

Safety Approval Form

For work with newly synthesized chemicals, biologically active substances*, or natural toxins** in experimental animals.

Before submitting an Animal Study Protocol or Animal Study Protocol Amendment to use chemicals with unknown properties (or not FDA approved) in the experimental animals, you must complete the questionnaire on the following pages.

This information is required for proper risk assessment evaluation to protect human health and prevent exposure. When complete, submit your form to animalresearchsafety@northwestern.edu.

*Biologically Active Substance (BAS): Substance that is produced by or extracted from a biological source, such as micro-organisms, organs and tissues of either plant or animal origin, cells or fluids of human or animal origin, and biotechnological cell constructs and for which a combination of physico-chemical-biological testing and the production process and its control is needed for its characterization and the determination of its quality. Examples: snake venom, antibodies.

**Natural toxins: toxic compounds that are naturally produced by living organisms. These toxins are not harmful to the organisms themselves but they may be toxic to other creatures, including humans. These chemical compounds have diverse structures and differ in biological function and toxicity. Some toxins are produced by plants as a natural defense mechanism against predators, insects or microorganisms, or as consequence of infestation with microorganisms, such as mould, in response to climate stress (such as drought or extreme humidity). Examples: Muscimol from *Amanita muscaria* mushroom, algal toxins.

Safety Approval Form

For work with newly synthesized chemicals, biological active substances,
or natural toxins in experimental animals.

Name of Principal Investigator:

Person Submitting Form:

Section A: Physical and Chemical Properties

1. Full name of chemical (no abbreviations):

2. Chemical formula:

3. CAS number (If applicable):

If you supply CAS number, you do not need to complete the rest of this form.

4. Name and address of chemical supplier/source:

If chemical compounds were made internally, provide the department and PI name.

5. Potential hazards (check all that apply):

☐ Flammable

☐ Oxidizer

☐ Corrosive

☐ Toxic

☐ Carcinogen

☐ Irritant

☐ Other (please explain):

6. How will you receive this compound (check all that apply):

☐ Powder

☐ Solution or liquid

☐ Gas

☐ Solid

Section B: Toxicity to Humans

1. What is the intended use of the chemical?

Provide the proposed mechanism of action. For example, BrdU (Bromodeoxyuridine/5-bromo-2-deoxyuridine) is an analog of the nucleoside thymidine used in the BrdU assay to identify proliferating cells. During the BrdU assay, BrdU is incorporated into replicating DNA and can be detected using anti-BrdU antibodies.). Are there any analogs or similar FDA approved drugs or chemical compounds already on market? If so, please provide references.

2. What is the LD50 for the animal model and route of exposure?

If it is unknown, is the material hazardous to human? If so, how was toxicity established (for example cell toxicity studies)? Was this compound tested on humans in clinical trials?

3. What effect are you looking to cause in animals? Could the same effect occur in humans?

4. How many animals will be housed simultaneously in the animal facility? List animal species and approximate weight.

5. What is the administration dose, number of doses, amount used per procedure and delivery form (e.g., solution or food pellets)? Include routes of delivery (e.g., oral, gavage, topical, injection).

6. Will any hazardous metabolite or unmetabolized chemicals be excreted in the urine/feces?

☐ Yes

☐ No

Section C: Exposure Prevention

1. What PPE is required for drug preparation? (check all that apply)

☐ Lab coat

☐ Nitrile gloves

☐ Mask

☐ Other (please explain):

2. What PPE is required for personnel administering drug to animals? (check all that apply)

☐ Lab coat

☐ Nitrile gloves

☐ Mask

☐ Other (please explain):

3. Does the preparation process require a chemical fume hood?

☐ Yes

☐ No

4. Is a chemical fume hood/biosafety cabinet required for delivery to the animal?

☐ Yes

☐ No

5. Specify possible kinds of exposure (e.g., eye contact, dermal, ingestion, inhalation) and what first aid measures will be taken if exposure occurs.

Not required if manufacturer's Safety Data Sheet is available.

Save your completed form and send to animalresearchsafety@northwestern.edu.