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CHEMICAL SAFETY PROTOCOL - NOTICE OF INTENT (NOI) GUIDELINE

A Chemical Safety Notice of Intent (NOI) is required when:

• A chemical is administered (via IP, IV, food, water, etc.) to a research animal for experimental purposes.

NOTE: EHSO exempts standard of care medications, anesthetics and perfusion fixatives from the NOI process as long as they are used for their intended purpose.

• The chemical has - or is expected to have - one or more of the characteristics listed in the following table.

HAZARD	CRITERIA	EXAMPLES
Acetyl cholinesterase inhibitors	All	Parathion, Physostigmine, Diisopropylfluorophosphate
Carcinogens	Regulated as an OSHA carcinogen	Benzidine, Ethyleneimine
	Listed by NTP as a Part A or Part B carcinogen	Cyclophosphamide, Tamoxifen, Doxorubicin HCl, ENU, MNU, PCBs, Streptozotocin
	Listed by IARC as a Group 1, 2A, or 2B carcinogen	Nickel compounds, Dimethyl sulfate, Etoposide (VP-16), Urethane
	Other known carcinogens	Azoxymethane
Chemotherapeutics	All	Busulfan, Cisplatin, Paclitaxel, Erlotinib, Fludara, Sutent, Pentostatin
Highly regulated chemicals	RCRA P-Listed chemicals	Heptachlor, Physostigmine
	RCRA U-Listed chemicals	DDT, ENU, MNU, Streptozotocin
	RCRA D-listed chemicals	Cadmium, Chromium, Lead, Mercury
	EPA PIC banned or severely restricted pesticides	DDT, Aldrin, Dieldrin, Heptachlor
	Severe environmental hazards	PCBs
Irritants (cause a severe reversible inflammatory effect at the site of contact)	Strong irritants	5-FU, Phosgene
Irreversible illness	All	MPTP, Thalidomide
Mutagens	Known or suspected to cause mutations in humans	BRDU
	Known to cause mutations in animals	Bleomycin Sulfate
Nanoparticles	All	Carbon nanotubes, polystyrene, titanium dioxide
Sensitizers (can cause an allergic reaction after repeated exposure)	All	Paclitaxel, Malathion, Isocyanates, Nickel salts
Teratogens	Known or suspected to cause teratogenic effects in humans	BRDU, Busulfan, 5-FU, Rotenone, RU 486, Thalidomide

Revision Date: 10-May-17

CHEMICAL SAFETY PROTOCOL - NOTICE OF INTENT (NOI) GUIDELINE

HAZARD	CRITERIA	EXAMPLES
	Known to cause	Bleomycin Sulfate, Erlotinib,
	teratogenic effects in animals	Fludara
Toxics and Toxins	LD50 (oral, rat) < 500	Tetrodotoxin, picrotoxin, 5-FU,
	mg/kg	Rotenone, Chlorpyrifos, DMBA
	LD50 (dermal, rat) <	Aldrin, Chlorpyrifos, Dieldrin
	1,000 mg/kg	
	LC50 (rat) < 200 ppm	Acrolein, Diisopropyl
		fluorophosphates, Dimethyl sulfate,
		Parathion, Phosgene
	Acute or chronic organ	Potassium Cyanide, PCBs, Nickel
	toxicity	Sulfide

Examples of exempt chemicals include, but are not limited to:

- Standard of care medications: Acetaminophen, Amiodarone, Aspirin, Heparin, Meloxicam, Prozac, Saline, Sodium bicarbonate
- Anesthetics & Analgesics: Buprenorphine, Isoflurane, Ketamine, Telazol, Tricaine
- Perfusion/tissue fixatives: Acrolein, Formalin, Formaldehyde, Glutaraldehyde, Paraformaldehyde

The Chemical Safety Protocol NOI Submission and Approval Process:

NOTE: the required forms are electronically writable

- The principal investigator (PI) must complete a Chemical Safety Protocol Notice of Intent Form and submit to EHSO. **NoTE**: All personnel must have taken Lab Safety Training within the past year to obtain approval.
- The Environmental Compliance Officer will review the NOI, conduct a risk assessment, and ask any applicable questions before submitting the NOI to the Chemical Safety Subcommittee of the IHBC.
- The Subcommittee will assign the chemical to an Animal Control Level between 1 and 4 (1 is the lowest risk; 4 the highest risk) which specifies the health and safety controls that must be in place while conducting the research.
- The assignment is based on the hazards of the chemical and/or its metabolites, the route of administration, dosing information, etc. Animal Control Level 4 is applied to the highest risk chemicals and has the most restrictive requirements.
- Depending on the Animal Control Level assigned, the personnel listed on the protocol may be required to attend further training. The PI will be notified via email if further training is required.
- The Environmental Compliance Officer and the veterinarian will approve the NOI when all requirements have been met. The approved NOI is then sent to the IHBC for final approval.
- An electronic copy of the Chemical Safety Protocol Approval Letter and Chemical Safety Protocol Hazard Assessment & Approval Form will be returned to the PI and specify any procedures (wearing certain personal protective equipment, using certain ventilation devices, posting signs, etc.) that must be followed in order to maintain approval.
- The EHSO or IACUC retains the right to inspect compliance with these procedures and suspend a protocol, if necessary.

Chemical Safety Protocol Amendments and Renewal Processes:

NOTE: the required forms are electronically writable

 The Chemical Safety Protocol must be amended if any of the following circumstances arise during the current approval year:

CHEMICAL SAFETY PROTOCOL - NOTICE OF INTENT (NOI) GUIDELINE

- Adding or removing personnel
- o Changing, adding, or deleting a title
- Adding a chemical agent
- o **NOTE**: Chemical Safety may request that another NOI be submitted.
- Changing routes of administration, dose, experiment duration, or days of treatment for the approved chemical agent.
- o Changing animal species, lab location, or animal housing location.
- Transferring the protocol to another PI at Emory
- Terminating the protocol
- Chemical Safety Protocols must be renewed annually. The EHSO will notify the PI (via email) two months prior to protocol expiration date.
- Complete the Chemical Safety Protocol Form: Amendment or Renewal Form electronically and submit to Environmental Compliance via email.

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