

INFORMED CONSENT DOCUMENT TO RELEASE CONTACT INFORMATION

Project Title: Early Life Exposures in Agriculture (ELEA)

Principal Investigator: Paul Romitti; study staff phone number 319-335-4503, email elea-cph@uiowa.edu

What is the purpose of releasing my contact information?

To identify people who are interested in being part of a research study to explore the effects of childhood farming exposures on health outcomes.

How many people will be asked to release their contact information?

Approximately 1,000 people will be contacted by investigators from the University of Iowa (UI) and asked to release their contact information (name and address) to investigators from the National Cancer Institute (NCI) and their contractor, Westat.

Is releasing my contact information voluntary?

Agreeing to release your contact information is completely voluntary. If you decide not to do so, you won't be penalized or lose any benefits for which you otherwise qualify.

What will I be asked to do and how long will it take to release my contact information?

To agree to release your contact information, you will use the UI website to enter the PIN included in the letter we mailed to you; this should take about 5 minutes. You will then be redirected to the secure NCI website to learn more and, if you choose to do so, enroll in the Early Life Exposures in Agriculture (ELEA) study.

Will it cost me anything or will I be paid to release my contact information?

You will not have any costs. We enclosed a small cash gift in your introductory letter as a thank you for thinking about joining the study. If you release your contact information and complete the online survey at the NCI website, NCI will provide an electronic Amazon gift card.

What are the risks and benefits of releasing my contact information?

There is a risk of loss of confidentiality of your contact information; however, we will do everything we can to prevent this from happening.

You will not benefit directly from agreeing to release your contact information; however, your participation in the ELEA study may help future generations.

What about confidentiality?

We will keep your contact information confidential to the extent permitted by law. However, it is possible that other people, such as those listed below, may become aware you have been contacted and inspect and copy records. Some of these records may contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the UI, and
- the UI Institutional Review Board (IRB), which is a committee that reviews and approves research studies

These people are also obligated to keep your information confidential. To help protect your confidentiality, we will store all hard copy records (paper files) in a locked cabinet, in a locked office. All electronic files will be stored in a password protected folder on a secure server with access restricted to research team members.

The Iowa Department of Health and Human Services (Iowa HHS) has agreed to allow the research team to receive vital record data for this study. The request to use Iowa HHS data was approved by the Iowa HHS Research and Ethics Review Committee and the University of Iowa IRB. The study Principal Investigator signed a research agreement to protect your data. As part of this agreement, the research team agreed to:

- keep your data confidential and stored securely and
- not release your data to others without permission from Iowa HHS or the IRB
- follow the Iowa HHS Disclosure of Confidential Public Health Information, Records or Data Policy for any publications or presentations created through this research project.

For questions about approvals to use Iowa HHS data, please submit an email to RERC@hhs.iowa.gov. You can also review Iowa HHS policies regarding research requests online here: <https://hhs.iowa.gov/about/open-records/public-health-data-requests>.

Who is funding this study?

The NCI is funding the ELEA study and UI investigators' assistance with ELEA study activities. This means the UI is receiving payments from the NCI to support these activities. No one on the UI research team will receive a direct payment or increase in salary from the NCI for conducting this study.

What if I have questions?

We encourage you to ask questions. If you have any questions about releasing your contact information, please contact us at 319-335-4503 or by email at elea-cph@uiowa.edu. If you have questions, concerns, or complaints about your rights as a research subject, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, <http://hso.research.uiowa.edu/>. To offer input about your experiences or speak to someone other than UI investigators, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen if you decide to release your contact information to the NCI. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that releasing your contact information has been explained to you, that your questions have been answered, and that you agree to release your contact information.

Subject's Name (printed): _____

(Signature of Subject)

(Date)