

REPRODUCTIVE HEALTH PROGRAM

APR 2022



USC University of
Southern California

Office of
Environmental
Health and Safety

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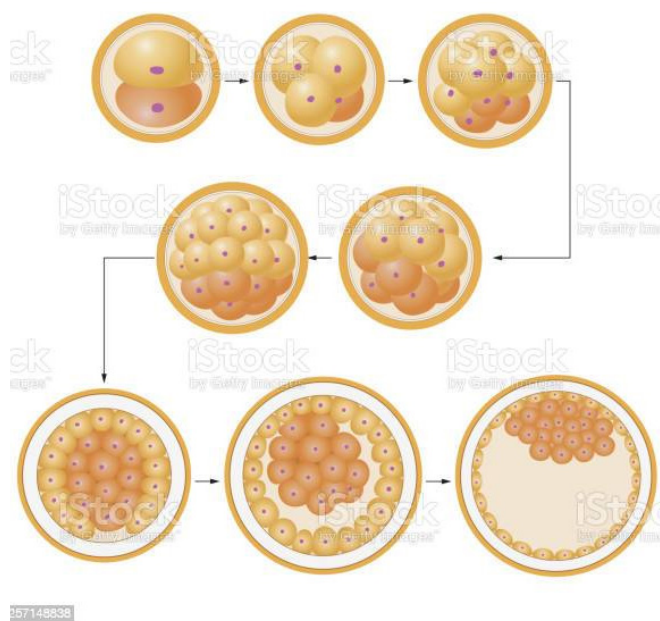


1.0 Purpose and Scope

The USC Reproductive Health Program (RHP) sets forth basic guidelines and best practices for USC faculty, staff, and students to work, study, or conduct research safely in USC facilities where possible exposures to reproductive hazards may exist. The RHP institutes additional safeguards for females who are pregnant or suspect they may be pregnant.

Unprotected exposure to ionizing radiation and certain hazardous materials may impact the developing fetus during the earliest stages of gestation and the rate of genetic abnormality. Standard laboratory safety precautions, outlined in USC safety rules, program manuals (Chemical Hygiene Plan, Biosafety Manual, Radiation Safety Manual), and Standard Operating Procedures (SOPs), are effective in reducing or eliminating reproductive health risks to male workers and non-pregnant female workers. For those working outside of laboratories, adherence to standard workplace safety precautions protects male and female reproductive health adequately.

Females who are pregnant, suspect they are pregnant, or planning a family that work with potential reproductive hazards are encouraged to discuss safety concerns with their healthcare provider, EH&S, or manager in advance of pregnancy whenever possible.



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2.0 Regulatory Requirements



Federal

OSHA

- Reproductive Hazards Overview: <https://www.osha.gov/reproductive-hazards>



State

CCR Title 8 General Industry Safety Orders

- [§5194. Hazard Communication](#)
- [§5191. Occupational Exposure to Hazardous Chemicals in Laboratories](#)



USC

[Biosafety Manual](#)

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3.0 Roles and Responsibilities

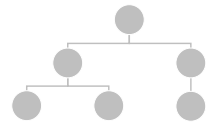
Schools/Departments

Schools, Departments, Research Institutes, and other sub-divisions of USC (e.g., FMS/FPM) shall support their managers in providing a safe working environment, including appropriate accommodation for pregnant workers.



Managers/Supervisors/Principal Investigators

Managers (including PIs) are responsible for providing a safe working environment. If a student or staff member brings reproductive health concerns to their manager, the manager shall endeavor to implement safety recommendations (e.g., modified work duties) made by EH&S or the individual's medical provider, and endeavor to provide reasonable accommodation requested by the individual.



Pregnant Workers

Workers have primary responsibility for their health decisions. When EH&S provides a University client with a safety assessment and safety recommendations under the RHP, it is the client's responsibility to discuss this information with their medical provider (e.g., primary care physician) in order to make informed health decisions.



Workers have discretion as to how and when to notify their manager of their pregnancy. EH&S will not communicate information relating to pregnant workers to managers without explicit consent. It is recommended that in order to best address potential safety concerns, workers notify managers of pregnancy in a timely manner.

Office of Environmental Health and Safety (EH&S)

EH&S shall manage and administer the RHP. Within EH&S, the division of responsibilities between the groups shall be as follows:

- **Occupational Health** - The principal owner of the RHP. Within Occ Health, the Industrial Hygienist shall be the lead on handling individual cases brought to EH&S and shall sign off on reports and recommendations provided to workers.
- **Lab Safety, Biosafety, Rad Safety, and Shop Safety** shall assist the Industrial Hygienist as needed in individual cases, to assess potential hazards and develop recommendations.



Safety Committees

The USC Safety Committees (Research Safety Oversight Committee (RSOC), Radiation Safety Committee (RSC), Institutional Biosafety Committee (IBC), Institutional Animal Care & Use Committee (IACUC), Campus-Wide Chemical Safety Committee (CCSC)) shall review the RHP, or relevant sections thereof, as appropriate.



Medical Providers

In general, EH&S always recommends that workers discuss reproductive health concerns with their medical provider. EH&S can provide information and assessment on specific hazards, and make safety recommendations (e.g., modified work practices or additional PPE); however, EH&S always advises that workers discuss this information with their medical provider and take decisions based on the medical provider's expert advice.





4.0 Workers

Radiation Workers

Fetuses are more sensitive than adult humans to mutagenic and other health effects of ionizing radiation. The US Nuclear Regulatory Commission (NRC) states: "The NRC has reviewed the available scientific literature and has concluded that the 0.5 rem (5 mSv) limit specified in 10 CFR 20.1208 provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers associated with radiation exposure during pregnancy." The 5 mSv limit is the maximum permissible dose to the embryo/fetus over the entire pregnancy. The NRC requires that any exposure be distributed reasonably evenly over time and not spiked over a small number of months.

Under NRC regulations, a radiation worker becomes a declared pregnant woman if they provide written notification of their pregnancy to their employer. Declaration is voluntary but highly recommended, because the low 5 mSv exposure limit only becomes enforceable when declaration is made. At USC, radiation workers may use the [Declaration of Pregnancy form](#) to declare pregnancy. Declared pregnant radiation workers will be issued a fetal dosimeter and the stricter dose limit will be enforced for the duration of the pregnancy.

Radiation workers with questions or concerns regarding prenatal radiation exposure may confidentially consult with the USC Radiation Safety Officer at any time. Supplemental information may be garnered from [EH&S' Radiation Safety FAQs](#), [NRC Guide 8.1.3 Instruction Concerning Prenatal Radiation Exposure](#), and [OSHA Ionizing Radiation, Pregnant Workers](#).

Non-Radiation Laboratory Workers

Appropriate use of and adherence to safety controls (e.g., fume hoods, biosafety cabinets, written standard operating procedures (SOPs), and personal protective equipment (PPE)) prevent laboratory personnel from receiving significant exposures to health-hazardous chemical and biological materials. However, due to the higher sensitivity of pregnant workers to some hazards coupled with an appropriately raised level of caution, normal safety controls may be deemed insufficient to protect pregnant lab workers from certain hazards. In such cases, additional safety precautions may be recommended, for example additional PPE or modified work duties to avoid working with particular hazardous materials.

Laboratory workers who are pregnant or suspect they are pregnant and who have any concerns about workplace safety may contact EH&S confidentially by emailing the Occupational Health at EHS@usc.edu.

Once an email is received, inquiries are generally handled as follows:

1. The query is passed to the Industrial Hygienist (IH) within Occupational Health. The IH contacts the worker to obtain more information, particularly the identity of any chemical or biological hazards the worker might be exposed to, and any procedures which may give increased risk or intensity of exposure. It is recommended the worker include their manager in the discussion, but this is entirely at the discretion of the worker.
2. The IH will review the hazards and risks, with the assistance of the Chemical Hygiene Officer and Biosafety Officer, as needed. Risk assessment may necessitate a site visit.
 - a. While extra care is warranted with any chemical work during pregnancy, some classes of chemicals require particular scrutiny. Chemicals that are classified as Reproductive Toxicants, Effects via Lactation, or Germ Cell Mutagen in SDSs will be assessed. Consideration will also be given to usage of acutely toxic materials, carcinogens, and other substances of significant health hazard, including materials listed as reproductive toxicants in the California Proposition 65 list.
 - b. In addition to the identity of chemicals, the conditions of use will be assessed. Close attention will be given to procedures which may result in higher exposures, for example, the use of volatile substances outside of a fume hood.
 - c. Pregnancy increases the hazards and risks of exposure to certain biohazardous agents, for example, enteroviruses, Cytomegalovirus (CMV), Zika virus, *Listeria* bacteria (*Listeria monocytogenes*), and *Toxoplasma* parasites. This will be assessed by the Biosafety officer.
 - i. Infectious agents that pose minimal risk to healthy individuals may pose a higher risk to pregnant woman or a developing fetus due to the changes in the immune response that occur during pregnancy. Some pathogens can cause significant damage to the fetus *in utero*. The classic group of teratogenic pathogens called TORCH includes *Treponema pallidum*, rubella virus, *Cytomegalovirus* (CMV) and herpes simplex virus. There are other infectious agents that may injure the fetus and impact placenta development and functions, including parvovirus B19, HIV, Varicella zoster, Zika virus, lymphocytic choriomeningitis virus (LCMV), Group B streptococcus, *Listeria monocytogenes*, *Neisseria gonorrhea*, *Coxiella burnetii*, and some parasites (*Toxoplasma*, *Plasmodium*, and *Trypanosoma*) and fungi *Coccidioides*.
 - ii. Live vaccine material may be a source of potential exposure. Varicella (chicken pox) and smallpox vaccines, MMR (measles, mumps, and rubella), HPV, and live flu (nasal) vaccines are not recommended during pregnancy. Certain travel vaccines like yellow fever, typhoid fever, and Japanese encephalitis should be avoided as well.
 - iii. Emerging infectious diseases may pose inadequately understood threats to pregnant females - see <https://wwwnc.cdc.gov/eid/article/12/11/pdfs/06-0152.pdf>.
3. The IH will develop safety recommendations based on the risk assessment and prepare a report (see Appendix for an example report). The report will be sent to the worker.

4. It is highly recommended that the worker give careful consideration to discussing the report with their healthcare provider, the most appropriate authority to advise on health-related decisions. It is also recommended that the worker share the report with their manager in order to begin discussing and implementing any safety recommendations.
5. With the worker's expressed permission, EH&S may solicit review/advice on a particular case by the safety committee or subcommittee having jurisdiction. No disclosure of any kind shall take place without explicit permission of the worker.

Safety recommendations may vary widely depending on the specific case. However, in most cases, the risk of hazardous exposure is very low. Therefore, the worker would be recommended to discuss certain aspects of the work (e.g., particular chemicals) with their healthcare provider. In rarer cases, the risk is judged to be greater and modified work practices or additional precautions may be recommended. For example, it may be recommended to stop working with a particular material or procedure, or to use a respirator under the voluntary program as an additional precaution. Recommendations will be made with an abundance of caution in mind. The worker should discuss the risk assessment and recommendations with their healthcare provider and follow their guidance.

EH&S will not pass any information to the worker's manager (who may be a Principal Investigator (PI)) without explicit consent from the worker. It is recommended that workers notify their manager of their pregnancy at an early stage to allow the manager to be included in safety discussions, but this is entirely at the discretion of the worker.

Non-Laboratory Workers

Non-laboratory positions may involve exposure to potentially hazardous chemicals (e.g. paints, solvents, adhesives), although usually less hazardous than chemicals encountered in labs. Other non-lab jobs may place physical demands on employees which may not be appropriate for personnel who are pregnant. For example, certain jobs require an ability to stand for long periods, run, or lift heavy equipment, parcels, or boxes. Physical hazards usually pose increasing risk as the pregnancy advances.

Non-laboratory workers who are pregnant or suspect they may be pregnant and who have any concerns about possible workplace chemical or physical hazards may discuss their concerns with their healthcare provider, manager, or the EH&S Occupational Health team at (323) 442-2200 EHS@usc.edu. All information will be handled confidentially.

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5.0 Non-Compliance

If a pregnant worker is concerned that insufficient effort was made to provide them with a safe working environment, the worker may confidentially report their concerns to EH&S by emailing EHS@usc.edu.

Effective resolution of the pregnant worker's concerns may require involvement of the school/department's upper management, school/department safety officers, the Office of Culture, Ethics and Compliance, and Safety Committees (school/department and campus-wide) and the sharing of critical information on behalf of the pregnant worker. The expressed consent of the pregnant worker would be needed.

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6.0 Appendix

Sample Report

Date: Month Day, 202X

To: XXXXXXXXXXXXXXXXX

From: XXXXXXXXXXXXXXXXX

Subject: Personal Risk Assessment - [Requestor]

Purpose of Assessment

[Requestor] contacted [EH&S contact] (EH&S/Biosafety) to request a personal risk assessment be conducted by EH&S. [EH&S contact] referred the request to [OHS Specialist] (EH&S/Occupational Health & Safety). [Requestor] is a Research Associate in the [Name], School/Department) under the supervision of [PI], PhD. According to [Requestor], she has worked in her current position for [XXX] years and [XX] months. [Requestor] works in ABC (building name) Laboratory XXX and in the Vivarium (ABC XXX). The building address is [3434 S. Grand Avenue, Los Angeles, CA 90089]. Originally, [Requestor] reported to EH&S that in the near future she was planning for pregnancy. On [Date], I received an update from [Requestor] that currently she is pregnant.

Actions

1. On [Date], I conducted a conference call with [Name] and requested additional information by email.
2. On [Date], I received the additional information from [Name].
3. On [Date], I sent the personal risk report to [Name].

Summary of Exposure to Animals, Biological Agents, Chemicals, Radiation, etc.

1. Animals – Yes. Mice in the vivarium (ABC XXX).
2. Biological – No biological agents used.
3. Chemicals – Yes. Laboratory (ABC XXX).
4. Radiation – No exposure to ionizing radiation.
5. Ergonomics – Not evaluated.

Chemicals, Drugs, Anesthetic Agents, Routine Tasks (where applicable, comments/precautions/hazard statements related to reproductive toxicity added below)

1. Naphthalene solution is prepared in ABC XXX. [Requestor] will be not be preparing the solution herself; and the technicians inject the mice. Hazard Statements: Germ cell mutagenicity - Mutagenicity (mammal cell test) chromosome aberration. Carcinogenicity - IARC (International Agency for Research on Cancer) Group 2B (possibly carcinogenic to humans); California Prop 65 carcinogen). (Ref. Sigma-Aldrich SDS (safety data sheet) dated 1/15/2020).
2. Anesthesia – Ketamine/Xylazine mixture used to inject the mice. According to [Requestor], Isoflurane and Sevoflurane anesthesia are not used because the lungs of the mice are studied.
3. TRI Reagent (contains <50% Phenol, <30% Thiocyanate compounds) is used for isolation of RNA. (Ref. SDS dated 1/5/2015). [Requestor] stated she is aware of the hazards of this solution and is having the technician perform the procedures involving TRI Reagent. Hazard Statements: There is a high level of developmental/reproductive toxicity concern for phenol, based on evidence for developmental toxicity in animals. Prenatal exposure to phenol has been associated with reductions in fetal weight and viability, and with an increase in unusual neurological symptoms. (Ref: <https://oehha.ca.gov/media/downloads/cnr/phenoldatasum.pdf>)
4. Retrieving caged mice and euthanasia – [Requestor] routinely travels to the vivarium (ABC XXX) to pick up the caged mice and moves them to the laboratory (ABC XXX). She euthanizes the mice by injecting Euthasol® (pentobarbital sodium and phenytoin sodium).
5. Tamoxifen – Hazard Statements: Reproductive toxicity Category 1B H360 (May damage fertility or unborn child). Carcinogenicity IARC Group 1 (Carcinogenic to humans). (Ref. Sigma-Aldrich SDS (safety data sheet) dated 12/15/2019)
6. Dissection of mice that were injected with Tamoxifen or Naphthalene – According to [Requestor], the mice are dissected after she waits for at least three days (usually more) after the technician has injected the mice with Tamoxifen or Naphthalene.
7. Bleomycin – Mice are administered Bleomycin via intratracheal instillation. The technician injects the mice with a Ketamine/Xylazine solution; then, [Requestor] prepares and instills the Bleomycin. Procedure performed under an exhaust hood in ABC XXX (see photo below). (Ref. Bleomycin info <https://ndclist.com/ndc/61703-332/package/61703-332-18>)
8. Placing lungs (or cells) in 4% Paraformaldehyde solution – According to [Requestor], she does not prepare the solution herself, someone else does and stores it at -20 Celsius. She will thaw the solution and use it to inflate the lungs and to place the lungs into it. Warnings: Germ cell mutagenicity - Mutagenicity (mammal cell test) chromosome aberration. Carcinogenicity - IARC (International Agency for Research on Cancer) Group 2B (possibly carcinogenic to humans); California Prop 65 carcinogen). (Ref. Sigma-Aldrich SDS dated 1/15/2020)

Biological Agents

[Requestor] confirmed that she does not work and will not be working with any of the following bio agents:

Bacteria	Viruses	Parasites	Fungi
• <i>Borrelia burgdorferi</i> (Lyme disease)	• Arenaviruses (Hemorrhagic fever, Lassa fever)	• Plasmodium sp. (malaria)	• Blastomyces dermatitidis (blastomycosis)
• <i>Campylobacter</i> sp.	• Cytomegalovirus	• Toxoplasma gondii (toxoplasmosis)	
• <i>Chlamydia psitaci</i> (psittacosis)	• Filoviruses (Marburg virus, Ebola virus)		
• <i>Chlamydia trachomatis</i>	• Hepatitis B virus		
• <i>Clostridium perfringens</i>	• Hepatitis C virus		
• <i>Listeria monocytogenes</i>	• Herpes simplex virus		
• <i>Mycobacterium tuberculosis</i>	• Human immunodeficiency virus (HIV-1)		
• <i>Mycobacterium leprae</i>	• Measles virus		
• <i>Neisseria gonorrhoeae</i>	• Mumps virus		
• <i>Pasteurella multocida</i>	• Parvovirus B19		
• <i>Borrelia</i> sp. (relapsing fever)	• Rubella virus		
• <i>Salmonella</i> sp.	• Varicella-zoster virus		
• <i>Treponema pallidum</i>			

Conclusions & Recommendations

1. You may share this information including the SDSs with your personal physician and supervisor.
2. Your personal physician can provide you with accommodations as deemed appropriate.
3. Follow the precautions described in the Chemical Hygiene Plan.

Thank you for contacting the Office of Environmental Health & Safety.

Industrial Hygiene Program Lead
Environmental Health & Safety

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