedures will be initiated:

1. IBC discovers significant, new information that is not on an approved registration
    a. Only the IBC will determine the significance of the omitted information
2. The IBCA will send out a correspondence informing the PI
    a. The PI will be given **thirty (30) days** to submit a registration amendment to SciShield
    b. After thirty (30) days, if the amendment is not provided:
        i) The Approved Registration will be designated as "Disapproved" in the SciShield system
        ii) A new compliance timeline will begin from the date of the letter and lasts until a new, updated registration is certified and approved
3. Once the PI submits a certified registration, the lab's registration status is changed to "*Awaiting IBC*"
    a. Depending on the details of the new changes/modifications, the IBC Chair(s)(s) will determine whether the new registration will go to full committee, sub-committee or if a Chair(s) can approve
    b. The original annual review date will remain unchanged
4. The registration will then follow the procedures of Initial and Annual Registrations

Annual Review

An IBC registration must be re-evaluated and approved on an annual basis. The PI will receive an email from the IBCA, at approximately sixty (60) days before the expiration of a registration's approval. This email will include the date of the next IBC meeting date, a submission date (SciShield *Submission Deadline)* and SciShield instructions.

At **one (1) month prior** to the expiration date of the existing approval period, the PI is to log-in and review the registration in SciShield. After review and changes are made (if any), the PI must ***certify*** the registration.

All *ANNUAL REVIEW STATEMENTS* to the registration **must be** in **EMPHASIZED FONT**, with the review year preceding the stated changes (IF ANY) - see examples below.

- If the registration has **NO CHANGE(S)**, the PI is to include this as a statement at the bottom of the project description, for each project, by the deadline. The IBC

Chair(s)(s) will then review the registration and impart a decision.

EXAMPLE: 2020 ANNUAL REVIEW – THERE ARE NO CHANGES TO BIOLOGICAL AGENTS OR TECHNIQUES BEING USED FOR THIS PROJECT

- If the registration **HAS CHANGE(S)**, the PI is to list these changes in a statement at the bottom of the project description, for each project, by the deadline. The IBC Chair(s)(s) will then review the proposed registration and determine whether the changes warrant the registration going to full committee for review.

EXAMPLE: 2020 ANNUAL REVIEW – E.COLI STRAIN "XYZ" WAS ADDED AND WE NOW DO SELDI ANALYSIS FOR THIS PROJECT

Registration Renewals

Institutional Biosafety Committee (IBC) registrations are valid for a span of five (5) years. After four (4) annual reviews, PIs are required to submit their registration as an *initial registration* (5-yr Renewal) to be reviewed in its entirety at least one month prior to its expiration date.

PIs are required to do the following:

1. Log into the SciShield system (https://evms.bioraft.com) and review the entire registration. Check if the projects, personnel, IRB/IACUC protocol numbers, reagents, etc. are accurate and current.
2. Delete ALL the annual statements at the bottom of each project description. For a 5-year Renewal, no annual statements are needed.
3. After completing all changes (if any) to the registration, scroll to the bottom of the page and click "Certify" in order to submit the registration.
4. Principal Investigators using recombinant or synthetic nucleic acid molecules are required to complete the "NIH Guidelines Training" available in SciShield at the time of renewal as a requirement for IBC approval (unless taken within the previous year).

Non-Compliance

The IBC will investigate suspected or alleged violations of protocols, external regulations, or institutional policies that involve recombinant or synthetic nucleic acid molecules and/or other biological materials. Included in the institutional policies are the IBC policies for submitting registrations, both Initial and Annual Reviews. If violations are not resolved through normal channels of communications with the PI, the corresponding Department Chair(s), and the Institutional Official, the PI will be notified of the violation and a timeline for resolution will be established.

Timeline

- **Level 1** – A letter will be sent to the Principal Investigator informing them they are not in compliance and requesting corrective action within thirty (30) days from the letter date.
- **Level 2** – A letter will be sent to the Principal Investigator, their Department Chair(s), and the Institutional Official detailing the compliance issues. The letter will request corrective action within fourteen (14) days from the letter date.
- **Level 3** – A letter will be sent to the Principal Investigator, their Department Chair(s), and the Institutional Official detailing the compliance issues. A deadline to prevent IBC sanctions will be set for fourteen (14) days from the date of the letter.
- **Level 4** – IBC sanctions commence.

Important: The submission of a late registration ***does not*** change the registration review date. The original review date will remain for subsequent submissions.

EVMS Sanctions

The EVMS IBC has the authority to establish sanctions for laboratories that have not followed IBC requirements, recommendations or if serious consequences have occurred.

These sanctions may include any or all of the following:

- Notify the relevant federal agencies of IBC non-compliance, including the NIH and/or CDC
- Notify the relevant research compliance committees of IBC non-compliance, including the IRB and/or IACUC
- Notify the EVMS Office of Compliance of IBC non-compliance
- Authorize access restrictions to research areas and materials
- Halt funding release for the initiation of relevant projects
- Request the IO to consult the Dean for suspending funding for ongoing projects
- Summon the Principal Investigator to appear before the IBC

Reporting to Federal Agencies

The EVMS IBC is obliged to report non-compliance to NIH, the CDC, and other federal agencies. Failure to comply with the IBC or other regulatory guidelines may result in:

- Suspension, limitation, or termination of financial assistance for the non-compliant NIH-funded research project and of NIH funds for other recombinant or synthetic nucleic acid molecules research at the institution.

- Requirement for prior NIH approval of any or all recombinant DNA projects at the institution as described in the *NIH Guidelines* Section I-D-1.

Section I-D-1: All NIH-funded projects involving recombinant or synthetic nucleic acid molecules must comply with the NIH Guidelines. Non-compliance may result in: (i) suspension, limitation, or termination of financial assistance for the noncompliant NIH-funded research project and of NIH funds for other recombinant or synthetic nucleic acid molecule research at the institution, or (ii) a requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecule projects at the institution.

Closed/Terminated Registrations

For all closed or terminated registrations, the PI will be required to send an email to the IBCA and/or BSO prior to closing/terminating the registration. In the closure/termination email, the PI will convey the disposition of the biohazardous materials related to the registration in the form of one or more options:

- The PI may transfer materials to another PI or responsible party
- The PI can make arrangements for proper disposal of the materials
- The PI can state the materials will remain stored under their supervision

If the biohazardous materials have been ***transferred to another PI***, both the original PI and the new responsible party must acknowledge transfer via email. The email must state the following:

- The PI accepting the biohazardous material
- Where the biohazardous material will be stored

The new responsible party (accepting transferred biohazardous material(s)) **MUST** modify/amend their SciShield registration to include the changes/modifications.

If materials are to be ***disposed of***, it is the responsibility of the PI to ensure that all biohazardous and regulated medical waste is disposed of in the proper manner.

If these materials will ***be stored***, the PI will be required to document in detail where the material is (i.e. building, room number, freezer number, labeling, etc.).

Training

Responsibility

Ensuring the completion of proper training of laboratory staff is the responsibility of the individual Principal Investigator. All laboratory personnel listed on the registration, including the Principal Investigator, must be trained for the hazards contained in the registration, and the training must be up-to-date. Registrations will be approved only after the appropriate training has been completed/updated, as necessary, by lab members. Until final approval is granted, the non-compliance timeline remains active.

Types of Training

Training on SciShield

Training on SciShield is located under the "Training" tab in the system. For each course/training, select "Launch course," view the presentation, complete the quiz and select "Submit." Information about all EVMS training requirements can be found at: https://myportal.evms.edu/research/reserach_compliance/required_training/

Biosafety Training

It is mandatory that all faculty, staff, and students working in a laboratory setting containing biohazardous materials satisfactorily complete Biological Safety training. Completion of the biosafety training is required **every five (5) years**.

Autoclave Training

It is mandatory that all faculty, staff, and students working in a laboratory setting containing biohazardous materials must satisfactorily complete Autoclave Safety training. Completion of the autoclave training is required **every five (5) years**.

Shipping Training

It is mandatory that all faculty, staff, and students who are involved in shipping or receiving biohazardous materials at EVMS must satisfactorily complete Biohazardous Materials Shipping training. Completion of this course satisfies requirements of both the International Air Transport Association (*IATA*) and the Department of Transportation (*DOT*) for infectious substances shipping training. If the laboratory ships or receives biohazardous materials, **at least one (1) person** associated with the lab must complete shipping training. Completion of the shipping training is required **every two (2) years**, as long as the laboratory/person is still involved with shipping.

NIH Guidelines Training

NIH Guidelines Training is recommended by *NIH* for all IBC Members and at a minimum, faculty involved in recombinant or synthetic nucleic acid molecules research. PIs are required to complete/update the *NIH Guidelines* training at the time of Initial Review submission and at each

subsequent 5-year renewal (unless taken within the previous year). Principal Investigators are responsible for the training of their laboratory members in the *NIH Guidelines*.

Other Required Trainings

Bloodborne Pathogen Training

EVMS personnel with exposure to human blood or other potentially infectious materials covered by the OSHA Bloodborne Pathogen Standards are required to complete annual Bloodborne Pathogen Training. Investigators are required to use "Standard Precautions" when handling specimens of blood, blood products, or "other potentially infectious material" as stipulated in the EVMS Bloodborne Pathogen Exposure Control Plan.

Other Potentially Infectious Materials (OPIM) includes all of the following that can transmit bloodborne pathogens:

- Unfixed human cells, tissue, or organ samples or cultures
- Human cell culture supernatant
- Any solutions containing HIV, HBV, HCV or other BBPs
- Any body fluid visibly contaminated with blood or OPIM
- Cerebrospinal, pericardial, synovial, pleural and peritoneal fluids
- Vaginal secretions
- Amniotic fluid
- Semen
- Blood, organs or tissues from animals infected with HIV, HCV, HBV or other BBPs
- Saliva during dental procedures
- Any fluids where it is difficult to identify the presence or absence of blood.

  - Breast Milk: although not considered OPIM, Standard Precautions should still be utilized and gloves should be used when in situations where exposures to breast milk might be frequent.

Initial Bloodborne Pathogen Training is provided through Human Resources (HR) on Blackboard at http://evms.blackboard.com.

EVMS Bloodborne Pathogen Training for guest/visiting researchers and research staff who will be working with human blood or body fluids, Bloodborne Pathogen Training should be completed annually on Blackboard at http://evms.blackboard.com.

Live Training

Contact Environmental Health and Safety (EH&S) for scheduling live training.

Chemical Hygiene Plan (CHP)

All permanent faculty and staff working in a laboratory must obtain Chemical Hygiene Plan Training (CHP). CHP training is obtained by attendance in Environmental Health & Safety's CHP class. Upon completion of this class, participants will receive a certificate of Completion from EH&S. This training only needs to be completed **every five (5) years**.

Radiation Safety Training

Radiation safety training is required when personnel will be working with radioactive materials or products containing radioactive material. If working with radioactive materials, completion of the "Radiation Safety in the Laboratory" coursework is mandatory. After successful completion, personnel will receive their user documentation and may need to apply to the EVMS Radiation Safety Committee for approval to work with radioactive materials. Radiation Safety refresher training must be completed **annually** to be compliant.

> If personnel will only be working in the vicinity of radioactive materials (such as animals containing radioactive products), they may complete an abridged training course. While being able to work around radioactive materials, these personnel will not be users and are therefore not permitted to handle radioactive materials.

Other Committee Training

IACUC

The Institutional Animal Care and Use Committee (IACUC) reviews all research involving animal research. **It is the responsibility of the PI to contact the IACUC in regards to training.** Information regarding IACUC can be found at the following link:

https://myportal.evms.edu/research/research_compliance/committees/institutional_animal_care_and_use_committee/

Additionally, there is a Comp Med Facility Orientation for ALL animal users. Please contact the Comparative Medicine Facility Manager for details and scheduling.

IRB

The Institutional Review Board (IRB) reviews all research involving human subjects. **It is the responsibility of the PI to contact the IRB in regards to training.** The IRB will inform the PI as to whether their research falls under its review and what trainings must be completed.

Information regarding IRB can be found at the following link:
https://myportal.evms.edu/research/institutionalreviewboard/

VOLUNTEERS

Laboratory volunteers and other non-employee workers will follow the below procedures:

- PI or Program Coordinator contacts EVMS Human Resources (HR) to get a Volunteer Packet(s).
- Volunteer & PI completes packet and returns completed packet to HR.
- HR forwards the Job Description form (from the packet) to Occupational Health and EH&S for evaluation of requirements.
- Clarifications are addressed (if needed) and requirements are sent to HR for the volunteer.
- HR relays requirements to the volunteer and tracks the completion progress.
- Once all requirements are complete, HR will distribute an EVMS badge.

Special Circumstances

Select Agents and Toxins

The CDC defines Select Agents and Toxins as bacteria, viruses, and toxins that have the potential to be used as biological weapons. A table of Select Agents can be found at: https://www.selectagents.gov/sat/list.htm

Principal Investigators are to identify all Select Agents and Toxins desired to be used and stored in the laboratory in a written communication to EH&S ***before*** ordering. The BSO will respond to each request on an individual basis. The PI is ***not*** to order or receive any Select Agent or Toxin until given final approval from EH&S and the IBC.

Viral Vectors

The Committee will perform a risk assessment on each project using viral vectors. Depending on the nature and use of the virus, the Committee may determine that a lab-specific standard operating procedures (SOP) document and/or enhanced biosafety practices are required.

For work with lentiviral vectors, refer to the Appendix *Lentivirus Vector Information Supplement*.

Biological Toxins

Biological Toxins are toxic substances of natural origin produced by certain bacteria, fungi, protozoa, plants, and animals. Below is a listing of biotoxins that must be included in the Biological Toxins Survey of the Registration. This is not an exhaustive list and the IBC reserves the right to modify this listing

Abrin*

Anthrax Lethal Toxin (PA & LE)

Botulinum neurotoxins*

Brevetoxin

Bungarotoxin

Clostridium perfringenes epsilon toxin*

Conotoxin*

Endotoxin from *E. coli*

Diacetoxyscirpenol*

Microcystines

Palytoxin

Pertussis toxin

Phalloidin

Ricin*

Saxitoxin*

Shiga toxin*

Shiga-like ribosome inactivating proteins*

Staphylcoccal enterotoxins*

T-2 toxin*	Diptheria toxin
Tetrodotoxin*	Tetanus toxin

* Classified as a Select Toxin according to the Federal Government.

Use of Recombinant or Synthetic Nucleic Acid Molecules in Clinical and Field Studies

In order to have approval from the Institutional Biosafety Committee for any research involving the use of recombinant or synthetic nucleic acid molecules in clinical and field studies, the Principal Investigator will be required to complete a SciShield Registration. Recombinant or synthetic nucleic acid molecules must be prepared using approved procedures with appropriate analysis of product purity.

Human Gene Therapy Transfer of Recombinant or Synthetic Nucleic Acid Molecules into Human Subjects

The IBC is to review all consent documents relating to human gene therapy studies at EVMS. Also, if not previously registered with the IBC, the PI(s) involved in the human gene therapy research will complete a registration in SciShield. IBC, as well as IRB, approval are required ***prior to any studies taking place***.

Since human recombinant or synthetic nucleic acid molecules research falls under Section III-C-1 of the *NIH Guidelines* ("Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants"), the Principal Investigator will be required to complete the following:

- Institutional Biosafety Committee Registration (including appropriate project and survey form additions)
- IRB Letter of Approval
- Site Safety Inspection

If a **Phase I** or **Phase II** study, the following documents must be uploaded into SciShield:

- Report from the previous phase studies
- Report of all Adverse Events
- Letter from the hospital indicating:
  - Acceptance of the study
  - Acceptance of the subject
  - Responsibilities of the hospital
  - Responsibilities of the Principal Investigator
- The Investigator's Brochure

The principal investigator must be prepared to submit the registration to the Ad hoc Human Gene Therapy Subcommittee for review, if deemed necessary by the Institutional Biosafety Committee. The Committee may request the Principal Investigator attend the IBC meeting to answer questions the Committee deems necessary, in order to adequately review the study. Outside consultants may also be requested to assist the IBC in its review of the study.

Recombinant or Synthetic Nucleic Acid Molecules must be prepared using approved procedures with appropriate analysis of product purity.

Reporting Exposures and Adverse Events

Definitions

An "**exposure**" is any event involving exposure of any person to infectious materials, biological toxins or human blood/OPIM.

An "**adverse event**" is associated with the use of a gene transfer product when there is a reasonable possibility that the event may have been caused by the use of that product.

A "**serious adverse event**" is any event occurring at any dose of a gene transfer product that results in any of the following outcomes:

- Death
- A life-threatening event
- In-patient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly/birth defect

Important medical events that may not result in death, be life-threatening, or require hospitalization also may be considered a serious adverse event when, upon the basis of appropriate medical judgment, they may jeopardize the human gene transfer research subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

An "**unexpected serious adverse event**" is any serious adverse event for which the specificity or severity is not consistent with the risk information available in the current investigator's registration.

Procedure

In the event of a laboratory-related exposures (accidents, injuries, illnesses, near-misses) regardless of involving rDNA, consultation between Occupational Health, EH&S, the employee and the employee's supervisor is required for proper medical management and recordkeeping.
The following procedures should be followed if an EVMS employee suspects an illness is related to infectious agents in their work area.

1. Treat any exposure site(s) immediately.
2. Contact supervisor
3. Report to PMA Care 24 Nurse Call Service *as soon as possible*.

PMA Care 24 Nurse Call Service 1-800-411-0153.

4. Contact IBC regarding incident within 14 calendar days.
5. The IO must report the incidents to NIH OSP within 30 days.

Appendix - EVMS Policy on the use of human cell lines

Appendix - Lentivirus vector information supplement

Appendix - Project section template (for all SciShield registrations)

Appendix - EVMS training requirements

Abbreviations

BBP	Bloodborne Pathogens program
BMBL	Biosafety in Microbiological and Biomedical Laboratories, 6th edition (CDC/NIH)
BSC	Biological Safety Cabinet
BSL	Biological Safety Level
BSO	Biological Safety Officer
CDC	Centers for Disease Control and Prevention
CHP	EVMS Chemical Hygiene Plan
DOT	U.S. Department of Transportation
EH&S	Environmental Health and Safety Department
EVMS	Eastern Virginia Medical School
HHS	Department of Health and Human Services
HR	EVMS Human Resources
IACUC	EVMS Institutional Animal Care and Use Committee
IATA	International Air Transport Association
IBC	Institutional Biosafety Committee
IBCA	Institutional Biosafety Committee Administrator
IO	Institutional Official
IRB	Institutional Review Board
NIH	National Institute of Health
OPIM	Other potentially infectious materials
OSP	Office of Science Policy (at NIH)
PI	Principal Investigator
PPE	Personal Protective Equipment
rDNA	Recombinant DNA