# TRUDEAU INSTITUTE

March 15, 2006

Mr. Edward H. Hammond
Director
The Sunshine Project
PO Box 4197
Austin, TX 78704

Dr. Mr Hammond

Regarding your fax of March 13, 2006, and your request for minutes from our Biosafety Committee.

Our Institutional Biosafety Committee was formally registered with NIH in January, 2006 and will meet on a quarterly basis. Attached you will find the minutes of that meeting.

I hope this fulfills your request for information and in exchange, I would very much appreciate a copy of your national survey of compliance when it is completed.

Sincerely,

Tina Charbonneau
Biosafety Officer

Trudeau Institute, Inc., 154 Algonquin Avenue, Saranac Lake, NY 12983
*Telephone:* 518-891-3080 *Fax:* 518-891-5126 *Website:* www.trudeauinstitute.org

**Trudeau Institute**
**154 Algonquin Ave**
**Saranac Lake, NY 12983**
**518-891-3080**
**518-891-5126 (fax)**

**TO:** Edward Hammond
512-494-0545 (fax)

**FROM:** Tina Charbonneau, Biosafety Officer

**DATE:** March 16, 2006

**RE:** Request for IBC Minutes

As per your request.

**Number of pages including the cover sheet ( 5 )**

# TRUDEAU INSTITUTE, INC.
# BIOSAFETY COMMITTEE
# MINUTES OF A MEETING HELD FEBRUARY 8, 2006

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:30 p.m. Wednesday, February 8, 2006 in the Founder's Library at Trudeau Institute.

Attendance: Tina Charbonneau, Andrea Cooper (Chairperson) , Peter Sayles, Chip Eaton, Kelly Stanyon, Simon Monard, Ron LaCourse, Cyril Doucet, Brian Waters, Steve Jones, Rick Latt, Tammy Morgan and Mim Tracy (Absent – Steve Smiley)

## New Member Introductions

The new outside members of the committee, Marian Millar-Tracy (Mim) and Tammy Morgan were welcomed. Andrea reviewed the purpose of the committee and how that the main function is to protect staff from potential exposures to infectious agents or biologicals.

## Status of Outstanding Protocols and Amendments

1. Randall protocol for Rotovirus – Troy has received the Committee's recommendations and he will revise accordingly and will re-submit.

2. Haynes Lab amendment for sorting cells from Listeria monocytogenes infected animals. – Amendment discussed at length due to the potential for aerosol exposure to potentially infected cells. Issues for consideration, organism is BSL2 but carries an additional risk for immunocompromised or pregnant staff. Sorter is equipped with negative pressure hood and HEPA filtration. Committee approval was given for sorting with the following stipulation, cells can only be sorted during low activity times in the lab ( after 5pm) and door signage must indicate the presence of the infectious agent.

3. General discussion of other agents that would require the higher biosafety level in the Facs Room include the sorting of BCG, M. avium or T. gondii infected cells. All protocols for sorting of cells from animals infected with these agents will be done after 5pm.

4. Swain Lab protocol for the use of vero cells – though not an infectious agent, the lab was asked to submit a protocol since the origin of the cells are non-human primates. The cells would be used for culturing of reagents for possible infectious (viral) contaminants. The concern was raised that the culturing was going to be done in a "clean" lab, one that is NOT designated for work with infectious agents. The Committee agreed that the fact that potential unknown infectious agents MAY be cultured required the lab to have the appropriate

biosafety designation. Tina will contact the lab and ask that the protocol be clarified, either the current lab will need to be designated as BSL2 or the work can be transferred to a room that already has that designation.

Medical Surveillance Update

There was a general discussion of our medical surveillance program and screening for exposure to MTb. Periodicially employees become aware that an individual has changed PPD status and this gives rise to a generalized concern about containment of the mycobacteria used in the institute. Employee concerns included whether our surveillance program and response to potential exposure were appropriate. Tina has been reviewing the most recent CDC document on "Guidelines for Preventing the Transmission of MTb" and the Institute is indeed following the guildelines. Additionally, Tina reported that she has been able to access the Microbiology Lab at Albany Medical Center for assistance in performing the Quantiferon Gold assay for the diagnosis of latent MTb infection. This assay is specific for exposures to MTb and would provide us with the medical surveillance data for those who recently convert from PPD- to PPD+ and would be useful for staff that have a prior vaccination with BCG. Use of this assay as an adjunct to our medical surveillance will be important as it will help to distinguish "real" exposures from those that may be due to exposure to M. bovis(BCG). Tina will revise the current medical surveillance policy to include this testing and will share this with staff so that they have a clear understanding of the purpose of testing. Additionally, Tina has met with Dr. Cook and Sharon to review the assay and results so that appropriate medical follow-up can take place as necessary.

Status of IBC

Tina reported that Trudeau's IBC is now registered. The first application was denied because of the format of the roster and our community member Dr. Alan Woodard, was considered outside of our "geography. The revised application was submitted with Mim Tracy and this satisfied the requirement for a community member. The committee registered it's thanks to Tina for handling this registration process which took almost 2 years!

Protocols up for Renewal in 2006

Kelly reported that all PI's have been notified via e-mail as to which biosafety protocols are up for renewal this year. They are asked to have them to her by April 1st. All committee members are required to review the re-submitted protocols **prior** to our next quarterly meeting.

## Annual Training

Tina reported annual training was conducted in Oct. and Nov. last year. After reviewing the evaluations she noted that the laboratory staff may need some additional training on Biosafety Levels and risk assessment. She will be creating a specific biosafety training session similar to the one she conducted last spring on the use of biosafety cabinets. Lab staff as well as animal care staff will be encouraged to attend.

## Formation of Institute IRB and Human Studies

Andrea and Tina opened the discussion on the possible need to establish an IRB at Trudeau. Some of the principal investigators are voicing interest in working with human cell samples. The question brought before the committee is do we need an Institute IRB or can the Biosafety Committee review and approve of human sample work. One suggestion might be to conduct the work at another site which would eliminate the need for an IRB. Tina will look at the NIH site for specific information on establishing IRB's and send the committee the link for review. Further discussion will resume at the next quarterly meeting.

Meeting adjourned at 3:50 p.m.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
February 13, 2006

April 20, 2006

Mr. Edward H. Hammond
Director
The Sunshine Project
PO Box 4197
Austin, TX 78704

Dear. Mr Hammond

Regarding your email of 4/19/2006. Enclosed your will find the minutes from our IBC meetings from June, 2003 through the present. It was never my intention to misrepresent the Institute but rather my understanding that the minutes of our IBC meetings prior to registration with NIH were not subject to review by outside agencies.

Please also note, that as you review the minutes you will find that over the past 3 years, the Institute has made changes in how the IBC conducts business. We have implemented the various recommendations from NIH and have included questions related to rDNA work as well as infectious agents in our protocol requests.

This information should now comply with your original request.

Sincerely,

Tina Charbonneau
Biosafety Officer

Ed,
Here is another copy of our minutes from 2003-2006. It will and via registered mail to insure receipt within the next few days.
Tina
5/9/06

TRUDEAU INSTITUTE, INC.
BIOSAFETY COMMITTEE
MINUTES OF A MEETING HELD JUNE 20, 2003

A meeting of the Biosafety Committee of the Trudeau Institute was held at 1:00 p.m. Friday, June 20, 2003 in the Founder's Library at Trudeau Institute.

Attendance: Andrea Cooper (Chair), Tina Charbonneau, Cyril Doucet, Ron Lacourse, Simon Monard, Peter Sayles, Steve Smiley, Brian Waters

1. Safety Office & Coordinator

Mr. Doucet reviewed briefly the appointment of a Safety Coordinator (Tina Charbonneau), whose role, in consultation with the Institute's various safety committees, will be to develop and oversee the Institute's safety-related activities, including support for biosafety, radiation safety and chemical safety in the labs. Mr. Doucet added that this full-time position will also help ensure the Institute's compliance with OSHA regulations throughout its facilities (particularly the documentation and process requirements). Mr. Doucet emphasized that the over-riding goal of the safety office was to assist the principal investigators in their laboratory operations, and not to hinder the productivity of their labs.

Dr. Cooper encouraged committee members to support Tina's efforts and to provide feedback and assistance wherever possible to ensure a smooth and successful implementation of our various safety initiatives.

2. Biosafety Incidents and Investigation Reports

Mr. Doucet recalled that in February an employee who had previously tested negative for TB had tested positive. Subsequently, Dr. Cooper investigated the incident; Ms. Charbonneau interviewed the employee; and a sub-group of this Committee (Cooper, Charbonneau, Doucet, Waters) plus Dr. Robert North met to discuss the incident.

Mr. Doucet circulated a draft report on the incident, which has been revised and is attached as Appendix A. This report was also submitted to Dr. North for comment. The recommendations will be discussed and implemented in due course with the staff involved.

It was further recommended by the Committee that the Institute review and update its TB surveillance program.

Ms. Charbonneau reported on two other recent safety incidents:

(i) A mercury spill in a laboratory, which occurred without injury. The spill was contained and the area cleaned. Also, mercury spill kits were placed in appropriate locations and the staff notified. Subsequently, it was suggested that the Institute consider switching to thermometers that do not contain mercury. Ms. Charbonneau is exploring this option in consultation with Mr. Waters.

(ii) Two members of staff have expressed concern regarding possible radiation leakage in the irradiator room. Ms. Charbonneau investigated this issue, in consultation with Gail Huston (Radiation Safety Officer), and determined that the readings were normal. Staff have been informed and Ms. Charbonneau has reviewed the appropriate radiation safety procedures with them.

3. SIP Safety Guidelines

Ms. Charbonneau reviewed the SIP Safety Guidelines and requested guidance and feedback regarding the student's ability to use infectious agents. Following discussion, it was agreed to include the following guideline: work performed with infectious agents (BSL-2) should be minimized while supervision during those times maximized.

Dr. Cooper added that it is the responsibility of the PI for the project or their designee to ensure that the student follows safety protocols established by the Institute. Ms. Charbonneau reported that she will be meeting with the SIP mentors prior to the arrival of the students and she will also provide a safety overview to the students during their orientation.

Mr. Doucet agreed to review the future of SIP and the safety guidelines with faculty at the upcoming faculty lunch. (A copy of the final version is attached as Appendix B).

4. Hazard Identification Signage for Labs

Ms. Charbonneau reported that the design for hazard identification signage for lab doors has been completed and she displayed sample signs at the meeting. She also reviewed a sample "Room Survey Form" that PIs will be asked to complete. Following discussion, it was agreed to proceed. Mr. Doucet agreed to review the matter with faculty at the lunch on June 25th.

5. Guidelines on the Use of BL-2 Pathogens

Dr. Cooper reported on several recent requests for approval for use of biological agents from Dr. Lund. These requests raised the issue regarding the appropriate procedures for manipulation of BL2 infected animal tissue on the bench. She added that there appears to be a lot of scope for interpretation in the CDC guidelines/recommendations. She asked for comments. Following discussion, the committee agreed that the PIs must adhere to the CDC guidelines and that it is the PI's responsibility to ensure that pathogens are handled using appropriate precautions. It was also agreed that the Biosafety Committee should encourage the PIs to use the highest level of biosafety practices suggested by the CDC for the specific pathogen whenever practical.

Dr. Smiley suggested changes to the approval form to reflect the committee's discussion, and with the agreement of the committee, Dr. Smiley was asked to implement these changes:

(1) Under sections 4 and 5 (in vivo and in vivo use of the agent, respectively) the following text is proposed: It is the Principal Investigator's responsibility to ensure that the pathogen is handled using appropriate biosafety precautions. Minimally, Principal Investigators must adhere to the guidelines provided by the CDC/NIH in the book

entitled "Biosafety in Microbiological and Biomedical Laboratories". The entire book is accessible online at: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm and the specific biosafety practices for levels 1-4 can be found at: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s3.htm

(2) Under section 6 (signatures), the following line is proposed for the PI's section: that any use of this agent will be conducted using procedures and facilities consistent with the guidelines established by CDC/NIH for the biosafety levels indicated above.

6. Guidelines Regarding FACS Analysis of Unfixed Samples

Dr. Cooper and Mr. Monard reviewed the background regarding FACS analysis of unfixed samples and the various suggestions regarding the procedures to be adopted. Following discussion, it was agreed that gloves and lab coats would be mandatory within the FACS facility. Masks are not mandatory. It was further noted that this matter is to be discussed at a special meeting of the FACS Core scheduled for June 24th.

7. Outstanding Requests for Approval

Dr. Cooper reported that 5 proposals were received from Dr. Lund and there were two concerns requiring clarification from the committee:

(i) Dr. Lund has suggested the use of a mask in the FACS facility while analyzing Streptococcus pneumoniae. Following discussion, the committee agreed that there was no compelling reason or hazard which would necessitate such a precaution and the mask need not be worn.

(ii) Dr. Lund will be harvesting and disrupting BL-2 infected tissues on the bench. Following further discussion, and in keeping with the discussion of this issue under Item 5 of the agenda, Dr. Cooper agreed to draft the committee's comments to Dr. Lund. The subsequent wording, approved by the committee, was as follows: "The performance of these procedures outside of a Class II containment hood is covered by the CDC/NIH guidelines that are used as the industry standard. The guidelines provide for the discretion of the PI in deciding which activities have a low risk of aerosol generation and also whether despite a risk of aerosol a specific activity can be performed following BL-2 precautions on the bench within the PI's laboratory. If you feel that there is no aerosol risk and/or that your staff are conscientious in wearing the required BL-2 PPE for that pathogen then you are within the CDC guidelines to perform these activities on the bench top. The committee would suggest that any procedure currently cited as being performed on the bench top but about which you have concerns should be moved to a Class II biosafety cabinet and the specific approval request be resubmitted."

8. Other Biosafety Related Items

(a) Controlled Substances

Ms. Charbonneau reported that modifications are underway to bring the lab areas that use controlled substances into complete compliance with the applicable regulations.

(b) Control of Syringes and Needles
Mr. Doucet reported that the handling of syringes and needles within the Institute may not currently be in compliance with certain parts of the regulations. Use of syringes and needles may need to be inventoried and controlled in a manner similar to controlled substances (drugs). Tina Charbonneau is conducting research into the matter and exploring the policies within other similar organizations. Several suggested procedures were discussed. The committee agreed that the Institute should determine what is required and to advise and assist PIs regarding appropriate policies and procedures.

(c) Protective Clothing and Footwear
Mandatory use of personal protective equipment where appropriate or necessary is stipulated in the employee handbook. Ms. Charbonneau expressed concern that the use of inappropriate footwear is tolerated in some labs (because of the high temperatures experienced at times in these labs). The committee reconfirmed its support for the policy that open-toed shoes should not be worn in laboratories or other designated areas requiring personal protective equipment.

The meeting adjourned at 4:00 p.m.

Prepared by Cyril Doucet and
Submitted to Andrea Cooper, Chairperson
of the Committee, for approval

TRUDEAU INSTITUTE, INC.
BIOSAFETY COMMITTEE
MINUTES OF A MEETING HELD OCTOBER 20, 2003

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:00 p.m. Monday, October 20, 2003 in the Kirstein Conference Room at Trudeau Institute.

Attendance: Andrea Cooper (Chair), Tina Charbonneau, Cyril Doucet, Peter Sayles, Steve Smiley, Brian Waters (Absent members Marcy Blackman, Chip Eaton, Ron Lacourse and Simon Monard)

1. Biosafety Committee Members

After discussions at the management meeting, it was decided that post docs would serve on the safety committees. Assuming that we will be adding a post doc to the Biosafety committee, Marcy Blackman suggested she step down. Marcy will be replaced in about one month with a post doc. The Committee felt this was an excellent idea for disseminating information throughout the organization.

2. Outstanding Biosafety Protocols for Approval and /or Discussion

There were no outstanding protocols. The Committee discussed and approved of handling the Infectious Agents Approval Request Form electronically. Once the protocol is approved, then a hard copy with appropriate signatures will be submitted. A few additions were made to the form (see attached).

The addition of rDNA will be on hold until we can better define it.

3. Use of Infectious Agents with Radioisotopes

The Committee discussed the use of Tritium and infectious agents in room 201. As per the attached revised approval form the following question was added to include assays requiring radioisotopes:
"Will the agent or tissues from mice infected by the agent be used with any radioactive materials? Tina will send out a memo to Scientific Staff that states this change to the protocol. She will request that staff using or intending to use radioactive and infectious agents together submit their protocols to her.

4. BSL Cabinets vs Fume Hoods

Brian discussed the various Safety Cabinets and Fume Hoods in use at the Institute. He explained that the Fume Hoods draw air out of the containment area and exhaust out with no filtration. The exhaust goes out to the roof. Biosafety Cabinets use a hepa filter to refilter the exhaust . There are different classes of Biosafety Cabinets and Trudeau has all types. It is understood that individuals are using fume hoods without a hepa filter in place of a Biosafety Cabinet. Fran Lund was given approval by the Committee to use this type of hood on a temporary basis. She has made a request to renovate her work space, including the addition of a BSC. Cyril will check into this.

Also, signage will be placed on each hood explaining the type. We will also be looking at new training videos for Biosafety Cabinets.

5. "Grandfathered" Pathogens and Biosafety Protocols

The committee discussed the issue of pathogens being used without protocols (Grandfathered). The committee decided that this should no longer be accepted practice. Once a new policy is

written, Cyril and Andrea will speak with the PI's about the change. This will streamline the process and protect the Institute. The Committee decided that it would be perfectly acceptable for the PI's to copy Protocols already submitted for the same pathogen. Cyril and Andrea will develop a memo to be shared with the PI's explaining the change in policy. Tina will follow up with the PI's on which agents are grandfathered and will assist as necessary in the submission of the protocols.

6. Vaccinia Issues

Tina discussed Woody's work with Vaccinia. He does not let anyone who has not been vaccinated work in his lab. His protocol states that only vaccinated individuals can go in his labs. The issue now is one of documentation and "right to know". The Committee agreed that it is the PI's responsibility to know the risks for anyone getting the vaccine (born after 1972) and make sure the employee is provided with information regarding the use of the vaccine and its risks. Action item will be to provide literature that Tina has gathered on Vaccine.

7. Employee Surveillance Issues

The committee discussed the need for an active TB Surveillance program. The current program has lapsed due to fluctuation in the Medical Services Program at the Institute.

The committee decided that Tina would, with the assistance of Amy, determine the relative risk of each staff member with regard to TB exposure. Those at low risk would be screened yearly. Those at higher risk would be more actively screened, possibly at six month intervals. The full surveillance program will be implemented once Cyril has re-organized the Institutes Medical Services Program.

8. Other Issues

Brian discussed the use of UV germicidal lighting. We need to come out with an Institute wide policy for the use of UV Germicidal Lighting (ie.- where it's used and when it's used). Biosafety cabinet manufacturers are reticent to use them for issues with eye and skin safety. The Institute has had several cases of skin injury due to UV use. The lights used at the Institute need to be tested for efficiency and we need to evaluate their effectiveness against the agents used at Trudeau. Jeremy has an instrument that is used for testing the UV lights. Steve also suggested the use of "test strips" to check on the efficiency of the UV sterilization. Tina will check on these and obtain as necessary.

Meeting adjourned at 3:40 p.m. Next meeting will be held in January 2004.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
October 22, 2003

TRUDEAU INSTITUTE,INC.
BIOSAFETY COMMITTEE
MINUTES OF A MEETING HELD JANUARY 14, 2004

A meeting of the Biosafety Committee of the Trudeau Institute was held at 3:00 p.m. Wednesday, January 14, 2004 in the Kirstein Conference Room at the Trudeau Institute.

Attendance: Andrea Cooper (Chair), Tina Charbonneau, Cyril Doucet, Peter Sayes, Steve Smiley, Chip Eaton, Simon Monard, Kelly Stanyon, Roslyn Kemp (Absent members Ron LaCourse and Brian Waters)

1. New Member

Roslyn Kemp joins the Biosafety Committee as a representative for the post docs at Trudeau. We all welcomed Roslyn to the committee.

2. Status of the "Grandfathered" Agents

Cyril spoke about this issue at the last Faculty meeting. Memos will be put in all Faculty mailboxes asking them to verify the use or discontinued use of each "grandfathered" pathogen. If agent is still in use a protocol must be submitted. If agent is no longer in use, but the PI is keeping the agent, the committee should be notified of this status. If the agent is no longer used and is being disposed, committee should be notified of disposal.

3. Protocol and Amendment Procedures

Andrea sent an e-mail reminding all Faculty of the revised form and procedures. In reference to amendments, it was discussed that a formal e-mail will be sent to the committee, at which time they will decide if a new form needs to be submitted. Adding individuals to the protocol will not require a new form, but the individuals will have to sign the original document stored in the Library after reading it through . An annual review of approved protocols was also discussed and the committee agreed protocols would be reviewed every 3 years. The Safety Office will also keep track of room sign changes through review of these applications and amendments.

4. Medical Surveillance Program, Update

Tina reported that the program is in place. Beginning next week, all employees will attend a quarterly clinic that falls within their month of hire. Category 3 individuals who work with TB will be screened twice a year, including filling out a medical evaluation form. Chest x-rays and PPD tests are offered to all employees annually at their quarterly clinic.

Individuals working with vaccinia will get a packet of "right to know" information on the hazards associated with working with vaccinia viruses. For the level used here at the Institute, no vaccination or pre-vaccination is recommended. A declination form is included in the packet.

The committee also discussed the possibility of Dr. Cook joining the committee as a consultant. He is very interested in keeping up to date with the infectious agents used here at the Institute.

5. Training Update

Tina commented on the need to re-vamp the current requirements for new employee's training/orientation. She asked the Committee for their support and suggestions. Recommendations by the Committee members included:

- All videos seen by new employees will be reviewed.

- Basic safety orientation will happen during the employees first week on the job. The Safety Officer would then meet with the employee to go over any questions they may have in reference to the videos.

- After the basic safety orientation, a more extensive safety review would take place geared towards the individuals specific job

This process is in the planning stages.

6. "Buddy System" in BSL-3 Areas

We do not have a formal system in place at the institute. Question to be addressed is what is done in off-hours? An informal response might be to make sure someone knows where you are at all times when in the lab area. Andrea Cooper's Lab follows this practice.

Meeting adjourned at 4:10 p.m. Next meeting to be held in April 2004.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
January 19, 2004

TRUDEAU INSTITUTE, INC.
BIOSAFETY COMMITTEE
MINUTES OF A MEETING HELD May 5, 2004

A meeting of the Biosafety Committee of the Trudeau Institute was held at 3:00 p.m. Wednesday, May 5, 2004 in the Kirstein Conference Room at Trudeau Institute.

Attendance: Andrea Cooper (Chair), Tina Charbonneau, Cyril Doucet, Peter Sayles, Steve Smiley, Brian Waters, Chip Eaton, Simon Monard, Roslyn Kemp and Kelly Stanyon (Absent – Ron LaCourse)

Status of Outstanding Protocols and Amendments

The Committee reviewed procedures for personnel additions, procedural changes and amendments to biosafety protocols. All were in agreement that personnel changes/additions did not need to go to the full committee. Tina will review all other amendments and either make a decision herself or, if the changes are substantial, submit the amendment to the full committee for review.

Biosafety in Relation to the Plethysmograph

The first step in relation to biosafety and the use of the Plethysmograph is to determine the efficacy of the machine. The committee (Andrea) will contact Technical Services to determine whether the machine is working and also how the machine will be used. If the machine is working and we receive a request to approve use of infected mice within the machine, then there are several questions that need to be answered:

1. What is the potential for animals to get infected in the machine?
2. To what extent can UV exposure be used to disinfect the holding containers?
3. To what extent is the prospective pathogen shed from the animals being tested?

The committee will need to develop a cleaning protocol in conjunction with technical services and the PI requesting use of the machine.

Employee Incident and the use of BCG in the Infected Procedure Room

It was reported that an employee tested positive in their PPD test. The employee does not work with BCG. It is not possible to determine how or where this exposure took place (whether at work or outside the Institute). However, Tina has investigated the potential for exposure at work by interviewing the employee and highlighted two possible situations where exposure could theoretically occur. Firstly, the employee has been in the infected procedure room when BCG was being handled. Secondly, it is possible that the employee was in the FACS facility when unfixed BCG samples were being screened (unknown). Further action is dependent upon the results of the May PPD screening clinic. If there are no other positive PPD reactions, no further action will be taken; if there are more positive reactions then a more detailed investigation will take place.

PI's using BCG are D. Dalton, R. North, A. Cooper and P. Sayles. The committee chair will discuss with these PI's possible changes to the use of BCG in the institute, specifically precluding the presence of other investigators within the rooms when mice are being infected with BCG and when unfixed BCG samples are being examined in the FACS facility. Tina will generate signs that indicate BCG is in use and that entry to joint facilities is restricted during BCG use. In order to limit the impact of this limited use policy it is requested that users of BCG perform injections and unfixed FACS analysis after normal working hours.

All decisions regarding use of the procedure and animal rooms with regard to BCG will be communicated to the Animal committee. Tina will make signs to post on doors when room is in use.

SIP Projects

Six SIP projects were submitted for review by the Committee and all were approved. Tina will be meeting with the responsible staff members to review safety guidelines (PPE) and protocols.

Other

As a result of Tina's attendance at the Biosafety class last week the following issues are being investigated:

Recombinant DNA – are we doing work the rDNA that requires review by a biosafety committee? If so, do we need to be registered with NIH? This needs careful review of the regulations. Tina was unable to obtain a clear answer from NIH personnel. Tina and Cyril will investigate further.

If we do need to be registered then the IBC requires two more members. Dr. Cook can be one and the second could be a researcher from another institution.

Review the TB protocols – committee would like to see uniform protocols throughout the Institute. Andrea and Tina agreed to explore the OSHA and CDC requirements in this area.

Meeting adjourned at 4:15 p.m. Next meeting will be held in July 2004.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
May 6, 2004

TRUDEAU INSTITUTE, INC.
BIOSAFETY COMMITTEE
MINUTES OF A MEETING HELD July 28, 2004

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:00 p.m. Wednesday, July 28, 2004 in the Founder's Library at Trudeau Institute.

Attendance: Andrea Cooper (Chair), Tina Charbonneau, Ron LaCourse, Peter Sayles, Steve Smiley, Brian Waters, Chip Eaton, Roslyn Kemp and Kelly Stanyon (Absent – Cyril Doucet, Simon Monard)

Status of Outstanding Protocols and Amendments

The Committee agreed that there was no need for PI's to go to the full committee for dual use of pathogens already approved. For example the use of sendai and influenza. Both are approved for use in the Woodland and therefore, he could use both agents in a single study protocol. The only outstanding protocol was P. Sayle's request to use Influenza virus strain A/PR/8/34.

Follow-Up on Plethysmograph Use

Andrea reported that nothing has been done about the use of the plethysmograph since no one has requested to use it. Since the plethysmograph will be used with pathogens already approved by the committee, requestor will update current protocol by submitting an amendment.

Additional Precautions for Use of BCG Follow-Up

As per discussion in the previous meeting, Andrea reported that she had contacted all PI's who are currently using BCG and put forward suggestions for the use of additional precautions when infecting their mice or performing Facs analysis on unfixed cells. Specifically, that injections are to be performed in the procedure rooms when other staff is not present and that joint areas such as the Facs Room be used "after hours" if cells are not fixed. Upon hearing that there were no serious concerns from the PI's using this pathogen the Committee discussed and approved the recommendation that staff who are working with BCG wear N95 respirators. Additionally, it was decided that staff who are working with BCG sign up for the use of both hoods within the Infected Procedure Room. This will help to minimize potential exposure of lab personnel who do not work with BCG. Additionally, a specific sign will be generated that will be posted on the procedure room door that restricts entry during protocols with BCG. The Committee was reminded that when Dyana's protocol for facs analysis of unfixed BCG infected cells was approved, she was restricted to performing the analysis during "off hours" i.e. after 5pm. The Committee now recommends this for all protocols approved for BCG in which there is a requirement to perform facs analysis on unfixed cells. As with the procedure room, a specific sign will be generated for use in the Facs room that cautions staff of the use of BCG. Andrea will share these revised recommendations with the appropriate PI's.

Medical Surveillance Update

Tina reported two more surveillance programs were conducted and no additional positive PPD tests were reported. The Committee agreed that the use of a new whole blood test, not yet approved by the FDA, is worth further research. This test might be used on staff that have been exposed to TB.

Institutional Biosafety Policy

Tina provided the committee with a draft copy of a proposed Institutional Biosafety Policy. The purpose of the policy was to clearly define the role of the Biosafety Committee and to assist Institute staff by providing a consistent document that could be used for grant submissions. The draft was modeled after Harvard's policy and there were several areas that are not in keeping with how we do business here. Therefore, the Committee was asked to review the draft and provide feedback to Tina. She will compile the changes and re-submit to the Committee for approval before it is submitted for Administrative approval.

Respiratory Protection Program

Tina reported on a 1999 regulation from OSHA that indicates a Respiratory Protection Program is necessary when employees are required to wear respiratory protection (N95 masks) as part of their job. At least 30% of the staff at the institute are required to wear N95 or higher respirators. This program requires a medical evaluation, training and fit testing. Tina reported that she has been working with Dr. Cook on the medical evaluation and that training and fit testing will follow once his medical approval has been given. Tina further stated that staff who are not required to wear the N95 masks but request to do so, will be enrolled voluntarily into the program.

Risk Assessment in the BSL-3 and ABSL-3 Facilities

Tina is conducting risk assessments in all areas working with TB. The risk assessments include looking at engineering, work areas and the gowning/de-gowning areas. The assessments will be shared with the directors of each facility. It will be up to each director to act on any recommendations made by the Safety Officer.

Other

Rosyln Kemp announced her departure from the committee and it was suggested that Stephen Jones take her place. The Committee Chair will notify the committee when a replacement has been found.

The committee discussed whether Tech Services be included on the PI's protocols. The committee agreed that Tech Service staff should inquire whether any procedure they are asked to perform involves the use of a pathogen and that if the answer is yes then they should read the protocols and sign off on them as they work with each pathogen. Tina will inform Jody of this new procedure.

A concern was brought up about the decibel level of the biosafety hoods and the frequency of certification. Brian did not think that tests had been done on any of the BSC's with regards to noise levels, but they are checked annually and re-certified. HEPA filters are changed approximately every 5 years. The committee agreed that the noise level was a topic for the Safety committee.

Meeting adjourned at 3:07 p.m.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
July 29, 2004

TRUDEAU INSTITUTE, INC.
BIOSAFETY COMMITTEE
MINUTES OF A MEETING HELD October 25, 2004

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:30 p.m. Tuesday, October 25, 2004 in the Founder's Library at Trudeau Institute.

Attendance: Andrea Cooper (Chair), Tina Charbonneau, Ron LaCourse, Peter Sayles, Steve Smiley, Brian Waters, Chip Eaton, Steve Jones, Kelly Stanyon, Simon Monard, and Dr. George Lathrop (Absent – Cyril Doucet)

Welcome New Members

The group welcomed Steve Jones to the Committee who is taking the place of Roslyn Kemp who has left Trudeau Institute. Also present was Dr. George Lathrop, Trudeau Institute's Director of Animal Facilities who will be a new member.

Status of Outstanding Protocols/Amendments

Dyana Dalton's amendment to protocol B-05-02 requesting sorting of cells from BCG-infected mice was approved after a lengthy discussion by the committee with the caveat that sorting will be done after 5:00 p.m. or before 7:00 a.m.

In connection with Dyana's protocol, Simon explained how the enclosure around the sorter should contain bio-aerosols. He further discussed that the unit underwent an initial calibration using a live agent and was found adequate to contain bio-aerosols.

He further stated that he would periodically test the flow rate with an anonmeter. Suggestions were made by the committee that Simon maintains a log to indicate that flow rate is checked periodically and falls within acceptable limits.

FACS Protocol Update

The Committee reviewed and approved the revised FACS Protocol for unfixed infectious agents. Protocol will be distributed to all Scientific staff and will be revisited in another six months as to it's effectiveness.

Institutional Biosafety Policy Draft

Tina reported that only 1 comment came in on the draft. This draft is in a holding pattern until the committee makes a decision with regards to the NIH Guidelines.

Update on Medical Surveillance Program

Tina reported one screening conducted since our last meeting. Dr. Lathrop suggested reviewing and re-evaluating the medical surveillance program. Tina also mentioned that she will be focusing on immunocompromised issues in the upcoming re-training.

Risk Assessment for BSL3 Facilities

It was reported that the assessments have been completed and shared with the PIs. Some suggestions have been implemented. We are awaiting discussion.

rDNA Guidelines

Continuing discussions from our last meeting, Tina was able to provide information from NIH sources that would indicate that Trudeau would be required to follow the NIH guidelines for rDNA. In doing so, we would have to register our Biosafety Committee (BSC) with NIH.

The implication for registering would mean that our meeting minutes, as well as any research activities would become a matter of public knowledge per the Freedom of Information Act (FOIA).

In a document that Tina received from NIH, the recommendations was to have PI's review section 3 of the guidelines and determine whether their research met the exempt or non-exempt status.

With appropriate sections and other reference information, further action on this item will be pending outcome of survey and discussion at the next faculty luncheon.

Update on Biosafety Meetings in San Antonio

Tina attended a very informative Advance Risk Assessment class which will help her in classifying the work we do. She also attended a shipping class. Brian sat in on the BSL3 sections.

Other

Steve brought up the possibility of staff carrying medical cards that would identify the pathogens each worked with in the case of a medical emergency.

Meeting adjourned at 4:00 p.m.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
October 27, 2004

TRUDEAU INSTITUTE, INC.
BIOSAFETY COMMITTEE
MINUTES OF A MEETING HELD January 26, 2005

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:30 p.m. Wednesday, January 26, 2005 in the Founder's Library at Trudeau Institute.

Attendance: Tina Charbonneau, , Peter Sayles, Steve Smiley, Brian Waters, Chip Eaton, , Kelly Stanyon, Simon Monard, and Dr. George Lathrop (Absent – Cyril Doucet, Andrea Cooper (Chair), Ron LaCourse, Steve Jones)

Status of Outstanding Protocols/Amendments

Steve Smiley's BCG protocol was approved by the committee. In relation to the discussion the committee had on Steve's work, it was suggested that basic guidelines for working in a BL1, BL2 and BL3 lab be put on the Intranet, along with the new FACS protocol created by Simon. Having these documents on the Intranet will assist the PI's in completing the protocol forms.

Annual Training Update

Tina received a few comments on lab signage. Some felt it was not good enough and wanted something more 'official'. The committee will welcome any suggestions.

Medical Surveillance Program

Tina met with Dr. Cook and his nurse Sharon concerning emergency response to infectious agents. Dr. Cook is very open to assistance from others. Dr. Weiner, a Trudeau Board member, has agreed to help Tina write a fact sheet for each organism we work with at Trudeau. This fact sheet will include how one might get infected and the appropriate medical intervention. Dr. Cook will have this booklet in his office, along with the emergency room at AMC and all labs.

Protocol Renewals

The new Biosafety protocol form was discussed and approved by the committee. Tina will have Sandy post it to the Biosafety Intranet page. Kelly will be sending out e-mails to the PI's whose protocols are due for renewal (2002 approved protocols). The e-mail will include the new form and will ask that the forms be returned no later than 4/1/05. We will also ask the PI to let us know if they do not plan on renewing their protocol. The committee will then review all of the renewals and be prepared to approve at our next quarterly meeting. Even if the PI has no changes to their protocol they will still need to complete the forms especially since most of the protocols approved in 2002 were on either an old form or no form at all (memo format).

Registering IBC

Steve reported that he presented the faculty with the rules for registering an IBC. It was concluded that since we use transgenic mice at Trudeau we do need to register our IBC. There was agreement by the committee that we will initiate the process to register our IBC with NIH. The following action items were discussed and agreed upon:

- The format for the IBC will be reviewed. Tina will revise the guidelines that were submitted to the group last fall to incorporate the suggestion of a sub-committee that will handle strictly biosafety practices with the IBC handling the approval of protocols. This may mean separate meetings and minutes. The IBC meeting would be scheduled to coincide with the annual review and approval of protocol renewals.
- Biosketches will be submitted as required by NIH for registering our IBC. Tina will look into the format for submitting.
- We need to identify two outside members. Suggestions included Tammy Morgan, a Biology teacher in the Lake Placid School system, Dr. Alan Woodard, an environmental program specialist with DEC, Mim Tracy, and infection control nurse at AMC and Dr. Lynda Zaunbrecher, retired MD from the Public Health Corps. We will ask Andrea to discuss these suggestions with both Suzy and Cyril for approval. Further action will be pending that decision.
- It was also noted that we do not have anyone at Trudeau that is experienced in rDNA work and it was suggested that we possibly look for an outside member who could fill this position.

Meeting adjourned at 3:35 p.m.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
January 28, 2005

## Quarterly Biosafety Committee Meeting

## 2nd Quarter Meeting May 11, 2005 2:30pm Founders Library

**Attendance:** Andrea Cooper (Chair), Tina Charbonneau, Cyril Doucet, Brian Waters, Chip Eaton, Steve Jones, Simon Monard, Ron LaCourse and Peter Sayles. Absent: Steve Smiley and Kelly Stanyon.

Prior to the meeting, the committee received the most recent draft of the Institute's Biosafety Policy. Andrea opened the floor for discussion. Though Steve Smiley was absent he had sent comments to Tina and he indicated that the policy needed to be more clear as to why there was now a sub-commmittee to handle biosafety policies. Chip also felt that this was unclear. Andrea and Tina explained the purpose of an IBC is to review the use of infectious agents or r-DNA within the Institute. The composition of an IBC is clearly outlined by NIH and therefore it's function is of most concern to NIH. That explains the requirement for submission of meeting minutes. The Policies Sub-committee is not required by NIH and therefore has no specific requirements for members or minutes. Peter suggested that we add a statement to this effect to the policy. Additionally, there was discussion on the need to review the policy on an annual basis. The committee voted to accept the policy with these additions and to have Cyril and Andrea present it at the monthly Faculty meeting on May 25th.

Twelve biosafety protocols were up for renewal. As per our policy, protocols are approved for a period of 3 years. It was decided at the last meeting that requests for renewal would happen each year in April. This would facilitate submission by the Principal Investigators and review by the committee. All protocols were submitted to the Safety Office in a timely fashion. Tina gave them an initial review and then they were submitted to the Committee as a group for review prior to this meeting. When Andrea asked for comments, it appeared that members had not reviewed them as requested. Therefore, each protocol was presented briefly for discussion and approval. The discussion included the use of the appropriate biosafety level for the organism and disinfection protocols. There was also discussion on the implications for analyzing un-fixed samples on the flow cytometer and the use of shared facilities i.e cryostat in the histology lab. One common practice used by the PI's when submitting the protocols is to state "BSL2 practices will be used". The committee members felt that this was a very general statement and that PI's needed to be more explicit in how they interpreted the BSL2 practices. Additionally, there is a general use of "standard PPE" where PI's indicate gowns, gloves and masks but Tina questioned whether this was really the cases in some of the labs as she noted during her audits that these practices were not always followed. Each protocol was approved separately or a request was made for further clarification of specific issues. Andrea will contact the PI's, who submitted protocols that did not receive immediate approval, to indicate the areas for clarification. Once these have been addressed it is anticipated that they will also receive approval. Kelly will generate the new #IAA numbers and will send approval letters to the PI's. The action taken on each is summarized as follows:

| Biosafety Level | Agent | Strain/Isolate | Investigator | IAA# | Action |
|---|---|---|---|---|---|
| BSL2 | Murine gamma herpes | MHV-68 mutants, recombinant vaccinia | Blackman | B-12-02 | approved 05/11/05 |
| BSL2 | Streptococcus pneumoniae | Type 4 | Blackman | B-13-02 | approved 05/11/05 |
| BSL2 | Salmonella typhmurium | C5R | Blackman | B-14-02 | approved 05/11/05 |
| BSL2 | Influenza | HKx31 | Dalton | B-17-02 | combined w/ B-18-02 |
| BSL2 | M. bovis (BCG) | rBCG:fluNP, Pasteur TM1011 | Dalton | B-18-02 | needs clarification |
| BSL2 | M. bovis (BCG) | BCG | Dalton | B-5-02 | needs clarification |
| BSL2 | Influenza | PR8 | Haynes | B-4-02 | needs clarification |
| BSL2 | S. typhimurium | CR5 | Lund | B-1-02 | approved 05/11/05 |
| BSL2 | Shistosoma mansoni | NMRI | Lund | B-2-02 | approved 05/11/05 |
| BSL2 | Human derived cells | | Lund | B-3-02 | chose not to renew |
| BSL2 | S. typhimurium | LT2aroAA544:Tn10. AroA- (attenuated) | Lund | B-7-02 | combined w/ B-1-02 |
| BSL2 | retroviral vector | pBMN-IRES-EGFP, p-MX-IRES-EGFP | Randall | B-16-02 | approved 05/11/05 |
| BSL2 | T. gondii | | Sayles | B-10-02 | approved 05/11/05 |
| BSL1 | H. polygyrus | | Sayles | B-11-02 | approved 05/11/05 |
| BSL2 | Human samples | | Sayles | B-6-02 | chose not to renew |
| BSL2 | S. typhimurium | CR5 | Smiley | B-15-02 | approved 05/11/05 |

Tina provided an update on the protocol for shipping dangerous (infectious) goods. She has been working with Sandy to provide a request form on the Intranet that is very similar to the forms used for requesting animals. There are "pull down" boxes for PI's, approved agents and grants. Tina has also categorized the agents as to their proper designation for shipping. Hopefully this system will ease the problems of shipping out these reagents. Peter asked about shipping animals as this recently come up when he wanted to ship out BCG vaccinated mice. Chip stated that in the past PI's made all of the arrangements but that now, Animal Services would take the lead to insure that all appropriate documents for shipping and handling the mice are completed.

Andrea had no new information to report with regards to registering our IBC with NIH. We were waiting for the Biosafety Policy to be approved before going any further. Once we have the endorsement from the Faculty and Suzy, steps will be taken to find outside members and begin the process.

Tina reported that thus far, Dr. Weiner, our infectious disease consultant and a member of our board, has reviewed 6 separate emergency response sheets. These facts sheets would be used by Dr. Cook or the ER staff at AMC in the event of an occupational exposure to an infectious agent. This would help to insure that staff are treated promptly and appropriately.

A new protocol was submitted from Dr. Larry Johnson for studies involving Cryptococcus neoformans. This organism was previously used at the Institute but was never submitted formally for review. Dr. Karen Aguirre, an adjunt faculty member will be working with the agent during the summer. The protocol was approved by the Committee. Tina also indicated that an amendment to Dr. Woodland's influenza protocol had been submitted. Typically amendments do not require committee approval unless they included major changes to the approved protocol. This amendment involved the use of a hazardous chemical, 2,3,7,8 tetrachlorodibenzodioxin (TCDD). This now made the amendment subject to approval by the Chemical Safety Committee rather than the Biosafety group. Tina further explained that the Chemical Committee discussed the use and disposal of TCDD at length and approved the amendment with very specific recommendations for training staff and handling the waste. There was no further discussion of this by the Committee.

All of the SIP proposals were approved of as written.

Tina reported on the results of her annual lab audits. This year the audits were more detailed and included specific questions on biosafety, chemical and radiation safety. For this committee, Tina reported on her biosafety concerns. Throughout the Institute, there seems to be a general lack of knowledge on the part of the technical staff as to the appropriate use of biological safety cabinets (BSC). Tina found many of the cabinets overly crowded with lab supplies, such that the back grill work was completely blocked. Staff did not seem to understand the significance of this and how it affects the overall functioning of the hood. There are also some labs that are using disinfectants improperly i.e. pipet buckets of 5% bleach that have been sitting for days to weeks without being changed. Her findings precipitated a discussion by the committee members with regards to standard BSL 2 practices. This term is used frequently in the biosafety protocols but it appears that staff do not know what these practices may be. Tina also noted that the Lund/Randall Labs continued to process tissue ( grinding) in their fume hood rather than in the BSC. The lab had received provisional approval to follow this protocol but it was expected that as soon as the BSC's were installed in the lab this practice would cease. Andrea will follow up with Fran on this issue. Tina was encouraged to report her findings to the PI's and to indicate areas where corrective action would be appropriate. She should also let the PI's know that the Biosafety Committee supports this action.

Lastly, based upon the audits, Tina suggested that she hold a general training session for staff that would include the video "Working safely in a BSC' and a discussion on good lab practices. The Committee approved and encouraged this program.

The meeting was adjourned at 4:30pm.

Submitted 5/11/05
Tina Charbonneau (acting secretary in Kelly's absence)

# TRUDEAU INSTITUTE, INC.
# BIOSAFETY COMMITTEE
# MINUTES OF A MEETING HELD July 27, 2005

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:30 p.m. Wednesday, July 27, 2005 in the Founder's Library at Trudeau Institute.

Attendance: Tina Charbonneau, Andrea Cooper , Peter Sayles, Steve Smiley, Kelly Stanyon, Simon Monard, Ron LaCourse, and Steve Jones (Absent - Cyril Doucet, Brian Waters and Chip Eaton)

Introduction: Andrea stated that Dr. Richard Latt, our veterinarian, would now be a member of this committee but he was not able to attend this session.

Status of Outstanding Protocols

The Committee is still awaiting Dyana Dalton's revised renewals. Andrea will send her an e-mail with a deadline for submission. Andrea also mentioned that a new centrifuge with an aerosol containment has been approved for purchase per Dr. Dalton's request.

Medical Surveillance Program

Tina reported that the semi-annual TB clinic was held last week and the 3rd quarter clinic will take place next week. Tina has been in touch with the company, Celestis, that manufacturers the Quantiferon assay for TB testing. The assay will help to determine the difference between a true exposure to Mycobacterium tuberculosis versus atypical mycobacteria. There is a lab in New Jersey (UMDNJ) which is working to get licensed to offer the test . One drawback in the FDA approval for this assay system is the requirement for the analysis to be done on freshly drawn wholeblood samples. There is another laboratory in St. Johnsbury, Vt. that is also in the process of obtaining a license to offer the test. This may be a better alternative. The Institute has 10 to 15 staff members that we would like to screen using this test. As a committee we recommend that this test become an integral part of the medical surveillance system and that it be used primarily when a change in PPD status for a staff member is observed.

Lab Audits & Training

Tina reported that the Safe Use of Biosafety Cabinet training went O.K. There was poor attendance by the two labs, that were cited for unsafe practices during the audits. Tina will monitor these labs and take additional action if deemed necessary. The committee agreed that if correct practices are not followed the Safety officer and the Biosafety committee should recommend disciplinary action by the administration. Tina has used the following process for communicating to staff about failure to follow safety practices:

1. Verbal warning
2. e-mail to staff member
3. e-mail to staff member and PI

The committee suggested that if a fourth warning/citation becomes necessary, Cyril , Amy and the Biosafety Committee should be copied as well.

Status of Biosafety Policy and Registering IBC

The committee had discussed the draft policy at our last meeting then Andrea presented

it to the faculty. Fran voiced her concern about the rDNA statement being too broad. The next step will be to choose outside members before registering the IBC. Dr. Woodard, who currently works for the DEC and is on the IBC for Albany Medical has agreed to join Trudeau's IBC and is awaiting a formal letter. Tammy Morgan and Marie McBride were suggested as community representatives. Tina will check with Tammy to see if she is interested. Letters will go out to selected outside committee members in mid-August and then we will register our IBC with NIH. The registering process includes bio-sketches on each member and the role they will fill on the Committee. Tina will send write-ups to each committee member for their review. As soon as Cyril gives final approval to the policy it will be placed on the Intranet under Safety -> Biosafety ..

The full committee, including outside members, will meet on an annual basis (typically in April) to review protocol renewals and any other business. The policy sub-committee will continue to meet on a quarterly basis to discuss all internal policy issues.

Other

rDNA work was the next topic for discussion. Steve Smiley had gone through the Stanford questionnaire on classifying rDNA work and culled it down to fit Trudeau's needs. Whenever a PI is considering doing rDNA work, they can go through this questionnaire to classify their work. The questionnaire will be linked to a section of the Biosafety Protocol form on the Intranet. The committee needs to determine what work needs approval from NIH and what only needs Biosafety approval. Steve will work on the final form/questionnaire to be put on the Safety intranet site. In reference to Marcy's question on the rDNA work that she is conducting for Bayhill Therapeutics, the committee approved her request as long as mice are discarded per Trudeau's policy. No infectious agent is involved in this project. Andrea will respond to Marcy accordingly.

Under other new business, the committee decided to send out another institute wide notice about the use of BCG in infectious procedure rooms. Dr. Latt was concerned that staff are still entering the rooms while BCG is being used. The committee chair will remind staff via email that when a notice stating that BCG is being used in a shared animal procedure room then the staff should not enter that room. Use of the FACS facility to analyze or sort unfixed BCG infected samples requires an external notice but this notice does not exclude other staff members from using the facility.

Finally, the committee discussed the potential for exposure to LCMV which was recently discovered by Radil during routine surveillance testing in the EAM. This is typically a Level 2 pathogen that is considered a zoonotic agent. When the source of the pathogen is unknown, as in this case, additional precautions need to be put into place. Andrea was concerned about this issue not only because of it's potential danger to the staff, but because key staff were not informed of the situation. Andrea proposed that the IBC should be notified whenever there was a report from Radil which indicated the presence of zoonotic agent. Tina felt that committee notification was too great an initial response. After discussion, the committee recommended that both the Safety officer and the Chair of the Biosafety committee should be notified whenever a potential pathogen is identified in the animal facility. Based upon the agent found and the results, additional action could include consultation with the Committee.

Meeting adjourned at 3:50 p.m.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
July 29, 2005

# TRUDEAU INSTITUTE, INC.
## BIOSAFETY COMMITTEE
## MINUTES OF A MEETING HELD November 10, 2005

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:30 p.m. Thursday, November 10, 2005 in the Founder's Library at Trudeau Institute.

Attendance: Tina Charbonneau, Andrea Cooper , Peter Sayles, Steve Smiley, Kelly Stanyon, Simon Monard, Ron LaCourse, Cyril Doucet, Brian Waters and Steve Jones (Absent – Rick Latt and Chip Eaton)

Status of Outstanding Protocols

Steve Smiley's protocol requesting to use Plasmodium chabaudi is awaiting Andrea's approval. All other members have sent in their comments and all have approved of the proposal as written. Fran Lund submitted an amendment to use a different, less virulent strain of Streptococcus pneumoniae (B-40-03). This amendment was submitted as an email to Andrea and Tina. Based upon the information submitted, full committee review was not necessary and it was approved accordingly. This prompted discussion on the amendment process. There are no other outstanding protocols for review.

Medical Surveillance Update

Tina reported the 3rd quarter PPD screening clinic (held In August) went without incident. The 4th quarter clinic will be held next week. In conjunction with the annual training, Tina will remind all staff that the health forms need to be completed in full even if they decline the PPD screening. It is very important to obtain emergency contact information.

IBC Registration and IBC Policy Follow-up

Tina reported that Dr. Alan Woodard and Ms. Tammy Morgan have formally accepted membership to the committee. Both members will be invited to the quarterly meetings and will be sent the biosafety protocols to review prior to each meeting.

I n connection with approving protocols, Tina reported from the biosafety meeting she recently attended that when we register our IBC, approving protocols by e-mail will not be accepted. They must be discussed and approved face to face at each quarterly meeting with approval noted in the meeting minutes. The committee agreed that e-mail will continue to be used for discussion with pending approval granted for each protocol. Staff can work on a pending approval, with final approval granted at the next quarterly meeting.

Tina also reported on other concerns with regards to our established policy. Our Biosafety Policy currently distinguishes between protocol discussion (Institute Biosafety Committee) and discussions on Institute policy (Biosafety Policies sub-committee). Tina was concerned that these two separate committees would not be considered acceptable upon review by NIH. Andrea indicated that the policy as written is what we will follow. Therefore, our outside members will be notified of the quarterly meetings and they will attend only the session where we discuss the actual Biosafety Protocols. Once that discussion has been recorded, that facet of the meeting will be closed and their attendance at the policy discussions will not be necessary. We will institute this format for our meetings once we have registered the IBC with NIH.

Tina has the information and cover memo needed to register our IBC ready to send to NIH. She is waiting for an updated resume from Ron LaCourse, Stephen Jones and Chip Eaton. When Trudeau registers with NIH we must also register with the State of New York. The same information can be sent to NYS. The Committee approved sending the IBC registration to both agencies.

Influenza Work Group/Emergency Preparedness

Andrea reported on a meeting that was held at Trudeau Institute with Essex and Franklin County Department of Health staff and the Infection Control specialist from Adirondack Medical Center. The focus of the meeting was to begin discussions in connection with community emergency preparedness and the possibility of a bird flu pandemic. Tina will represent the Institute at further meetings of this group. The Institute's emergency plan has not been developed at this time. Andrea questioned whether the Biosafety committee should take a role in this planning. Cyril indicated that the topic of emergency preparedness has been in discussion at the Directors meetings and that a small internal working committee would be organized. The IBC agreed that this EP group needs to come up with a plan for how the Institute will respond to various emergencies albeit natural disasters or medical emergencies such as a pandemic influenza outbreak. The Biosafety Committeee will be looking for a document from this group at our next meeting.

Influenza Season 2005-06

Two clinics for flu vaccination were held in November. Tina has been asked by Administration to include influenza infection control during her annual safety training seminars. This will include cough etiquette, washing hands often and other preventative measures for battling infection. Tina will also ask the PI's and department managers to be cognizant of staff absences and to notify the safety office if there appears to be increased absence within a given department.

Cyril suggested that the Emergency Preparedness group should also discuss this absenteeism factor to determine what a realistic rate should be. The committee agreed.

1918 Flu Strain

Recently the 1918 strain of influenza has been added to the list of Select Agents. Labs working with this strain will be required to register with NIH and follow all applicable rules and regulations. Many labs within the Institute work with influenza but this strain is not among those currently being studied. Therefore, at this time, there is no need for the Institute to register the research with NIH.

The committee discussed the need to have biosafety approval for any flu strain being used at the institute. This has not always been done in the past. Currently, the Biosafety Protocol submission form allows for the applicant to write "any" under strain designation. There was discussion by the group that indicated this may not be the best process as some strains of a particular organism may require changes in biosafety levels or practices. The influenza virus is an example. Therefore, it was decided by the committee that protocols need to be specific for the strain being used. If a PI then wants to use additional strains, an amendment to the existing protocol will need to be submitted. Steve Smiley agreed to develop a "form" for the amendments, Tina agreed to contact Sandy to have the current form changed to reflect the addition of specific

strains and Andrea will notify the PI's of this change in procedure with emphasis on the fact that all approval documents apply only to the strains specified on the application.



Use of Toxins/Antitoxins

The question arose as to the appropriate committee to handle the approval for the use of toxins/antitoxins. IACUC is looking for direction in this area when these agents are used in mice. The committee was not sure this was necessary or whether "we" were the appropriate committee to make the decisions. . The suggestion was made to remind PI's they are responsible for the use of toxins/antitoxins and if there was any question as to the proper use, should consult with the Safety Office. Tina indicated that we currently have animal safety, biosafety, chemical safety and now radiation safety protocol requests. It is her hope that through the process of submission she will be alerted to any agent that may require "special" handling. Tina will remind staff during the annual training to be aware of the potential hazards of working with various chemicals and biologicals and to seek additional information if they are uncertain as to how they should be handled.

Import/Export Permits

Tina reported on attending a training session on "Regulatory Biosafety: Regulations and permit procedures for animal products, pathogens and pests affecting humans and animals." During this session she learned about the APHIS/USDA requirement to obtain **interstate** import/export permits for agents capable of causing disease in animals. This requirement has been in effect for sometime (since select agent regulations) but it does not appear to be strictly enforced by companies who transport the agents as dangerous goods. The permits are obtained directly through APHIS and are typically for 1 year. The committee decided that more information is needed before any action is taken and the issue was tabled for the future discussion.

Annual Training

The Committee is fully supportive of the annual safety training program conducted by the Safety Office. They also agreed that the PI is 100% responsible for staff training and that the staff should be encouraged to ask questions of the PI, co-workers or the Safety office. Tina also noted that it is her intention to have periodic training sessions during the year to cover specific safety issues.

Meeting adjourned at 4:10 p.m.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
November 15, 2005

TRUDEAU INSTITUTE, INC.
BIOSAFETY COMMITTEE
MINUTES OF A MEETING HELD FEBRUARY 8, 2006

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:30 p.m. Wednesday, February 8, 2006 in the Founder's Library at Trudeau Institute.

Attendance: Tina Charbonneau, Andrea Cooper (Chairperson) , Peter Sayles, Chip Eaton, Kelly Stanyon, Simon Monard, Ron LaCourse, Cyril Doucet, Brian Waters, Steve Jones, Rick Latt, Tammy Morgan and Mim Tracy (Absent – Steve Smiley)

New Member Introductions

The new outside members of the committee, Marian Millar-Tracy (Mim) and Tammy Morgan were welcomed. Andrea reviewed the purpose of the committee and how that the main function is to protect staff from potential exposures to infectious agents or biologicals.

Status of Outstanding Protocols and Amendments

1. Randall protocol for Rotovirus – Troy has received the Committee's recommendations and he will revise accordingly and will re-submit.

2. Haynes Lab amendment for sorting cells from Listeria monocytogenes infected animals. – Amendment discussed at length due to the potential for aerosol exposure to potentially infected cells. Issues for consideration, organism is BSL2 but carries an additional risk for immunocompromised or pregnant staff. Sorter is equipped with negative pressure hood and HEPA filtration. Committee approval was given for sorting with the following stipulation, cells can only be sorted during low activity times in the lab ( after 5pm) and door signage must indicate the presence of the infectious agent.

3. General discussion of other agents that would require the higher biosafety level in the Facs Room include the sorting of BCG, M. avium or T. gondii infected cells. All protocols for sorting of cells from animals infected with these agents will be done after 5pm.

4. Swain Lab protocol for the use of vero cells – though not an infectious agent, the lab was asked to submit a protocol since the origin of the cells are non-human primates. The cells would be used for culturing of reagents for possible infectious (viral) contaminants. The concern was raised that the culturing was going to be done in a "clean" lab, one that is NOT designated for work with infectious agents. The Committee agreed that the fact that potential unknown infectious agents MAY be cultured required the lab to have the appropriate

biosafety designation. Tina will contact the lab and ask that the protocol be clarified, either the current lab will need to be designated as BSL2 or the work can be transferred to a room that already has that designation.

Medical Surveillance Update

There was a general discussion of our medical surveillance program and screening for exposure to MTb. Periodicially employees become aware that an individual has changed PPD status and this gives rise to a generalized concern about containment of the mycobacteria used in the institute. Employee concerns included whether our surveillance program and response to potential exposure were appropriate. Tina has been reviewing the most recent CDC document on "Guidelines for Preventing the Transmission of MTb" and the Institute is indeed following the guildelines. Additionally, Tina reported that she has been able to access the Microbiology Lab at Albany Medical Center for assistance in performing the Quantiferon Gold assay for the diagnosis of latent MTb infection. This assay is specific for exposures to MTb and would provide us with the medical surveillance data for those who recently convert from PPD- to PPD+ and would be useful for staff that have a prior vaccination with BCG. Use of this assay as an adjunct to our medical surveillance will be important as it will help to distinguish "real" exposures from those that may be due to exposure to M. bovis(BCG). Tina will revise the current medical surveillance policy to include this testing and will share this with staff so that they have a clear understanding of the purpose of testing. Additionally, Tina has met with Dr. Cook and Sharon to review the assay and results so that appropriate medical follow-up can take place as necessary.

Status of IBC

Tina reported that Trudeau's IBC is now registered. The first application was denied because of the format of the roster and our community member Dr. Alan Woodard, was considered outside of our "geography. The revised application was submitted with Mim Tracy and this satisfied the requirement for a community member. The committee registered it's thanks to Tina for handling this registration process which took almost 2 years!

Protocols up for Renewal in 2006

Kelly reported that all PI's have been notified via e-mail as to which biosafety protocols are up for renewal this year. They are asked to have them to her by April 1st. All committee members are required to review the re-submitted protocols **prior** to our next quarterly meeting.

Annual Training

Tina reported annual training was conducted in Oct. and Nov. last year. After reviewing the evaluations she noted that the laboratory staff may need some additional training on Biosafety Levels and risk assessment. She will be creating a specific biosafety training session similar to the one she conducted last spring on the use of biosafety cabinets. Lab staff as well as animal care staff will be encouraged to attend.

Formation of Institute IRB and Human Studies

Andrea and Tina opened the discussion on the possible need to establish an IRB at Trudeau. Some of the principal investigators are voicing interest in working with human cell samples. The question brought before the committee is do we need an Institute IRB or can the Biosafety Committee review and approve of human sample work. One suggestion might be to conduct the work at another site which would eliminate the need for an IRB. Tina will look at the NIH site for specific information on establishing IRB's and send the committee the link for review. Further discussion will resume at the next quarterly meeting.

Meeting adjourned at 3:50 p.m.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
February 13, 2006

# TRUDEAU INSTITUTE, INC.
# BIOSAFETY COMMITTEE
# MINUTES OF A MEETING HELD APRIL 19, 2006

A meeting of the Biosafety Committee of the Trudeau Institute was held at 2:30 p.m. Wednesday, April 19, 2006 in the Founder's Library at Trudeau Institute.

Attendance: Tina Charbonneau, Andrea Cooper (Chairperson) , Peter Sayles, Chip Eaton, Kelly Stanyon, Ron LaCourse, Cyril Doucet, Brian Waters, Steve Jones, Rick Latt, Steve Smiley , Tammy Morgan and Mim Tracy (Absent –Simon Monard)

Review and Approve Protocols for Renewal

The committee reviewed and commented on the following protocols up for renewal in 2006: Following each protocol are procedural comments and areas that need clarification or correction.

Blackman Lab

Influenza A (PR8, x-31, Alaska) – Corrections to be made: Agent needs to be listed as " Influenza A". Correct statement that it is pathogenic to animals. Use term BSL2 for Biosafety Level 2. Add statement in both sections 4 and 5 that work will be performed in a biosafety cabinet. Protocol approved pending corrections.

Staphylococcal entyerotoxin B – used at exempt quantities (<5mg total at any time) therefore does not require registration as a select agent. Protocol approved, as written.

Cooper Lab

Mycobacterium tuberculosis (H37Rv, Erdman, no drug resistant strains)– Facs analysis of unfixed tissue will be performed in the BSL3 facility. Stipulates use of RACAL for work with cryostat in BSL3 facility as well as when the agent is aerosolized and when injections are performed. Approved as written.

Mycobacterium avium (ATCC 724, 2-151, 101, 104, 2447, Transposon mutants)– BSL2 but some work is performed at the BSL3 level. This should be clarified in the protocol as to why. Also needs to stipulate reason for using N95 masks. Sorting is performed in the Facs facility after 5pm. Protocol approved pending corrections.

Mycobacterium bovix BCG (Pasteur) – BSL2 agent but worked with at BSL3 level for some tasks. This should be clarified. Correct section 4 in vitro studies which lists agents as MAC rather than BCG. Protocol approved pending corrections.

Johnson Lab

Toxoplasma gondii (ME49, ts-4, RH, Pru, RH mutants) – correct animal procedure room number to 353. Lab only works with fixed cells in Facs room. This is a key biosafety consideration when the RH strains are being studied. Protocol approved pending corrections.

Lund Lab

E. coli (any commercially available subcloning streains – DH5alpha) - Strains of

E. coli used for molecular work are considered BSL1. Well written. Protocol approved as written

Heligmosomoides polygyrus – BSL1 agent . Protocol approved as written

Influenza A (A/PR/8/34/WSN OVA1, WSN-OVAII, A/Alaska Cr9 (cold adapted) – Delete statement on mouse adapted strains and efficiency of infection in humans. Protocol approved pending corrections

Listeria monocytogenes (EGD, Listeria-ova, Listeria ActA mutant) – Agent needs to be listed as zoonotic (section 2). Protocol approved pending corrections.

Retroviral vector (pBMN-IRES-EGFP, pMX-IRES-EGFP) – Included CDC/NIH questions on recombinant viruses. Vectors will be used at BSL2. Protocol approved as written.

Streptococcus pneumoniae (Type III) – Section 2 change to yes for vaccine available forhumans. Complete section on genetic alterations. Protocol states it is a BSL2 pathogen but some procedures will be performed on the benchtop. BSO will discuss further, perform a risk assessment and advise accordingly. Protocol approved pending corrections.

Mohrs Lab

Influenza (A/HK-x31, A/PR/8/34, and both strains missing PA and NP resp.) – Include Influenza A in name of agent. Protocol approved pending corrections.

Heligmosomoides polygyrus – Protocol approved as written

Toxoplasma gondii (ME-49, tx-4) – Protocol approved as written

North Lab

Mycobacterium bovis (BCG, Ravenel) – Section #2 on special considerations should indicate that only drug "susceptible" strains are used. Section #3 on information on the agent needs to be more explicit in what PPE will be used in the BSL3 facilities. Section #4 Explanation that BCG strain is BSL2 but used at BSL3 level. In vivo animal procedure room number should reflect the agents. If BCG mice are housed in Rm 353 if should be stated. Protocol approved pending corrections.

Mycobacterium tuberculosis (H37Rv, R1Rv, Erdman, CDC 1551) - Section #2 on special considerations should indicate that only drug "susceptible" strains are used. Section #3 on information on the agent needs to be more explicit in what PPE will be used in the BSL3 facilities. In vivo room should state ABSL3 suite in EAM not R 101-102. Protocol approved pending corrections.

Randall Lab

Heligmosomoides polygyrus – Protocol approved as written.

Influenza A (A/PR/8/34, X31, WSN OVA1, WSN-OVAII, A/Alaska Cr9 (cold adapted) - Protocol approved as written.

Listeria monocytogenes (EGD, LM-OVA) – Protocol approved as written.

Sayles Lab

Mycobacterium bovis BCG (Danish, Tokyo, Japan, Pasteur) – Protocol approved as written.

Smiley Lab

Listeria monocytogenes (EGD) – Section 4 in vitro studies, more specific wording for PPE, ie task specific. . Change animal procedure room to 353. Section 5 complete, procedures and room numbers it is not sufficient to indicate "same as for Part 4". Protocol approved pending corrections.

Streptococcus pneumoniae (Type 4 Klein Strain) – Section 4 in vitro studies, more specific wording for PPE, ie task specific. . Change animal procedure room to 353. Section 5 complete, procedures and room numbers it is not sufficient to indicate "same as for Part 4". Protocol approved pending corrections. Protocol approved pending corrections.

Toxoplasma gondii (ME49, tx-4) – Section 4 in vitro studies, more specific wording for PPE, ie task specific. . Change animal procedure room to 353. Section 5 complete, procedures and room numbers it is not sufficient to indicate "same as for Part 4". Protocol approved pending corrections.

Yersinia enterocolitica (WA 08) – Section 4 in vitro studies, more specific wording for PPE, ie task specific. . Change animal procedure room to 353. Section 5 complete, procedures and room numbers it is not sufficient to indicate "same as for Part 4". Protocol approved pending corrections.

Yersina pestis (Pgm-negative strains (KIM5/D27, KIM6/D28, KIM10, caf1-negative KIM5) or pCD1-negative strains (K*IM6+, KIM10+, caf1-negative KIM10+) – Special note, Y. petis vaccine strains are exempt from select agent registration. Include source ( institution) for various strains. Change animal procedure room to 353. Section 5 complete, procedures and room numbers it is not sufficient to indicate "same as for Part 4". Protocol approved pending corrections.

Swain Lab

Influenza A (A/PR/8/34/WSN (flu)-OVAII – change animal procedure room to 353. Dissections on the benchtop will require appropriate PPE (re-word). Protocol approved pending these corrections.

Retroviral vector (RV-GFP) – Section #5 on personal protection needs to be more specific rather than "universal precautions". Protocol approved pending corrections.

The following protocols were not renewed at the discretion of the investigator:

Flano Lab – MHV-68
Johnson Lab – Plasmodium chabaudi AS
Sayles Lab – M. smegmatis BCG, E. coli and Mycobacterium tuberculosis

For the record, the Dutton lab has amended Protocol B-87-05 to include the following strains of Influenza:

influenza A PR8, WSN-OVA, x31
A/Hong Kong/123/77 (H1N1) cold adapted virus
A/Alaska/6/77 and A/HK/123/77 HA and NA genes with internal proteins from A/AA/6/60 ca virus (H2N2).B/Ann Arbor/1/86 (B/AA); A/Johannesburg/82/96 H1N1 and A/Philippines/2/82/X-79 (X79 H3N2).

As part of the general discussion on the protocols for renewals the following issues were debated and agreed upon by the Committee:

1. What constitutes a "zoonotic agent"? It was decided that we would change the statement in the protocol from a yes/no question to one that is more descriptive Can exposure occur through handling the mice, caging or bedding. (Zoonotic). Can exposure occur through handling tissues from infected animals ( Occupationally acquired).
2. Labs are using the Histology Core ( cryostat) for tissues from infected animals. Is there a protocol in place for decontaminating the instrument and are staff trained in this aspect of use. Tina will contact Mike Tighe, who manages the histology lab to ensure that this is in place.
3. Fran referred to the specific CDC/NIH questions on recombinant viruses in her protocol. We will now include these questions as a standard part of all protocol requests.

Status of Outstanding Protocols and Amendments

1. Mohrs lab request to use Sendai – the following concerns were brought forth by the committee: 1) processing of unfixed tissue outside of the ABSL3 suite - the application not only lists use of a cryostat but the grinding of tissue. There is no indication of how the microscope room, the FACS facility and the Woodland labs will be protected from contamination or how the tissues will be removed for the ABSL3 suite. 2) the committee would like to see somewhere in the protocol the assurance that specific training for working in the ABSL3 lab will be conducted. This needs to be documented before Dr. Mohrs staff obtain fob access to the facility. 3) general concern about the decontamination of the cryostate following cutting of infected samples – is there a protocol?

   Committee requested re-submission with corrections.

2. Haynes Lab request to use M.bovis (BCG) –the following concerns were brought forth by the committee: 1) M. bovis (BCG) should be listed as zoonotic, it is not. 2) PI should not state that there have been no incidents of infection in the Institute 3) lab should be made aware that if they use the procedure room for harvesting, they must post a note on the door and sign out the entire room 4) Protocol listed that a hazardous chemical will be used, but there is nothing listed. What chemical will they be using? 5) Why are they not fixing samples?

   Committee requested re-submission with corrections

Student Intern Proposals (SIP)

The following proposals were submitted to the Committee for review and approval for the summer student intern program. The Committee members were reminded of the "guidelines" to be used for the student interns.

Blackman Lab proposal "cloning and sequencing of PCR products". Work will be done with molecular grade E. coli (BSL1) and does not involve any other infectious agent. Project was approved.

Haynes Lab will examine T cell responses in aged mice. No infectious agents will be used. Project was approved.

Swain Lab will examine T cell responses and phenotype of naïve, effector and memory cells. No infectious agent will be used. Studies will be performed in Rm 207 which is used for influenza work. Post-Doc mentors will be reminded that the student cannot work in the lab at the same time as the infectious work is being conducted. Project approved.

Woodland Lab proposed the examination of viral titers from tisuues of influenza and sendai infected mice. After discussion, the committee decided that this was not an appropriate task for the student. The PCR aspect of the project is acceptable as long as the student is not isolating the viral RNA from the tissues but works with the samples after the fact. This project needs to be re-written and submitted for approval.

Dutton Lab proposal is incomplete . IThere is an indication of what assays and techniques the student will use but not the source of the cells or tissues. This needs to be clarified and the project re-submitted for approval.

Meeting adjourned at 4:40 p.m.

Prepared by Kelly Stanyon and
Submitted to the Chair, Andrea Cooper
February 13, 2006