A. Registration Requirements for Using Biological Agents at Texas A&M Health Science Center

1. All research conducted by Texas A&M Health Science Center employees or students, involving any of the agents/materials listed below, must be approved by the Texas A&M University Institutional Biosafety Committee (IBC) prior to initiation:

   - Pathogens and potential pathogens of humans, animals or plants;
   - Materials potentially containing human pathogens (including human blood, tissue, and cell lines; non-human primate blood, tissue, and cell lines);
   - Recombinant DNA (and RNA) including creation or use of transgenic plants and animals;
   - Select agents and toxins (see http://www.cdc.gov/od/sap/docs/salist.pdf) including strains and amounts exempted from the select agent regulations;
   - Any material requiring a CDC import license or a USDA permit.

The web site for the TAMU IBC is found at http://rcb.tamu.edu. Forms for new applications as well as amendments and contact information for the Biosafety Officer and Associate Biosafety Officers can be found at this site. If you have any questions completing the forms contact the Office of Research Compliance and Biosafety (biosafety@tamu.edu) and they will assist you in completing the required paperwork.

2. After approval of your application you will receive an approval letter from the IBC Chair that lists the agents, in-vitro/in-vivo use and locations approved for the Principal Investigator (PI). Any agent or work locations not listed on the letter CANNOT be used until approval is obtained from the IBC. Changes to your approved application are done by completing an amendment form: https://imedris.tamu.edu/ submitting it to the committee and receiving approval (any changes will be indicated on the approval letter, see figure 1 for an example of the approval letter).

The approval letter will also list any additional conditions that must be met such as: “Enrollment in the Occupational Health Program”, “Personal Protective Equipment”, “Training” and the need for contacting other compliance committees and granting agency.

3. The IBC Office will also supply the PI with a list of “Approved Personnel” for their IBC Permit. Personnel are listed during the initial application process or can be added by amendment form after initial approval is granted. Addition is done by completing an Amendment form, submitting it to the committee and having it approved PRIOR to allowing the individual to work in the lab, see figure 2 for an example of the Approved Personnel Letter.
MEMORANDUM

TO: Dr. Bob Boman
Assistant Professor
Baylor College of Dentistry
3502 Gaston Avenue
Dallas, Texas 75246

FROM: Dr. L. Gary Adams
Institutional Biosafety Committee (IBC) Chair
MS 1136

SUBJECT: IBC Permit - Use of Recombinant DNA/Riskful Biosafety Material 2012/001 - Bismarck

PERMIT EXPIRATION: June 22, 2012

Your registration document was reviewed and approved, subject to completion of some requested items, by the Institutional Biosafety Committee (IBC) at its May 23, 2012, convened meeting. This notification signifies the acceptable completion of all requested items. Therefore, you are APPROVED to work with and store the agents linked below in the biosafety group. Please note this approval is subject to all requirements and notes provided below. Upon issuance of this permit, your IBC Permit 2012/001 - Bismarck is now terminated.

<table>
<thead>
<tr>
<th>Agent (in vitro)</th>
<th>BL Required</th>
<th>NDB Guidelines</th>
<th>Building</th>
<th>Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Escherichia coli (K-12 strain)</td>
<td>1</td>
<td>III-B-6</td>
<td>0061</td>
<td>245</td>
</tr>
<tr>
<td>2. Listeria monocytogenes (recovery optional)</td>
<td>2</td>
<td>III-B-1</td>
<td>0061</td>
<td>245</td>
</tr>
<tr>
<td>3. Human cells (transduced)</td>
<td>2</td>
<td>III-B-1</td>
<td>0061</td>
<td>245</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Agent (in vivo)</th>
<th>BL Required</th>
<th>NDB Guidelines</th>
<th>Building</th>
<th>Room</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Human cells (transduced) in mice</td>
<td>ASL-2</td>
<td>III-D-4</td>
<td>0061</td>
<td>Any approved ASL-2 room</td>
</tr>
</tbody>
</table>

**Additional Requirements/Notes**

A) Please note that "BL Required" is the minimum biological safety level required for work with the noted agent(s).
B) All personnel must be compliant in the Biosafety Occupational Health Program.

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D) Annual Training Requirement: Please see [https://rcb.tamu.edu/training](https://rcb.tamu.edu/training)
- BL2 training (required of all laboratory personnel, including PI)
- NIB Guidelines training (required of PI only)
- Bloodborne Pathogen training (BBP) (required of all laboratory personnel, including PI)

Please note:
1. You must adhere to the requirements set forth in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).
2. You must adhere to the requirements set forth in the NIB Guidelines.
3. Any modifications to your research must be reviewed and approved before the initiation of work. Modifications must be submitted through the Amendment process.
4. An Annual Permit Renewal is required sixty (60) days prior to the first and second anniversary of the approval date.
5. The Principal Investigator is required to submit a new IBC Permit Registration Form sixty (60) days prior to the expiration of the IBC Permit.
6. While the work conducted is approved at the specified biological safety level (BL) of containment, the IBC is not responsible for ensuring that the product is available.
7. Only personnel, who have met all training and occupational health requirements for this protocol and received written approval from the IBC, may conduct work listed in the permit.
8. If your project will involve direct work with genetically manipulated animals, please contact the Animal Welfare Assurance Program at [http://rcb.tamu.edu/animals](http://rcb.tamu.edu/animals).

9. Please forward copies of your grant manuscripts agency coordinator forwarding to your granting agencies as applicable. Copies have been distributed only as referenced below.

pc: [BCM]

732 Aggieland Road, Suite 3501
1188 TAMU
College Station, TX 77842-1188
Tel: 979.458.2524 Fax: 979.862.3176
bcm@tamu.edu
[http://rcb.tamu.edu/bcm](http://rcb.tamu.edu/bcm)
MEMORANDUM

TO: Dr. Bob Boiman
Assistant Professor
Baylor College of Dentistry
3502 Gaston Avenue
Dallas, Texas 75246

FROM: Ms. Kim Zemanský
Research Compliance Coordinator
Office of Biosafety
MS 1186

SUBJECT: Approved Personnel for IBC Permit - 2013001 - Boiman

PERMIT EXPIRATION: June 22, 2012

Below is the current list of personnel authorized to work on your IBC Permit 2013001 - Boiman. Please note this list only reflects those individuals that have met all protocol requirements.

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Date Added to IBC Permit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Bob Boiman</td>
<td>June 22, 2012</td>
</tr>
<tr>
<td>Barry Fink</td>
<td>June 22, 2012</td>
</tr>
<tr>
<td>John Fellers</td>
<td>June 22, 2012</td>
</tr>
</tbody>
</table>

Additional Requirements/Notes:

A) This approved personnel memo added personnel 19 to the permit.
B) Please note that Dr. Smith has not met all training requirements and therefore cannot have access to the laboratories. You will receive a revised approved personnel memo once our office can verify all training requirements have been met.

Please note:

1. Any additional modifications in your personnel must be reviewed before individuals may begin work in the laboratory. Please note that the IBC must also be notified if you remove any personnel from your laboratory. All modifications to personnel must be submitted through the Amendment process.

D) Annual Training Requirements: Please see http://tech.tamu.edu/ibc:
- BL2 training (required of all laboratory personnel, including PI)
- NIH Guidelines training (required of PI only)
- Bioshelter Pathogen training (BSP) (required of all laboratory personnel, including PI)

Please note:
1. You must adhere to the requirements set forth in the Biosafety in Microbiological and Biomedical Laboratories (BMBL).
2. You must adhere to the requirements set forth in the NIH Guidelines.
3. Any modifications to your research must be reviewed and approved before the initiation of work. Modifications must be submitted through the Amendment process.
4. An Annual Permit Renewal is required sixty (60) days prior to the first and second anniversary of the approval date.
5. The Principal Investigator is required to submit a new IBC Permit Registration Form sixty (60) days prior to the expiration of the IBC Permit.
6. While the work conducted is approved at the specified biosafety level (BSL) of containment, the IBC is not responsible for ensuring that space is available.
7. Only personnel who have met all training and occupational health requirements for this protocol and received written approval from the IBC may conduct work listed in the permit.
8. If your project will involve direct work with genetically engineered organisms, please contact the Animal Welfare Assurance Program at http://tech.tamu.edu/animalwelfare if you have not already done so. Any work involving bacteria or human pathogens, please contact the Human Subjects Protection Program at http://tech.tamu.edu/humanresearch.
9. Please forward copies of your campus routing agency coordinator for forwarding to your granting agency, as applicable.

pc: IBC File
B. Standard Procedures for Research Laboratories

1. Signs must be posted on the doors to the laboratories (see example below). The sign must list the PI's Name, contact information, a list of agents used/stored in the lab, entrance and exit requirements. Doors to BL2 laboratories must be self closing and must remain closed at all times. The doors must be locked when the lab is unattended. A template for this signage is available from the TAMHSC Safety Office.

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Figure 3
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2. Lab coats must be worn at all times by everyone working in the BL2 lab. Gloves must be worn when working in the lab with hazardous materials. Prior to leaving the lab, gloves and lab coat MUST be removed and hands washed. NO LAB COATS or GLOVES are to be WORN OUTSIDE THE LAB into public areas.

3. If research samples must be carried outside one lab to another for continued analysis or storage the samples MUST be placed in a secondary container, the outside of the container disinfected and then carried to the next lab with ungloved hands. The secondary container must be able to contain the volume of the material in the event that the primary container fails or spills.

4. Aspirating cultures can create aerosols. HEPA filtered vacuum lines prevent aerosolized microbes from contaminating the vacuum line and possible release to the environment. All vacuum systems must be protected from contamination by use of an in-line HEPA filter. The vacuum flasks MUST be located in the biosafety cabinet, unless specific approval from the Office of Research Compliance and Biosafety authorizing use of a specialized aerosol tight vacuum system has been received.
One method to protect a house vacuum system during aspiration of infectious fluids is shown in Figure 4. The left suction flask (A) is used to collect the contaminated fluids into a suitable decontamination solution; the right flask serves as a fluid overflow collection vessel. An in-line HEPA filter (C) is used to protect the vacuum system (D) from aerosolized microorganisms.

The HEPA or PTFE filter must be replaced at least annually or whenever there is blockage / increased resistance. Several vacuum line protection filters are readily available from major scientific suppliers. Examples of filters available from Fisher Scientific are listed below:

<table>
<thead>
<tr>
<th>Whatman HEPA-Vent Filter</th>
<th>Millipore Millex Vacuum Line Protection and Tank/Bioreactor Venting Filter Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cat. #</td>
<td>Whatman #</td>
</tr>
<tr>
<td>09-744-79</td>
<td>6723-5000</td>
</tr>
</tbody>
</table>

5. Use of Biosafety Cabinets

All work with RG2/BSL2 agents must be performed in a functioning / certified Biosafety Cabinet (BSC) unless specific approval by the IBC is given to the PI. Such approval MUST be specified in the approval letter.
Figure 5
A typical layout for working “clean to dirty” within a Class II BSC. Clean cultures (left) can be inoculated (center); contaminated pipettes can be discarded in the shallow pan and other contaminated materials can be placed in the biohazard bag (right). This arrangement is reversed for left-handed persons.

Perform all procedures to minimize the creation of splashes and/or aerosols.

Every item removed from the BSC MUST be decontaminated prior to removal from the cabinet.

**Waste Containers**  
Waste generated in a Biosafety Cabinet(BSC) **MUST** be collected in appropriate containers placed inside the BSC. These containers must be closed in the BSC, the outside decontaminated and then removed from the BSC and placed in a larger waste container. Small autoclavable bags are available from several vendors. Autoclavable disposal containers are also available for pipettes (see Figure 6 for example). NEVER bring a pipette out of the BSC for disposal unless it is in a secondary container or it has been thoroughly decontaminated with an appropriate disinfectant.

<table>
<thead>
<tr>
<th>Terminal Pipet Keeper Disposal Container, Whitney Products</th>
<th>Bel-Art* Scienceware* Poxygrid* Desk Model Biohazard Bag Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>VWR Cat. #</td>
<td>Whitney Product #</td>
</tr>
<tr>
<td>1214-715</td>
<td>BH2006</td>
</tr>
</tbody>
</table>

Figure 6

6. Laboratory-specific biosafety manual

A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible. This manual shall contain the PI’s IBC Application and Amendments as well as all IBC Approval letters. A template for this manual is available from the TAMHSC Safety Office. **A BSL2 Laboratory Manual Checklist can be found at [http://rcb.tamu.edu/biohazards/forms/inspectinfo/bl-2-manual-checklist](http://rcb.tamu.edu/biohazards/forms/inspectinfo/bl-2-manual-checklist).**
7. Centrifugation

Aerosols can be released during centrifugation even when using sealed tubes. Micro-fractures in tubes can turn into cracks during centrifugation resulting in a loss of containment. Exposure to personnel and contamination of equipment can occur from the resulting spray, splatter or aerosols. This is of greatest concern when centrifuging substances containing microbes, toxins or human material which may be infected with bloodborne pathogens.

**RG2 / BSL2 materials may be centrifuged in the open laboratory only by using sealed rotor heads or centrifuge safety cups** (see Figure 7).

<table>
<thead>
<tr>
<th>Safety Cups</th>
<th>Sealed Rotors</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Safety Cups" /></td>
<td><img src="image2.png" alt="Sealed Rotors" /></td>
</tr>
</tbody>
</table>

**Figure 7**

**NOTE:** The centrifuge rotors or buckets MUST be loaded and unloaded in a functioning / certified biosafety cabinet.

8. Decontamination and Biohazardous Waste Procedures

Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant. The approved disinfectant for your work will be listed in the IBC approved copy of your protocol.

Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport: a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for
transport. b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.

Check your Approved IBC Protocol for the waste treatment method that has been approved by the IBC for the agents you use. As a rule, all liquid waste must be autoclaved unless special permission is given by the IBC for an alternative method.

Autoclaves must be tested regularly with biological indicators. The frequency of these tests will depend on the Biosafety Level of the lab.

9. **All personnel working in a BSL2 lab MUST be compliant in the Occupational Health Program.** Contact the HSC Safety Office with questions.

10. Other Requirements (taken from the *Biosafety in Microbiological and Biomedical Laboratories* [http://www.cdc.gov/od/OHS/biosfty/bmbl5/bmbl5toc.htm](http://www.cdc.gov/od/OHS/biosfty/bmbl5/bmbl5toc.htm))

   a. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
   
   b. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
   
   c. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented.
   
   d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.
   
   e. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Note: the IBC requires that all personnel working in a BSL2 lab attend a training class provided by the TAMU Biological Safety Officer (BSO). Contact the HSC Safety Office for more information or schedule for these classes.
   
   f. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
   
   g. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety safety manual. All such incidents must be reported to the laboratory supervisor and the BSO. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
   
   h. Wear protective eyewear when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.
   
   i. An eyewash station must be readily available.