SARS-CoV2 BSL2+ SOP: TEMPLATE

Biosafety Plan and Procedures for Handling and Processing Clinical Specimens from Persons experiencing COVID-19

Written and Implemented for the RC1N BSL2+ room bldg. & room #
1. GENERAL CONSIDERATIONS AND EXPOSURE DETERMINATION

List of job classifications in which all employees risk exposure to SARS-CoV2.

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<th>Title</th>
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<tr>
<td>Professor</td>
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<td>Associate Professor</td>
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<td>Assistant Professor</td>
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<td>Senior Professional Research Assistant</td>
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<td>Professional Research Assistant</td>
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<td>Research Associate</td>
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<td>Post-Doctorate Fellow</td>
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<td>Graduate Research Assistant</td>
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1.2 General Considerations

- PIs must consent that an individual has sufficient training to work with COVID-19 clinical specimens.
- All personnel must have completed the training outlined in this manual before they will be authorized for this work.
- All employees must be educated on the possible consequences of exposure to SARS-CoV2 infection by the PI.
- Persons over the age of 60yrs of age, underlying health conditions, and immune suppression are at higher risk of complications in case of exposure.
- There are no approved vaccines or specific therapies against SARS-CoV2 currently available.

1.2 Potential Hazards

The following tasks are identified as potential hazards, regardless of the use of personal protective equipment:

- Handling/Transporting clinical specimens. All primary specimen containers are sealed and decontaminated. Primary containers are transported in a sealed secondary container (i.e. Nalgene BioTransport Carrier).
- Preparing, freezing, or thawing clinical specimens.
- Handling contaminated sharps/contaminated sharps disposal.
- Handling of contaminated laboratory supplies and waste generated during procedures.
- Any procedure that produces aerosols such as centrifugation.
- Routine cleaning and maintenance of biological safety cabinets, equipment, and laboratory space used for working with COVID-19 clinical specimens.

- PIs must consent that an individual has sufficient training to work with COVID-19 clinical specimens.
  All personnel must have completed the training outlined in this manual before they will be authorized for this work.
- All employees must be educated on the possible consequences of SARS-CoV2 exposure by the PI.

2. SCHEDULES AND METHODS OF IMPLEMENTATION: BSL2+ (bldg. & room #)

1. Methods of Compliance

- Each person entering the COVID-19 BSL2+ laboratory (bldg. & room #) shall be held responsible for his or her own safety and that of others. The PI will counsel all employees on the risks of working with COVID-19 clinical specimens. The room (bldg. & room #) will be card access controlled and entry limited to approved personnel.
- All employees must be screened for relevant respiratory and other health issues associated with increased risk of severe COVID-19 disease by UCD Occupational Health prior to working with COVID-19 clinical specimens.
- Standard microbiological practices shall be used in the BSL2+, and all wastes shall be autoclaved or otherwise disinfected. All potentially infectious materials shall be handled using Standard Precautions and good microbiological practices.
- Standard operating procedures (SOPs) for individual laboratory tasks are published as separate documents.
- Knowledge of these protocols will be required for BSL2+ training certification and everyone must follow the specified techniques.
- For the safety of others, failure to comply with safety standards, standard operating procedures, and special practices, will result in termination of access privileges to the BSL2+.

2.1 (a) Standard Precautions

- Standard Precautions and Work Practice Controls will underlie all aspects of work undertaken in the BSL2+ research laboratories.
- Standard Precautions state that all procedures performed within the BSL2+ laboratory will be planned and executed as if all specimens are infectious.

2.1 (b) General Engineering and Work Practice Controls

- General Work Practice Control principles govern the planning and execution of specific tasks in which procedures are designed to minimize the chances for accidental exposure (such as aerosolization control).
- Eating, drinking, smoking, applying cosmetics or lip balm, handling contact lenses, etc. is strictly prohibited in all parts of the BSL2+ laboratory.
- The doors of the BSL2+ room must remain closed when performing work with COVID-19 clinical specimens.
- Storage of food or drink in any part of the BSL2+ is strictly prohibited.
- In addition to the policies below, standard operating procedures (SOPs) should be written out for each major task to be performed in the BSL2+ room, and should be mindful of the Standard Precautions and Work Practice Controls approach to task planning and execution.
- Knowledge of these protocols will be required for BSL2+ training certification. All individuals working in the BSL2+ facility must follow the specified techniques.
• Failure to follow these protocols will result in termination of access to the BSL2+ facility.

2.1 (b)(1) Hand Washing

• Hand washing facilities are available within the BLS2+ room (bldg. & room #)
• Researchers must wash hands immediately or as soon as feasible after removal of gloves and other personal protective equipment, and prior to leaving the BSL2+ room.

2.1 (b)(2) Direct Skin Exposure

• In the event of direct skin contact, employees must wash hands and any other skin with soap and water, or flush mucous membranes with water at the eyewash located at the sink inside/outside the BSL2+ room (bldg. & room #), immediately or as soon as feasible following contact of such body areas with potentially infectious materials.
• All exposures and potential exposures will be reported to the immediate supervisor and UCD|AMC Biosafety Officer as soon as feasible.

2.1 (b)(3) Handling Contaminated Needles and Other Contaminated Sharps

• Use of sharps (needles) and glassware is discouraged unless other items are not suitable for the procedures.
• Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed unless the PI can demonstrate that no alternative is feasible or that such action is required by a specific procedure. Any such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.
• Broken glassware should not be handled without tongs, broom, or some other mechanical aid.
• Re-useable sharps are not to be placed in containers such that a person may need to reach in and be injured.

2.1 (b)(4) Disposing of Contaminated Needles and Other Contaminated Sharps

Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers. An appropriate container must be labeled or color-coded, closable, leak-proof, and puncture resistant. Do not recap, bend, or shear needles.

2.1 (b)(5) Pipetting

• All pipetting will be accomplished with mechanical devices.
• Mouth pipetting/suctioning of any materials is absolutely prohibited.

2.1 (b)(6) Aerosol Minimization

• All procedures involving potentially infectious material shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.
• Containment within the biosafety cabinet (BSC) is the standard for all manipulations, unless equipment does not fit within a BSC.
• All appropriate steps will be taken to prevent the generation of aerosols or droplets, even within the biosafety cabinet (BSC).

2.1 (b)(7) Specimen Storage and Transportation
• Specimens of potentially infectious material shall be placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
• Any infectious material that is permitted to be removed from the BSL2+ room must be in:
  o A watertight primary receptacle
  o Watertight secondary packaging
  o An absorbent material placed between the primary and secondary packaging
  o Transported in an appropriately sealed and gasketed transport container, and clearly marked with warning labels indicating the nature of the hazard.
  o The route of transport shall be designed to avoid public areas as much as possible.
• All packaging or opening of packages containing COVID-19 clinical material will be performed inside BSCs in the BSL2+-approved laboratories.

2.1 (b)(8) Contaminated Equipment
• Any equipment which may become contaminated with potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the UCD can demonstrate that decontamination of such equipment or portions or such equipment is not feasible.
• A readily observable label in accordance with OSHA standards shall be attached to the equipment, stating which portions remain contaminated. UCD shall ensure that this information is communicated to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, and prior to handling, servicing, or shipping, so that appropriate precautions will be taken.

2.1 (c) Personal Protective Equipment (PPE)
• Appropriate personal protective equipment is to be worn at all times when working with COVID-19 specimens in the BSL2+ room (bldg. & room #).
• PPE shall be donned prior to initiating work.
• PPE is to be removed when work is completed.

2.1 (c)(1) Providing PPE
• The employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection.
• Furthermore, protective equipment is considered “appropriate” only if it “does not permit potentially infectious materials to pass through to or reach the employee’s work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous
membranes under normal conditions of use and for the duration of time which the protective equipment will be used.¹

2.1 (c)(2) Use of Personal Protective Equipment

Required PPE includes:

Laboratory gown. BSL2+ users must wear a laboratory gown over personal clothing when working with COVID-19 clinical specimens. These gowns will be stored in the BLS2+ room (bldg. & room #). Worn or contaminated gowns must be disposed, autoclaved, and replaced.

Gloves. Two pairs are required. Hypoallergenic gloves are available for employees who are sensitive to latex.

Eye Protection. When working with COVID-19 clinical specimens, all users must use eye protection consisting of a face shield. Face shields will be decontaminated after use and stored in the BLS2+ room (bldg. & room #).

Mask. For work with specimens in the BSC, a standard surgical mask to prevent mucosal exposure will be utilized.

2.1 (c)(3) Accessibility of Personal Protective Equipment

All personal protective equipment shall be accessible to employees.

2.1 (c)(5) Repair and Replacement of Personal Protective Equipment

Gloves are disposable items and should not be re-used. Laboratory personnel are responsible for periodically inventorying stock of personal protection equipment and reordering equipment.

2.1 (c)(6) Contamination and Removal of Personal Protective Equipment

If a piece of personal protective equipment is contaminated by potentially infectious material, the garment(s) shall be removed immediately or as soon as feasible. All personal protective equipment shall be removed prior to leaving the BSL2+ room (bldg. & room #), except in the case of very extreme emergency. When disposable personal protective equipment is removed, it shall be immediately placed in the appropriately designated waste tub for autoclaving.

2.1 (c) (7) Gloves

Gloves are required when working in the BSL2+ room (bldg. & room #).

If a worker is sensitive to latex, hypoallergenic gloves will be provided.

2.1 (d) Housekeeping

For cleaning and disinfecting potential contaminated areas, a *disinfectant name & concentration* should be used. A mix of 10% bleach solution in water is also an acceptable decontamination agent.

2.1 (d)(1) General Cleaning Guidelines

General OSHA guidelines require that clean, sanitary conditions are maintained.

Daily cleaning should include: autoclaving all trash and replenishing biohazard bags, and cleaning of the BSC and research laboratory used by the employee. Daily cleaning should follow all of the relevant procedures listed below.

2.1 (d)(2) Surfaces

All equipment and environmental and working surfaces shall be cleaned and decontaminated after work with potentially infectious materials.

Work surfaces shall be decontaminated with a *disinfectant name & concentration* after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill or potentially infectious materials; and at the end of the work shift.

The working surface of the BSC must be decontaminated with *disinfectant name & concentration* after each use.

2.1 (d)(3) Receptacles

Pails, basins, bins are inspected for leakage, decontaminated after use, and cleaned. All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated shall be inspected and decontaminated on a regularly scheduled basis and cleaned immediately or as soon as feasible upon visible contamination.

2.1 (d)(4) Glassware and Sharps

The use of glassware and sharps (needles) is discouraged unless other items are not suitable for the procedures.

Broken glassware should not be handled without tongs, broom, or some other mechanical aid.

Re-useable sharps are not to be placed in containers such that a person may need to reach in and be injured.

2.1 (d)(5) Regulated Medical Waste/Biomedical Wastes

Contaminated sharps shall be discarded immediately or as soon as feasible in sharps containers that are closable, puncture resistant, leak-proof, and labeled or color-coded.

During use, containers for contaminated sharps shall be easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can
be reasonably anticipated to be found; maintained upright throughout use; and, replaced routinely and not be allowed to overfill.

Contaminated needles should be placed in the sharps container provided. When full, the sharps container shall be closed, and then autoclaved prior to final disposal in the red tubs provided for biomedical wastes.

A small point of use container should be placed in or near the BSC to hold contaminated trash generated within the BSC. This container will be partially filled with Coverage Plus at an appropriate working concentration. Be careful not to block the grills or vents on the back or side of the BSC. All wastes from the laboratory must be disposed of using autoclaving procedures.

Liquid wastes should be placed in an autoclave safe container. If needed, a pipet tray with Coverage Plus disinfectant at an appropriate concentration will serve this function. Containers must be properly covered placed in the autoclave and sterilized. Contaminated liquid waste must never be poured into the sanitary sewer system. If outside contamination of the regulated waste container occurs, it shall be placed in an appropriate secondary container.

2.1 (d)(6) Autoclave

Autoclave quality control: Use temperature sensitive autoclave tape in each load. Use time and temperature sensitive chemical indicator in each load.

At least quarterly quality control using biological indicators will be performed to ensure sterilization effectiveness of the autoclave cycle parameters. The EHS is responsible for conducting this testing, and they will follow appropriate biosafety procedures and observe appropriate standards.

2.1 (d)(8) Biological Safety Cabinet (BSC)

Daily: Check the reading on the negative pressure indicator on the cabinet.

Yearly: Complete recertification and inspection per NSF Standard 49 by an outside contractor. HEPA filters will be changed as needed.

(a) Standard Microbiological Practices

All activities involving potentially infectious materials shall be conducted in biological safety cabinets within the BSL2+ room (bldg. & room #). No work with potentially infectious materials shall be conducted on the open bench.

2.2 (b)(7) Spill or Accident involving COVID-19 clinical specimens

In the event of a spill or accident, follow these steps:

1. Use the phone for help, if necessary. If in immediate danger, dial 9-1-1 on a campus phone or (303)724-4444 on a mobile phone.
2. Control the Spill. The laboratory is equipped with respirators, absorbent material, tongs, gloves, and appropriate disinfectants.

To control the spill take the following steps:
- **Surround** the area of the spill with absorbent material, to keep it from spreading.
- **Saturate** the spill and absorbent material with appropriate disinfectant. Leave the spill covered with disinfectant for at least an hour before removing and bagging the absorbent materials into an autoclave bag and autoclaving.
- **Surround** the area again with absorbent materials and flood with disinfectant, for another hour, repeat one more time, bagging the wastes for autoclaving at each step. Clean the entire affected area thoroughly with bleach and water.

3. After the spill is under control, notify others working in the BSL-2+ laboratory.

4. If your PPE has been contaminated it must be removed and autoclaved or discarded in red RMW bin for disposal.

5. The spill must be reported as soon as possible to the worker’s Principal Investigator and to the UCD|AMC Biosafety Officer. An INCIDENT REPORT should be completed as soon as possible. This will document the date and nature of the accident, initiate the proper medical evaluation and follow-up, and facilitate the disbursement of funds to cover the employee’s potential medical costs, workman’s compensation, etc.

**2.2 (b)(8) Spill or Accident That Results in a Potential Exposure Incident**

Any spill occurring outside of the BSC must be treated as a spill that results in an exposure incident.

Spill Exposure Incident Guidelines:

1. Use the phone for help, if necessary. If in immediate danger, dial 9-1-1 (red button).

2. Follow the procedures for a spill or accident listed above in Section 2.2 (b)(11).

3. The spill must be reported as soon as possible to the worker’s Principal Investigator and to the UCD|AMC Biosafety Officer.

4. In the event that a spill creates a possible occupational exposure to virus, an INCIDENT REPORT should be completed as soon as possible. This will document the date and nature of the accident, initiate the proper medical evaluation and follow-up, and facilitate the disbursement of funds to cover the employee’s potential medical costs, workman’s compensation, etc.

**Sharps Exposure Incident:**

1. Do not panic. Deal with the situation in as calm a manner as possible.
2. Use the phone for help, if necessary. If in immediate danger, dial 9-1-1 on a campus phone or (303)724-4444 on a mobile phone.

3. Wash the wound with soap and water for 10 minutes. Apply pressure to the puncture wound and bleed freely to cleanse. There is a first aid kit located in each research suite. Cover the wound and exit the laboratory.

4. Report the incident immediately to your Principal Investigator and to the UCD|AMC Biosafety Officer.

5. An INCIDENT REPORT shall be completed as soon as possible. This will document the date and nature of the accident, initiate the proper medical evaluation and follow-up, and facilitate the disbursement of funds to cover the employee's potential medical costs, workman's compensation, etc.

2.2 (b)(9) Incidents Involving the Loss of Power in the BSCs

Incidents involving the loss of power that results in the triggering of the alarm(s) in the BSL2+ laboratory may occur if power is interrupted to the Anschutz Medical Campus, the Research Building or to individual floors within the building.

Visible and audible signals in the BSL2+ facility will also go into alarm.

The research staff will respond by:
- Stopping all work
- Putting away all work materials
- Exiting the BSL2+ laboratories

Once the situation has been assessed and all power and ventilation issues have been resolved the alarms will be reset or silenced and normal work may resume.

2.2 (b)(9) Biosafety Plan Requirement

Per federal regulation, this BSL2+ Biosafety Plan is reviewed and updated at least annually, or more often if necessary. The responsible PI is charged with ensuring that their version of the BSL2+ Biosafety Plan is current and accurate.

Everyone working in the BSL2+ room (bldg. & room #) shall be advised of potential hazards, shall be required to read instructions on practices and procedures as contained in the Biosafety Plan and any other relevant documents, and shall be required to strictly follow them.

2.2 (c) Containment Equipment

Certified biological safety cabinets or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, and sealed centrifuge rotors shall be used for all activities with potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.
3.1 Pre-Exposure Tests

No pre-exposure tests are required.

3.2 Reporting an Exposure Incident

3.2 (a) Purpose

The purpose of an Incident Report is to document the date and nature of the accident, initiate the proper medical evaluation and follow-up, and facilitate the disbursement of funds to cover the employee’s potential medical costs, workman’s compensation, etc.

Additionally, reports of exposure incidents will be reviewed by the UCD|AMC Biosafety Officer to determine how to decrease future exposure incidents in the BSL2+ facility.

3.2 (b) When to File an Incident Report

An Incident Report must be submitted to the PI and the Biological Safety Officer for the following:
- Any spill of COVID-2 clinical specimens outside the biological safety cabinet.
- Any accident within the BSL2+ laboratory that results in an injury.
- Any other situation where there may have been an exposure incident.

Exposure and injuries must also be reported immediately to the PI and Biological Safety Officer, in accordance with this policy and UCD Workers’ Compensation programs. (Appendix E)

3.2 (c) Timeliness

The Incident Report should be completed as soon as possible after the immediate problem has been taken care of properly.

Inform the PI(s) and Biological Safety Officer that there has been an exposure incident; they will coordinate notification of the proper officials (consulting physicians, etc.) to ensure that the employee receives appropriate medical evaluation, counseling and follow-up care, and that is able to support this treatment financially.

Submit a copy of the Incident Report as soon as possible to the Biological Safety Officer and the responsible P.I.

The Biological Safety Officer shall notify the Centers for Disease Control and Prevention (CDC) and the Colorado Dept. of Public Health and Environment (CDPHE) in cases of SARS-CoV2 exposure or release to the environment.

3.2 (d) What To Include in an Incident Report (form available on EHS website)

Items to be included in the incident report:
- The name of the employee(s) involved and the names of any others present in the BSL2+ room (bldg. & room #) at the time of the incident.
- The date, time and location in which the accident or alarm occurred.
- The circumstances of the accident or alarm.
Route(s) of possible bacterial exposure.
Nature of the strain to which the employee has been exposed (strain name, drug-resistance information, whatever else is known that might be beneficial in evaluation or treatment).

3.3 Exposure Incident/Post-Exposure Evaluation and Follow-Up

3.3 (a) General Follow-Up Procedure: Post-Exposure Evaluation and Follow-Up Report

In the case of occupational exposure to an infectious agent, the employer must provide a post-exposure medical evaluation, counseling and follow-up of the employee’s health by a licensed health professional.

A post-exposure evaluation and follow-up report shall be made available to all employees who have had an exposure incident.

Any post-exposure medical treatment, as recommended by the U. S. Public Health Service, and counseling, must be provided by the employer free of charge.

Federal law requires that all medical evaluations and procedures regarding exposure evaluation and follow-up, including prophylaxis, are: made available at no cost to the employee, made available at a reasonable time and place, performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional, and provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place. 29 C.F.R. § 1910.1030 (f)(ii). Furthermore, the employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee. 29 C.F.R. § 1910.1030 (f)(iii).

The federal regulations also include provisions for counseling and an evaluation of reported illnesses. It states that “[t]his evaluation must be confidential and include the following information: the route(s) of infection, the circumstances under which the incident occurred, and the identification of the source of contamination, if possible.”

3.3 (b) Information Provided to Healthcare Professional

The health professional must be provided with a description of the exposed employee’s job duties as they relate to the exposure incident; of the route(s) of exposure and circumstances under which exposure occurred; results of any blood testing, if available; and, any other pertinent medical information.

3.3 (c) Requirements for Medical Evaluation and Treatment Following a Potential Exposure Incident

Definition of a SARS-CoV2 exposure: Exposure is defined as needle sticks or cuts with contaminated material, splash to unprotected face, direct contact of contaminated material with mucous membranes, direct contact of contaminated material with broken skin, failure of respiratory protection with aerosol generating event outside of BSC.

Medical Evaluation and treatment for a person potentially exposed to SARS-CoV2 will include the following:
- A thorough medical examination and an initial blood draw.
- Illness surveillance: elevated temperature, dry cough, fatigue, shortness of breath
- A nasal swab will be collected if symptoms develop for SARS-CoV2 NAAT.
- A serum sample will be collected again at 14 days post-exposure to test for SARS-CoV2-specific antibody responses.

The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information: (i) that the employee has been informed of the results of the evaluation; and (ii) that the employee has been told about any medical conditions resulting from exposure to potentially infectious materials which require further evaluation or treatment.

All other findings or diagnosis shall remain confidential and shall not be included in the written report.

3.3 (d) Employee Access to Exposure Records

The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements: (i) documentation of the route(s) of exposure, and (ii) the circumstances under which the exposure incident occurred.

Exposure Incident: Minimization/Communication of Hazard to Employees

3.4 (1) General

All employees working in the BSL2+ room (bldg. & room #) shall participate in a training program. The program is provided at no cost to the employee and is administered during working hours. Material appropriate in content and vocabulary to educational level, literacy and language of employees shall be used, i.e. training for principle investigators may not be entirely suitable for graduate student researchers who have little laboratory experience.

Training shall be provided at the time of initial assignment to tasks where occupational exposure may occur and at least annually thereafter.

In the event that an employee has no prior experience in handling human pathogens, the responsible Principle Investigator shall provide and document special additional training to the employee.

Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The principle investigator shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.
3.4 (2) Additional Training Requirements

Additional training shall be provided when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee’s occupational exposure.

3.4 (3) Minimum Required Elements in Training

Included in employee training is, at the least, the following:

- An accessible copy of the regulatory text of this biosafety manual, any referenced standards and an explanation of the contents
- A general explanation of the epidemiology and symptoms of COVID-19 disease
- An explanation of the modes of transmission of SARS-CoV2
- An explanation of the employer’s exposure control plan and the means by which the employee can obtain a personal copy of the written plan
- An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to potentially infectious materials
- An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment. Information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment;
- An explanation of the basis for the selection of personal protective equipment;
- Information on the appropriate actions to take and persons to contact in an emergency involving potentially infectious materials;
- An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;
- Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;
- An explanation of the signs and/or color coding used in the BSL-2 facility; and,
- An opportunity for interactive questions and answers with the person conducting the training session.

Additionally, the person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the work place that the training will address.

3.4 (b)(4) Demonstrable Aptitude

The Principal Investigator shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before the employee is allowed to conduct any unsupervised work with COVID-19 clinical specimens.

4.1 Medical Records

4.1 (a) General Requirement
Each Principal Investigator shall establish and maintain an accurate Employee Occupational Health/Medical Surveillance record for each employee with potential occupational exposure, in accordance with 29 C.F.R. § 1910.1020.

These records will be maintained in accordance with any applicable University of Colorado Denver employment records, in the home Department of the employee.

4.1 (b) Confidentiality

The employer shall ensure that the employee medical records required by Section 2.5 (a)(1) and Section 3.5 (a) of this document are: (i) kept confidential; and (ii) Not disclosed or reported without the employee’s express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

4.1 (c) Archive and Access Requirements

The employer shall maintain exposed employee medical records for at least the duration of employment, plus thirty (30) years in accordance with 29 C.F.R. 1910.1020.

The employer must allow any employee access to his/her medical records within 15 days after a request is made; initial copies must be provided free of charge. An employee must also have access to the laboratory exposure records (ruling described in 29 CFR 1910.20).

4.2 Training Records

4.2 (a) General Requirements

Training records shall include:
- the dates of the training session;
- the contents or a summary of the training session;
- the names and qualifications of persons conducting the training; and,
- the names and job titles of all persons attending the training sessions.

4.2 (b) Archive Requirements

Training records shall be maintained for three years from the date on which the training occurred.

4.3 Availability

The employer shall ensure that all records required by this Exposure Control Plan shall be made available upon request to appropriate inspection officials.

Additionally, employee training records shall be provided upon request for examination and copying to employees or employee representatives.

Furthermore, employee medical records shall be provided upon request for examination and copying to the subject employee, or to any one having written consent of the subject employee.
5.1 Specific Activities and Procedures

ADD OTHERS AS NEEDED

5.1 (a) Centrifugation of COVID-19 clinical specimens

1. Before using any centrifuge review the owner’s manual. The centrifuge should be used according to the manufacturer’s design parameters.

2. Do not exceed the maximum speed or mass for the rotor.


4. Tubes must be properly balanced in the rotor.

5. Never fill centrifuge tubes above the maximum recommended by the manufacturer.

6. Always use a safety centrifuge cup and check the integrity of the “O” ring before every use.

7. Samples will be loaded into rotor/rotor buckets and rotor/rotor buckets will be capped with safety cup in the BSC in the BSL2+ room (bldg. & room #). Surface decontaminate before removing from BSC. No uncovered tubes will be spun in the equipment.

8. Rotor/rotor buckets will be moved to the BSC in the BSL2+ room (bldg. & room #) to unload samples. Samples should NEVER be unloaded outside of BSC or the BSL2+ room.

9. Disinfect tubes, rotor, rotor buckets, centrifuge cups, and centrifuge interior with 70% EtOH after each use.

10. If the centrifuge is equipped with a vacuum pump. The pump must be protected with a HEPA filter. The HEPA filter will be dated and changed annually.

5.1 (b) Biohazard/Infectious Waste Bags

1. Red biohazard/infectious waste bags will be used for disposal of all solid wastes. This includes gloves, paper towels, paper wrappers, etc.

2. Do not let biohazard/infectious waste bags get more than 2/3 full. When 2/3 full, they will be disposed of by autoclaving. Place autoclave tape on the outside of the bag (as with each load that is to be autoclaved). Do not seal the bag so tightly that sterilizing steam cannot completely permeate the contents of the bag. Place a new biohazard trash bag back in the container.

5.1 (c) SARS-CoV2 Inactivation: general information and procedures

General Information regarding inactivation of coronaviruses:
Coronaviruses are enveloped viruses. Thus, they have marked sensitivity to disinfectants (Block, Seymour S., ed. Disinfection, Sterilization, and Preservation. 5th edition.)

Active agents (10 min. exposure at 20-25°C) include: halogens (chlorine), aldehydes (formaldehyde), quaternary ammonium compounds, phenolics, alcohols, H2O2, proteases, and detergents (Block, Seymour S., ed. Disinfection, Sterilization, and Preservation. 5th edition.)

**EPA approved agents** are recommended.

Inactivation of experimental samples:

Chemical Degradation (Phenolics, organic solvents, QACs, H2O2): Trizol, phenol/chloroform, methanol, ethanol, acetone

Lysis Buffer with detergents: 1% NP-40 or 1% Triton X-100

Fixatives: 1% paraformaldehyde (PFA), glutaraldehyde, for 24 hours.

Heat with validated protocol.

**5.1 (d) Autoclaving Contaminated Material**

All items removed from the BSL2+ must be autoclaved or surface disinfected with a **disinfectant name & concentration**. To autoclave, follow these steps:

1. All contaminated items should be autoclaved or disinfected as soon as possible after completion of your task.
2. Sign in on autoclave log sheet.
3. Autoclave on validated dry cycle or dispose of in the red bin of everything from within the BSL2+ facility.