NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

INFORMED CONSENT

Study: National Toxicology Program Level of Concern Categories Study

OMB #: 0925-XXXX

Expiration Date: XX/XXXX

Principal Investigators: Mary Wolfe, PhD, NIEHS, 919-541-7539
Kristina Thayer, PhD, NIEHS, 919-541-5021

Associate Investigator: Kyla Taylor, NIEHS, 919-316-4707

INTRODUCTION

You are invited to take part in a research study being conducted by the National Toxicology Program at the National Institute of Environmental Health Sciences (NIEHS),

First, we want you to know that:

- Taking part in this research study is entirely voluntary.
- You may choose not to take part, or you may withdraw from the study at any time.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions.

What is the purpose of this study?

The purpose of this study is to update the Level of Concern framework to improve its use as a risk communication tool.

The National Toxicology Program (NTP) conducts literature-based evaluations to identify substances in our environment that are hazards for human health. NTP has used a five-point scale to communicate its opinion, or "level of concern" (LoC) conclusion, regarding the potential for environmental substances, physical agents, or mixtures (collectively referred to as "substances") to cause adverse health effects in humans under specific exposure conditions or for a specific population. Recently, NTP implemented a new approach with systematic-review methodologies for conduct of these evaluations. Although LoC categories have been a useful communication tool, NTP has identified confusion among some of its

scientific advisors and the public regarding what the LoC categories mean and how conclusions are reached.

As part of its implementation of systematic-review methodologies, NTP is now updating the LoC framework, including re-assessing the LoC categories, to determine what changes are needed to ensure integrated consideration of relevant and reliable data and enhance transparency in describing how conclusions are reached. This effort should improve the LoC framework as a risk communication tool.

How many volunteers will take part in this study?

Up to 160 volunteers overall are needed to take part in this study.

Who is funding this study?

The National Institute of Environmental Health Sciences (NIEHS), which is a part of the National Institutes of Health (NIH) will provide all funding for this study. There is no compensation to individuals who participate.

Why am I being invited to take part in this study?

You are being asked to take part in this study because you are a scientist from one of five NTP stakeholder sectors (academia, industry, non-governmental organization, and federal and state agencies). This study is limited to scientists from these sectors because they use LoC conclusions from NTP literature-based evaluations, are familiar with NTP and its research and analysis activities, and/or are familiar with the conduct, analysis, interpretation, and use of data from environmental health hazard assessments.

What will happen if I agree to take part in this study?

If you agree to participate, you will be asked to complete four separate web-based sessions over a six-month period, each session lasting approximately 1-2 hours. If you do not agree to participate there is nothing else you will need to do.

How long will my participation in this study last?

Your participation in this study will require approximately 6 hours (average 1.5 hours per session) of your time, spread out over 6 months.

What will I be asked to do in this study?

During each session, you will be asked to read electronic cards that describe various hazard-exposure scenarios and based upon your expertise, place each card into a bin that reflects your opinion regarding the LoC for an identified target population. In some instances, you will be asked to identify factors (e.g., information from human and/or animal studies or on exposure) that influenced your decision and rate your confidence in your decision. At the beginning of each of the four sessions, you will view an approximately 10-minute video with instructions on how to use the web-based instrument for sorting and binning the LoC cards. You would be allotted 2 weeks to complete a session and you would be allowed to work on a session over several days.

Study Reminder Calls or Communications

During the study, you would be contacted by email. Your responses in the LoC card sessions would be identified in our database by a User ID and not linked to you specifically.

What are the possible benefits of the study?

There is no direct benefit to you from participating in the study. Through your participation, knowledge will be gained that would enable the NTP to improve its LoC framework as a risk communication tool.

What are the possible risks associated with the study?

There are no identified risks associated with participation in the study. It is your choice if you want to tell other people about participating in the study.

Do I have an alternative to participating?

Yes, the alternative to participating in this study is to not participate.

What will happen to the data collected from me?

The personal identifiable information you provided upon registration will be stored encrypted in a password-protected, restricted-access electronic database at NIEHS. Data from the LoC card-sorting exercises will be stored in a password-protected, restricted-access electronic database at NIEHS. Each study participant will have a User ID number that is linked with data from the LoC card-sorting exercises for data analysis. Data undergoing analysis will be kept in password-protected computers and only authorized study personnel and approved collaborators will have access to the data.

Will I be given results from the study?

The study will be published when complete. Anonymized individual response data will be released as part of the study report.

Will it cost me anything to participate in this study?

There are no costs to you other than your time for participating.

Will I be paid for participating in this study?

You will not be offered payment for your participation in the study.

What if I want to stop participating in this study or am withdrawn?

Your participation in this study is entirely voluntary and you may withdraw at any time. If you decide to withdraw, there will be no penalty or loss of benefits to which you are otherwise entitled. If you wish to discontinue your participation or if you have any concerns, please contact **Dr. Kristina Thayer at (919-541-5021) or Dr. Mary Wolfe at (919-541-7539)**.

Please note that NIEHS/NTP may stop the study at any time.

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in scientific journals or at scientific meetings, the people who take part are not named and identified.

2. Conflicts of Interest. The NIH reviews NIH staff researchers at least yearly for conflicts of interest. The following link contains details on this process: process http://sourcebook.od.nih.gov/ethic-conduct/COI_Guide_121209.pdf. You may ask your research team for additional information or a copy of the Protocol Review Guide.

3. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigators, Dr. Kris Thayer at **(919) 541-5021** or Dr. Mary Wolfe at **(919) 541-2454**.

If you have any questions about your rights as a research participant, please contact the NIEHS Office of Human Research Compliance (OHRC) at **919-541-3852**.

4. Consent Document. Please print a copy of this document in case you want to read it again.

STATEMENT OF VOLUNTARY CONSENT

For the purposes of this study, I am aware of the procedures to be followed and the risks and benefits. I understand whom to contact if I have questions and that if selected to participate, I may leave the study at any time.

I have read the explanation about this study and understand whom to contact if I have questions. I hereby consent to take part in this study, if selected.

☐Agree

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Name