OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 12731

To: Thayer, Kristina
NIEHS
530 DAVIS DR RM 2150

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
One hundred experts, about 20 from five sectors (federal government, state government, industry, academia, and non-government organizations) will be recruited, including toxicologists, epidemiologists, and experts in risk assessment. Experts will be instructed to sort through 30 "cards", cards are theoretical hazard identification and exposure level scenarios, into as many categories as they wish. The categories will represent their level of concern (LoC) based on the given scenario with the extreme categories representing

Original Request Received in OHSR on: 12/11/2014

Responsible NIH Research Investigator(s): Kristina Thayer, PhD NIEHS

OHSR review of your request dated Thu, Dec 4, 2014 has determined that:

☐ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☒ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person JE Admin Assist. CB

Note:

Julie M. Eiserman — Signature
Policy Analyst, OHSRP — Title
1/8/2014 — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

OHSRP #12731

REQUEST FORM: OHSRP DETERMINATION FORSURVEYS, INTERVIEW PROCEDURES, PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH

Date of Request: 12-4-14

Requestor's name: Kyla Taylor **Email:** taylorkw@niehs.nih.gov

Role: __Administrative support __Investigator _X_Other, explain: Contributor

Name of NIH Senior Investigator:

Senior investigators:
Kris Thayer, Ph.D., NIEHS/DNTP/OHAT
email: thayer@niehs.nih.gov
phone: 919-541-5021
building/room: Keystone 2150

Mary Wolfe, Ph.D., NIEHS/DNTP/OLPR
email: wolfe@niehs.nih.gov
phone: 919.541.7539
building/room: Keystone 2130

Is the NIH Senior Investigator an NIH employee(FTE)? _X___Yes _____No

Senior Investigator Signature: Kristi Thay
(*Signature of Investigator who will conduct research*)

Supervisor Signature: John R Bucher
(*Signature of official for IC, e.g., Lab/Branch Chief*)

Name of NIH investigator conducting research if not the NIH Senior Investigator: *(i.e, junior investigator, contractor investigator, fellow, student)*

Please provide the name and e-mail of any others who should receive a copy of the OHSRP determination: Kyla Taylor; taylorkw@niehs.nih.gov

1. **What role will the NIH investigator(s) have in this research project?** *(check all that apply)*
   _X_ Conduct research activity
   _X_ Analyze samples/data only
   __ Consultant/advisor to collaborator(s)
   _X_ Author on publication(s)/manuscript(s) pertaining to this research
   __ Other, please describe: _____

REQUEST FORM: OHSRP DETERMINATION FORSURVEYS, INTERVIEW PROCEDURES, PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH

2. Title: NTP Research Project: Updating Level of Concern Categories
(Provide a short title to distinguish this activity from other projects that you may have)

3. Describe in lay terms the research activity that will be performed:

One hundred experts, about 20 from five sectors (federal government, state government, industry, academia, and non-government organizations) will be recruited, including toxicologists, epidemiologists, and experts in risk assessment.

Experts will be instructed to sort through 30 "cards", cards are theoretical hazard identification and exposure level scenarios, into as many categories as they wish. The categories will represent their level of concern (LoC) based on the given scenario with the extreme categories representing "high" and "negligible" LoC scenarios. Each expert will be trained using a web-based instructional script with visual instructions on sorting the cards and documenting the results and will work independently. Each expert using a unique password will access the case-study cards on a password-protected Website. Using a web-based tool, experts will sort the cards into as many LoC categories as they wish. Experts will be given 2 weeks to complete the task (trial 1). The outcomes from individual experts will not be shared with the other experts.

Experts will repeat the exercise a second time (trial 2), approximately 3-5 weeks following the initial session, to evaluate consistency of response within individuals. For trial 2, the 30 cards will be reordered randomly. Following completion of the card sorting for trial 2, experts will be asked to provide descriptive labels for the LoC categories they identify.

4. Proposed start date March, 2015 **Proposed completion date** September, 2018

5. Specify the nature of the data: *(select all that apply)*

__ Interview procedure
X_ Survey
__ Educational Testing
__ Educational Research
__ Research on public benefit or service programs
X_ Other, describe: Risk communication

6. What kind of human data (e.g., private information, responses to questionnaires, test results, recordings) will be collected in your research?
Responses to survey questions

7. Will human data be? (*select all that apply*)

Collected Yes X_ No__
Received Yes__ No__

Sent Yes__ No__

8. If receiving or sending, list the collaborating investigator(s):

Name Institution/IC Address/e-mail FWA number*

---

9. Where are the subjects of this research activity located? *(Provide a general description or complete the institutional information below)*

This research will be web based

Institution: NA Contact Name: _____

Address: _____ Phone: _____

10. Will NIH investigator(s) have direct contact or intervention with the subjects of the study? (For example, by interviewing, surveying or recording the subjects?)

Yes X No __

If yes, what is the age range of subjects involved in the research?

___ Children aged < 18 years

__X__ Adults aged ≥ 18 years

11. Who will collect the data or information?

(a) ___ NIH Investigator

(b) ___ non-NIH Collaborator

(c) _X_ NIH Contractor

(d) __ Other, specify

If b or c, will an Honest Broker or data use agreement be used? Yes X No X

If yes, complete and attach the Honest Broker Assurance or data-use agreement to this submission; e-mail ohsr_nih_ddir@od.nih.gov to request a form.

12. Select the best description that applies to the human data or information:

_X_ Data or information will not contain any identifiable information, nor can it be linked to individual subjects by you or your collaborators.

__ Data or information will be recorded in such a manner that subjects can be identified directly or through identifiers linked to the subjects

13. Per NIH guidance, are all conflicts of interest by NIH employees (sender or receiver), if any, resolved? _X__Yes _____No**

**A Federalwide Assurance (FWA) is issued by the U.S. Department of Health and Human Services (DHHS)/ Office of Human Research Protections (OHRP) to institutions which receive Federal funds/support to conduct human subjects research. To search for the FWA# for domestic or international institutions go to http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc*

***If the answer is "No", note that OHSRP will be unable to make a determination and research may not proceed until all conflicts are resolved. For more information, see the October 2011, A Guide to Preventing Financial and Non-Financial Conflict of Interest in Human Subjects Research at NIH. For assistance review the list of Ethics Coordinators and find the contact for your IC: http://ethics.od.nih.gov/coord.pdf*

Eiserman, Julie (NIH/OD) [C]

From: Taylor, Kyla (NIH/NIEHS) [E]
Sent: Thursday, January 08, 2015 5:04 PM
To: Eiserman, Julie (NIH/OD) [C]
Cc: Thayer, Kristina (NIH/NIEHS) [E]; Wolfe, Mary (NIH/NIEHS) [E]
Subject: RE: Follow Up re: Req fo Determination OHSRP 12731

Hi Julie,

Thank you for your email. In answer to your questions:

Yes, all respondents will be adults over 18.

You are correct, we are not using an honest broker.

We believe we are doing research defined as *"*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

With the data we plan to update NTP's Level of concern framework (as part of implementing systematic reviews) to enhance transparency in describing how conclusions are reached, and identify strategies for improving the LoC framework as a risk communication tool.

We will get you the documents with the language that will be administered to the participants soon.

Thanks,
Kyla

From: Eiserman, Julie (NIH/OD) [C]
Sent: Thursday, January 08, 2015 2:45 PM
To: Taylor, Kyla (NIH/NIEHS) [E]
Subject: RE: Follow Up re: Req fo Determination OHSRP 12731

Hello Kyla,

I apologize for the delay. We were overloaded with determinations before the break and then I was on vacation. I am reviewing your request for determination and have some questions.

You didn't answer the age question. Can you confirm all respondents will be adults over 18? The honest broker question is still checked as "yes", but you aren't using one, correct?

I am still struggling with whether this is human subjects research or falls under the category of quality improvement or assessment. You mentioned that "The purpose of the research activity is to improve risk communication language used by the National Toxicology Program" which sounds like QI to me. It makes a difference in what type of determination I give you in our records (not human subjects research or exempt human subjects research). In other words, would you say that you are 'collecting data regarding the implementation of a practice for clinical, practical, or administrative purposes'? Or would you say you are doing research which is defined as *"*a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Can you explain what you plan to do with the data?

The form instructions (on the cover page) ask that you 'please attach the survey, questionnaire, interview script or test to the completed form together with the consent language that will be administered before the subject participates in the activity'. If you have those documents, could you please send them?

Julie M. Eiserman, MA, CCRP [C]
Health Science Policy Analyst
Office of Human Subjects Research Protections
10 Center Drive, Bldg. 10, Suite 2C146
Bethesda, MD 20892-1154
Office Phone: 301-402-3444
Fax: 301-402-3443
OHSRP website: https://federation.nih.gov/ohsr/nih/index.php (NIH login required)
Public site: http://ohsr.od.nih.gov/

From: OHSR (NIH/DDIR)
Sent: Thursday, January 08, 2015 1:44 PM
To: Taylor, Kyla (NIH/NIEHS) [E]
Subject: RE: Req fo Determination Rec'd_OHSRP 12731

Hi Kyla,
Thanks for your email. This submission should be sent out to you by Friday afternoon. Thanks for your patience through the holiday season delays.
Chris

From: Taylor, Kyla (NIH/NIEHS) [E]
Sent: Thursday, January 08, 2015 11:47 AM
To: OHSR (NIH/DDIR); Thayer, Kristina (NIH/NIEHS) [E]
Subject: RE: Req fo Determination Rec'd_OHSRP 12731

Hello Chris,

Could you please update us on the status of our Request for Determination: **OHSRP #12731**?

Thanks,
Kyla

From: OHSR (NIH/DDIR)
Sent: Wednesday, December 17, 2014 11:34 AM
To: Thayer, Kristina (NIH/NIEHS) [E]
Cc: Taylor, Kyla (NIH/NIEHS) [E]
Subject: Req fo Determination Rec'd_OHSRP 12731

Good morning Dr. Thayer,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12731.** Please use this number in any future correspondence regarding this study.

Protocol Title: NTP Research Project: Updating Level of Concern Categories

Thank you.
Sincerely,
Chris Brentin
OHSRP - National Institutes of Health

Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

OHSR (NIH/DDIR)

From: Taylor, Kyla (NIH/NIEHS) [E]
Sent: Thursday, December 11, 2014 11:09 AM
To: OHSR (NIH/DDIR)
Cc: Thayer, Kristina (NIH/NIEHS) [E]
Subject: RE: Honest broker form request
Attachments: OHSR Request Form 12-11-14.pdf

Julie,

I have made the changes you suggested and attached the document with signatures. Are you the person I should send this to? Please let me know if you need anything else.

Thanks for your help!
Kyla

From: OHSR (NIH/DDIR)
Sent: Tuesday, December 09, 2014 5:59 PM
To: Taylor, Kyla (NIH/NIEHS) [E]
Cc: Thayer, Kristina (NIH/NIEHS) [E]
Subject: RE: Honest broker form request

Hi Kyla,

I would make the following changes.

5. I would also check "survey"

10. How will subjects be recruited? I am guessing that someone will need to contact them to request that they participate and someone on the team will know who is being contacted? If so, I would change your answer here to "yes".

11. You can answer 'no' to the honest broker question.

Once you have made these changes and gotten the signatures, I think you are good to go.

Julie M. Eiserman, MA, CCRP [C]
Health Science Policy Analyst
Office of Human Subjects Research Protections
10 Center Drive, Bldg. 10, Suite 2C146
Bethesda, MD 20892-1154
Office Phone: 301-402-3444
Fax: 301-402-3443
OHSRP website: https://federation.nih.gov/ohsr/nih/index.php (NIH login required)
Public site: http://ohsr.od.nih.gov/

From: Taylor, Kyla (NIH/NIEHS) [E]
Sent: Tuesday, December 09, 2014 3:40 PM
To: OHSR (NIH/DDIR)

Cc: Thayer, Kristina (NIH/NIEHS) [E]
Subject: RE: Honest broker form request

Julia,

The purpose of the research activity is to improve risk communication language used by the National Toxicology Program. Participants will be non-scientists and experts in toxicology, epidemiology, and risk assessment. Experts would be required to have a Masters of Science, PhD, MD, or equivalent degree and at least 3 years' documented employment working in public health or a risk assessment-related activity, such as developing hazard identification conclusions based on human and/or animal data or conducting qualitative or quantitative characterizations of risk.

Data collection will be web based. Participants will be asked to complete an exercise where they read through different theoretical hazard identification and exposure scenarios and categorize the scenarios based on their level of concern. They will provide descriptive labels for the categories they create. We are not asking for any personal information.

I've attached the form as I've filled it out so far. Hopefully that will help. I've also CC'd my supervisor in case she wants to weigh in on the information I've provided.

Thanks,
Kyla

From: OHSR (NIH/DDIR)
Sent: Tuesday, December 09, 2014 3:09 PM
To: Taylor, Kyla (NIH/NIEHS) [E]
Subject: RE: Honest broker form request

I am sorry. I don't feel like I have enough information to help you and I think our form (which is being revised) is confusing. My questions to you are these:

What is the purpose of the research activity? In other words what do plan to do with the data? For example if it is for quality improvement purposes vs. to publish research data you may not need a determination.

Can you tell me more about who the research subjects be? What kinds of data will be collected? How the data be collected? Live, survey, telephone…. If the NIH contractor is a member of the research team then they can't be an honest broker.

It isn't necessarily a problem for you to have access to the identities of survey participants. It depends on what type of information you are collecting. I think it makes more sense for you to submit the form and a copy of the survey questions to our main email address and then I can review and we can talk about it more.

Julie M. Eiserman, MA, CCRP [C]
Health Science Policy Analyst
Office of Human Subjects Research Protections
10 Center Drive, Bldg. 10, Suite 2C146
Bethesda, MD 20892-1154
Office Phone: 301-402-3444
Fax: 301-402-3443
OHSRP website: https://federation.nih.gov/ohsr/nih/index.php (NIH login required)
Public site: http://ohsr.od.nih.gov/

From: Taylor, Kyla (NIH/NIEHS) [E]
Sent: Monday, December 08, 2014 10:47 AM
To: OHSR (NIH/DDIR)
Subject: RE: Honest broker form request

Hi Julia,

I am filling out an OHSRP request form called "OHSRP DETERMINATION FOR SURVEYS, INTERVIEW PROCEDURES, PROGRAM EVALUATION, EDUCATION TESTING AND RESEARCH". We are submitting this to see whether or not we need to go through IRB. Our study will have participants, who are all experts in risk assessment, answering questions about hypothetical scenarios. It seems that the main issue is whether or not we will have access to identifying information on the participants. We don't need to have access to this information for our study and the request form asks:

"Who will collect the data or information? If b or c, will an Honest Broker or data use agreement be used?" I've answered "c" which is an NIH contractor.
"*If yes, complete and attach the Honest Broker Assurance or data-use agreement to this submission; e-mail ohsr_nih_ddir@od.nih.gov to request a form."*

I assumed we would need an honest broker to show that we do not need access to identifying information. Is that correct?

Thanks,
Kyla

From: OHSR (NIH/DDIR)
Sent: Monday, December 08, 2014 10:38 AM
To: Taylor, Kyla (NIH/NIEHS) [E]
Subject: RE: Honest broker form request

I want to make sure that you understand that these items are not requirements necessarily. It depends on what you are trying to do.
A data use form is not a requirement when you submit a determination request, rather it is something that you would get from tech transfer, esp. if you are sending data out to another site.

The honest broker assurance form can be found here: https://federation.nih.gov/ohsr/nih/formtmp.php

An honest broker agreement is only needed in certain circumstances. Can you clarify what you are trying to do?

Julie M. Eiserman, MA, CCRP [C]
Health Science Policy Analyst
Office of Human Subjects Research Protections
10 Center Drive, Bldg. 10, Suite 2C146
Bethesda, MD 20892-1154
Office Phone: 301-402-3444
Fax: 301-402-3443
OHSRP website: https://federation.nih.gov/ohsr/nih/index.php (NIH login required)
Public site: http://ohsr.od.nih.gov/

From: Taylor, Kyla (NIH/NIEHS) [E]
Sent: Monday, December 08, 2014 9:13 AM
To: OHSR (NIH/DDIR)
Subject: Honest broker form request

Hello,

I'd like to request an Honest Broker Assurance and data-use agreement form to submit with my application to OHSRP.
Thanks,
Kyla

Kyla Taylor, MS
Health Scientist
Office of Health Assessment and Translation
National Toxicology Program
National Institute of Environmental Health Sciences

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Wednesday, December 17, 2014 11:34 AM
To: Thayer, Kristina (NIH/NIEHS) [E]
Cc: Taylor, Kyla (NIH/NIEHS) [E]
Subject: Req fo Determination Rec'd_OHSRP 12731

Good morning Dr. Thayer,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12731.** Please use this number in any future correspondence regarding this study.

Protocol Title: NTP Research Project: Updating Level of Concern Categories

Thank you.
Sincerely,
Chris Brentin
OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail

NTP
National Toxicology Program

Updating Level of Concern Categories

Kris Thayer, Ph.D., OHAT
Mary Wolfe, Ph.D., OLPR

PRC Meeting, October 31, 2014

Level of Concern (LoC) Project

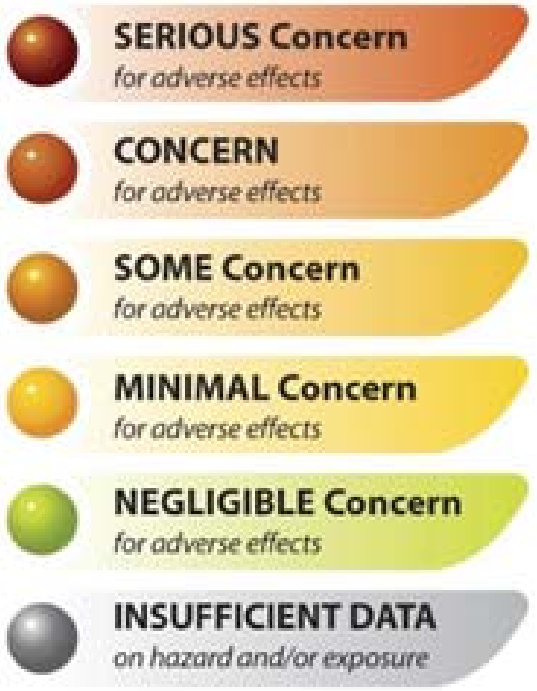
- Project leaders
  - Kris Thayer, OHAT
  - Mary Wolfe, OLPR
- Contributors
  - Kyla Taylor, OHAT
  - Shepherd Schurman, CRU
  - Grace Kissling, Biostatistics Branch
  - Mike Shelby, retired NIEHS
  - David Budescu, Fordham University (technical advisor)
  - Thomas Wallsten, University of Maryland (technical advisor)
  - Barbara Forsyth, private consultant

Outline

- Background on current LoC framework
- Project to revise LoC framework
- Specific Aim 1 of project
- Next steps: Specific Aims 2 and 3

Level of Concern (LoC)

- System used as a means for NTP to communicate its interpretation of the potential for the chemical under evaluation to adversely affect human reproductive health or children's development.
- NTP's conclusions are expressed as "level of concern"
- 5 categories plus 1 category for "insufficient data"



How are LoC conclusions reached?

Integrates evidence for toxicity + extent of human exposure

Separately determined for human and animal evidence

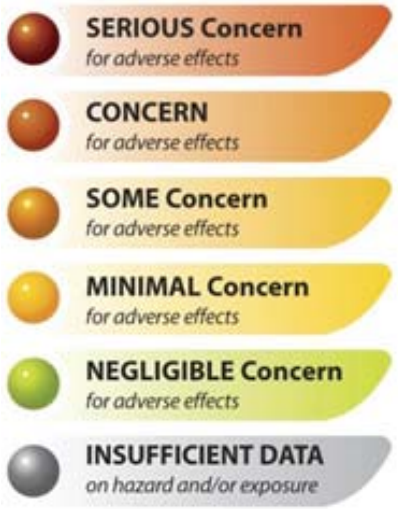
+

Extent of human exposure and other factors

=

LoC Conclusions

- LoC conclusions developed for 20 substances including acrylamide, amphetamines, BPA, bromopropanes, ethylene glycol, fluoxetine, hydroxyurea, methanol, methylphenidate, phthalates, propylene glycol, soy infant formula, and styrene
  - There is *serious concern* that certain intensive medical treatments of male infants may result in di-(2-ethylhexyl) phthalate exposure levels that adversely affect development of the male reproductive tract.
  - There is *some concern* for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A.
  - There is *negligible concern* for adverse developmental and reproductive effects from acrylamide exposure to the general population.
  - There are *insufficient* data to draw conclusions regarding possible reproductive effects of methylphenidate in humans.



Why does NTP need to update its LoC categories?

- Confusion over what the different LoC categories mean (e.g., “some concern” vs “minimal concern”)
  - Need to clarify what LoC categories mean and how NTP reaches a conclusion
- Is 5 “concern” categories the appropriate number?
- What are the best modalities to use (color, text, numbers, etc.) to communicate LoC?
- Can we address level of confidence / uncertainty in communicating LoC conclusion?
- OHAT Approach for systematic review has a new process and categories to describe hazard conclusions (Rooney *et al.* 2014)
  - Need to address how new hazard conclusions fit within LoC framework

Rooney *et al.* Systematic review and evidence integration for literature-based environmental health assessments. *Environ. Health Perspect*. 2014 Jul;122(7):711-8. doi: 10.1289/ehp.1307972. Epub 2014 Apr 18. PMID: 24755067.

How are LoC conclusions reached?

Integrates evidence for toxicity + extent of human exposure

Separately determined for human and animal evidence

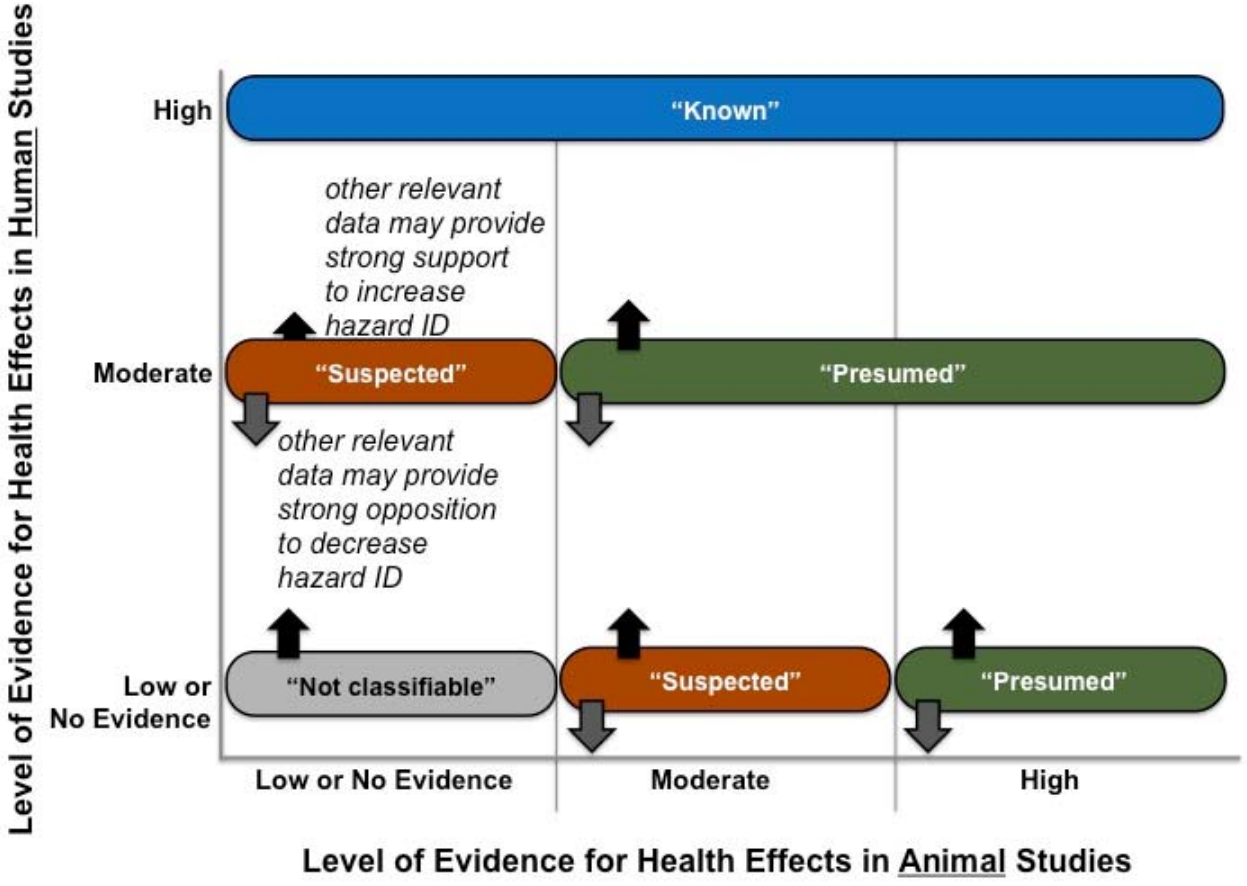
+

Extent of human exposure and other factors

=

New OHAT Approach for hazard identification?

Human and animal evidence are integrated with consideration of "other relevant data"



- Five categories:
  - Known to be a Hazard
  - Presumed to be a Hazard
  - Suspected to be a Hazard
  - Not Classifiable as a Hazard
  - Not Identified to be Hazard (high confidence of no health effect)

What LoC categories should NTP use?

Known to be a Hazard

Presumed to be a Hazard

Suspected to be a Hazard

Not Classifiable as a Hazard

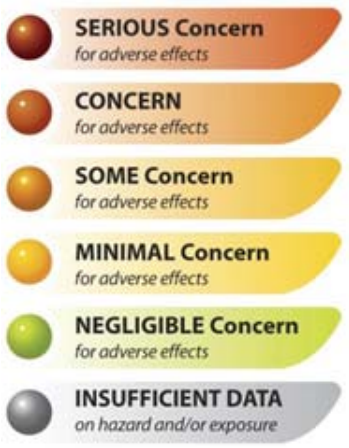
Not Identified to be a hazard

+

Extent of human exposure and other factors

=

LoC Categories 1998- Present



New LoC Categories

?

LoC Project to Update LoC Categories

Goals

- Address issues with current LoC system
- Integrate new OHAT Approach for reaching hazard identification conclusions with LoC framework
- Improve transparency of LoC conclusions
- Improve use of LoC as a communication tool

Objectives

- Reassess the number and labels used for LoC categories and identify visual and/or web-based strategies to enhance the communicability of LoC conclusions
- Determine whether the revised LoC framework is an improvement over the current framework in terms of transparency and use as a communication tool

LoC Project to Update LoC Categories

Specific Aim 1:	Determine the number of and descriptors for LoC categories
Phase 1:	Engage technical experts to determine the number of and descriptors for LoC categories
Phase 2:	Pilot test revised LoC categories with technical experts

LoC Case-Study Scenarios: LoC "Cards"

Hazard identification label: known, presumed, or suspected

- Level of evidence for animal studies (high, moderate, low, no) & basis
- Level of evidence from human studies (high, moderate, low, no) & basis

Extent of human exposure and other factors

- Level of exposure for human population group(s)
- Other factors (e.g., pharmacokinetics)

What is LoC for identified population group?

Obtain feedback on LoC cards from DNTP advisory group (5-6)

Sample LoC Card

Hazard ID label: Suspected hazard for humans	
Level of evidence for animals	**Moderate** Inhalation exposure of male rats to ≥500 ppm of chemical Y caused reduced testes weight…
Level of evidence for humans	**Low** Some female workers reported alterations in menstrual cycle length.
Exposure to human population:	0.01 – 0.035 ppm in worker breathing zones
Other factors:	Chemical “positive” for estrogen receptor agonist activity in HTS assays
What is your LoC for female workers of childbearing age?	

Technical Experts

- Recruit experts in toxicology, epidemiology, or risk assessment through targeted advertisements
- Inclusion criteria for experts
  - MS, PhD, MD or equivalent and at least 3 years' documented experience working in public health or on a risk assessment-related activity
  - 5 sectors: federal and state government, academia, industry, and nongovernment organizations
  - Informed consent

Specific Aim 1

Phase 1: Engage technical experts to determine optimal number of and descriptors for LoC categories

Trial 1

- Train 100 experts to use web-based sorting tool
- Randomly order 30 cards in web-based tool
- Experts independently sort cards into ≤15 LoC categories

Trial 2

- Randomly order same 30 cards in web-based tool
- Experts repeat card sorting into ≤15 LoC categories, 3-5 weeks after 1st session
- Experts provide descriptive labels for their LoC categories

Focus Group

- 10-15 experts from 5 sectors from Phase 1
- Experts provide input on features of LoC scenarios (e.g., margin of exposure, subpopulation, confidence in level of evidence for health effect) that best predict category

Phase 1

Collect data and conduct analyses to

- Determine most commonly selected number of LoC categories (mean, median, mode)
- Determine reliability of experts' card placements in trials 1 and 2
- Determine consistency in LoC categorization among technical experts from different sectors
- Determine if certain features of LoC scenarios best predict the category

Outcomes from Phase 1

- Revised LoC system with X categories
- Descriptors for each category

Phase 2: Pilot test revised LoC categories with technical experts

Experts

- Recruit ≤100 experts (60% new, 40% repeats)
- Repeat experts are from Phase 1, trial 2 who (1) chose X categories, (2) chose X-1 categories, or (3) X+1 categories
- Train new experts to use web-based sorting tool

Trial 2

- Randomly order 30 cards in web-based tool
- Experts place cards into current 5-level LoC categories and revised X-level LoC categories in cross-over design; experts randomly assigned
- Experts rate their confidence in card placements into revised and new LoC frameworks on 1-7 scale (1 “not confident” to 7 “highly confident”)

Focus Group

- Focus group from Phase 1
- Experts provide input on features of LoC scenarios that best predict category for revised LoC framework

Phase 2

Collect data and conduct analyses to

- Compare experts' categorization within current and revised LoC frameworks (both number of categories and descriptors)
- Determine consistency in LoC categorization among technical experts from different sectors
- Determine if certain features of LoC scenarios best predict the category
- Determine consistency in ratings of experts' confidence for categorization between two LoC frameworks (current and revised)

Outcomes from Phase 2

- Understanding of whether revised LoC framework is better than current LoC system
- An updated LoC framework for further development as a communication tool and for broader NTP stakeholder and public input

LoC Project to Update LoC Categories

Specific Aim 1:	Determine the number of and descriptors for LoC categories.
Phase 1:	Engage technical experts to determine the number of and descriptors for LoC categories
Phase 2	Pilot test revised LoC categories with technical experts

Updated LoC categories and descriptors

Specific Aim 2:	**Develop a variety of visual schemes using multiple modalities (e.g., text, color, numbers, interactive web graphics, etc.) to communicate LoC conclusions.**

Specific Aim 3:	**Utilize focus groups of NTP stakeholders and the general public to obtain feedback on the communication tools to refine them.**

NTP
National Toxicology Program

Questions?

Hazard Identification Categories

Hazard Categories 1998- 2014

New Hazard Categories

- **Known Hazard**
- **Presumed Hazard**
- **Suspected Hazard**
- **Not Classifiable**

Specific Aim 1

Phase 1

100 technical experts from five sectors

Determine optimal number of LoC categories

Determine consistency in LoC categorization among technical experts from different sectors

Identify the features of LoC scenarios (“cards”) that best predict the category

Phase 2

≤100 technical experts from five sectors

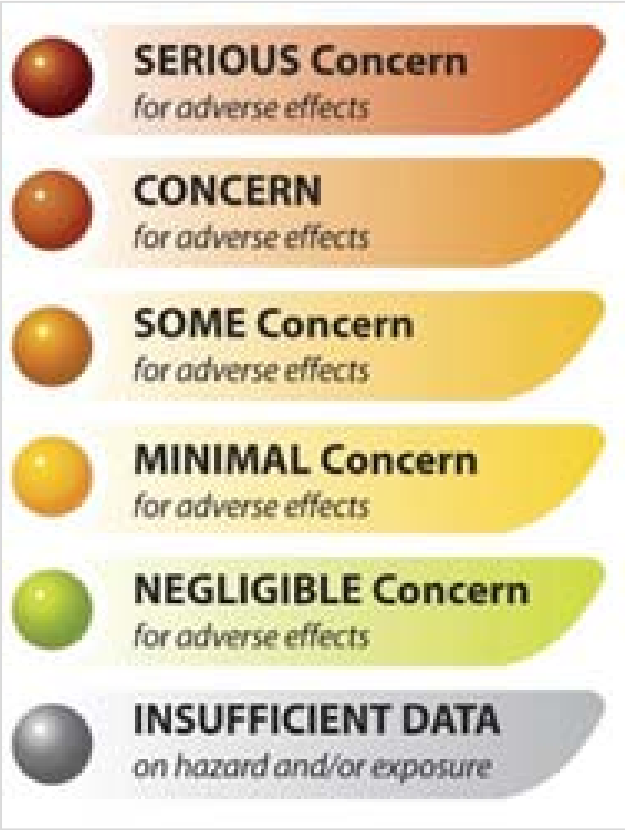
(60% new, 40% Phase 1)

Pilot test revised LoC categories vs current LoC categories

Determine consistency in LoC categorization among technical experts from different sectors

Identify the features of LoC scenarios (“cards”) that best predict the category

LoC Categories (1998 – current)



New LoC Categories

?

NTP's Current Level of Concern (LoC) Scale

- 5 categories plus 1 category for "insufficient data"