

MATERIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Materials Cooperative Research and Development Agreement ("Materials CRADA") has been adopted for use by the Environmental Protection Agency ("EPA") for collaborations that will not exceed one year in term; will involve transfers of essential material ("Research Material"), but no other resources; and are unlikely to result in new intellectual property. Typical applications include short-term studies to: 1) test new reagents or research tools when such assessments require collaboration between provider and recipient institutions or 2) determine the feasibility, optimal study design, and/or resource requirements for a long-term study between the collaborating institutions. Collaborative research and development studies not meeting these criteria must be submitted for approval using the standard CRADA agreement.

1. Silent Spring Institute ("Collaborator") agrees to transfer to the National Center for Computational Toxicology ("Laboratory") of the U.S. Environmental Protection Agency ("EPA") the following Research Material:

a.) In vivo and in vitro test data collected from our review of study reports and database entries on 216 chemicals to determine potential to cause mammary gland tumors.

b.) Product testing data from home cleaning and consumer products. Products include conventional and "green" products.

c.) Provide EPA with air, dust, and urine measurements for chemicals measured in our Cape Cod and Northern California Household Exposure Studies involving a total of 170 participants. Associated data collected by interview (e.g. building characteristics and participant behaviors) and through field measurement (e.g. temperature) would also be provided. These datasets will not include name and address of participants, but could be considered re-identifiable based on the personal information collected and so will probably need to be handled under EPA procedures for data from human subjects.

This Materials CRADA involves no other exchange of personnel or resources. This Agreement is made under authority of the Federal Technology Transfer Act, 15 U.S.C. § 3710a.

2. This Research Material will be used solely in connection with the Research Plan, attached as Appendix A, by the Laboratory in his/her laboratory under suitable containment conditions.

2(a). Are the Research Materials of human origin?

Yes

No

2(b). If Yes in 2(a), were the Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects?"

Yes (Please provide Assurance Number: 45 CFR 46)

Brown University IRB Protocol
Brown University IRB Approval
Mass Dept. of Public Health IRB Protocol
Mass Dept. of Public Health IRB Approval
 No

3. To the extent permitted by law, each Party agrees to treat as confidential any of the disclosing Party's written information about this Research Material that is stamped "CONFIDENTIAL" for a period of three (3) years from the date of the disclosure. The foregoing shall not apply to information that is or becomes publicly available or which is disclosed to a Party without a confidentiality obligation. Any oral disclosures by either party that the disclosing Party wishes to be treated as confidential shall be identified as being confidential at the time of disclosure and by written notice delivered to the receiving Party within (10) days of the oral disclosure. The Laboratory may publish or otherwise publicly disclose the results of the Research Plan, but if Collaborator has given CONFIDENTIAL information to the Laboratory, such public disclosure may be made only after Collaborator has had thirty (30) days to review the proposed disclosure to determine if it contains any CONFIDENTIAL information, to the extent such review period is permitted by law.

- ✓ Silent Spring is planning for a public web-based release of the household exposure study data. In this context, Silent Spring has been considering which data fields can be released with minimal risk of participant re-identification vs. those that will only be released to investigators operating under supervision of their own IRB. Silent Spring is also developing user agreements for people wishing to access these data, and developing the web platform for these data. At this point Silent Spring Institute believes it is reasonable to put air, dust, and urine measurements into publicly-available web-based data sharing platforms such as ExpoCastDB if there is a highly visible data use notice that informs users that attempts to re-identify participants are prohibited. At this time, air, dust, and urine measurements are considered low risk for re-identification because to our knowledge they are not independently observable or available for linking in other databases. Information from questionnaires and surveys, for example about house type or participant behavior, are vulnerable to re-identification and must be treated as confidential data by EPA and cannot be released. Silent Spring Institute continues to explore issues of data privacy and re-identification in partnership with computer scientists, community organizations, and study participants. Silent Spring Institute reserves the right to modify online data availability and user agreements as results of this research.
- ✓ Silent Spring is preparing manuscripts describing dust-air relationships in the California data and urine-air-dust relationships in the Cape Cod data. EPA should not share the California dust or Cape Cod urine data until these papers are published, unless Silent Spring provides permission.

4. The Laboratory agrees to retain control over this Research Material, and further agrees not to transfer the Research Material to other people not under his or her direct supervision without advance written approval of the Collaborator. The Collaborator reserves the right to distribute

the Research Material to others and to use it for its own purposes. When the Research Plan is completed or one (1) year has elapsed, whichever occurs first, or the Materials CRADA is terminated, the Laboratory will dispose of the Research Material as directed by the Collaborator.

5. This Research Material is provided as a service to the research community. IT IS BEING SUPPLIED TO THE LABORATORY WITH NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The Collaborator makes no representations that the use of the Research Material will not infringe any patent or proprietary rights of third parties. The Collaborator shall not be liable for any claims or damages arising from the Laboratory's use of the Research Material; however, no indemnification is provided or intended.

6. The Laboratory and the Collaborator believe that no Subject Inventions or Computer Software will be created during the work specified in this Agreement. Should it appear that any activity of this Agreement might involve the creation of Subject Inventions or Computer Software, the Laboratory and the Collaborator will negotiate a standard CRADA in good faith. The standard CRADA will assign responsibilities for obtaining patents or other intellectual property rights pertaining to the Subject Inventions or Computer Software and will provide for appropriate allocation of any patent or intellectual property rights resulting from those Subject Inventions or Computer Software. Subject Invention means any invention, conceived or first actually reduced to practice in the performance of this Agreement. Computer Software means computer software, computer programs, computer data bases, and documentation thereof developed, in whole or in part, under this Agreement.

7. Any dispute arising under this Agreement which cannot be readily resolved shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute. If the signatories are unable to jointly resolve a dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted by EPA to the Administrator of EPA or the Administrator's designee for resolution.

8. The illegality or invalidity of any provisions of this Materials CRADA shall not impair, affect or invalidate the other provisions of this Materials CRADA.

9. Neither this Materials CRADA nor any rights or obligations of any Party hereunder shall be assigned or otherwise transferred by either Party without the prior written consent of the other Party.

10. All notices pertaining to or required by this Agreement shall be in writing and shall be signed by an authorized representative and shall be delivered by hand (including private courier mail service) or sent by certified mail, return receipt requested, with postage prepaid, addressed as follows:

If to the Collaborator:
Ruthann Rudel
Silent Spring Institute

APPENDIX A

RESEARCH PLAN

EPA plans to add Silent Spring data (see Section 1) to ExpoCast and ACToR public databases, consistent with IRB and other restrictions to protect individual participants from re-identification.

EPA will receive data from Silent Spring for subsequent analysis of air and dust measures as predictors of urine levels of phthalates. In conjunction with such data from Silent Spring analysis of consumer products, relationships will be used to develop model parameters for ExpoCast program, including weighting values for ToxPi prioritization efforts. The aforementioned shall result in a collaborative effort to produce a manuscript based on the findings predictors of the urinary phthalate levels in the Cape Cod data set.