

APPENDIX F.1 – CROPS Demonstrator Informed Consent

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)
CENTERS FOR DISEASE CONTROL
U.S. PUBLIC HEALTH SERVICE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

You have been asked to participate in a NIOSH research study. We explain here the nature of your participation, describe your rights, and specify how NIOSH will treat your records.

(Project Officer - Format your document exactly as typed above)

I. DESCRIPTION

1. Title: Increasing Adoption of CROPS by Farmers and Manufacturers
2. Sponsor and/or Project Officer: David L. Hard, Ph.D.
3. Purpose and Benefits: The purpose of the research study is to determine barriers to adoption, and approaches, for encouraging farmers to retrofit their tractors with Cost-Effective Roll-Over Protective Structures (CROPS). You will be asked questions regarding the difficulty or ease of the process of retrofitting a Cost Effective Roll Over Protective Structure (CROPS) on your tractor. This aspect of the study will provide user feedback to NIOSH and external developers on assembly issues for a CROPS design retrofit under field conditions which should improve the design and process of retrofitting CROPS to tractors.

You will be allowed to keep the CROPS retrofit you demonstrate. One study found that farm tractor owner/operators who retrofit a roll over protective structure (ROPS), of which a CROPS is a specific type of ROPS, on their tractor will have the benefit of a reduction in risk from tractor roll over death of 80% and nonfatal injury of 50%.

II. CONDITIONS OF THE STUDY

1. You will be asked to demonstrate retrofitting a CROPS on your tractor. In some instances this will require the removal of parts of the tractor (i.e., fenders, with subsequent replacement) and the installation of the CROPS. NIOSH personnel will be onsite to assist you if needed. Also, you will be asked to identify other persons who potentially would be interested in observing the demonstration of CROPS retrofitting, answering demographic questions and questions regarding your knowledge, attitudes and beliefs about ROPS/CROPS. In addition, you will be asked questions regarding the difficulty or ease of the process of retrofitting the CROPS. You will be video taped in order capture the installation procedures and to determine if any ergonomic issues are revealed with the CROPS retrofitting process.
2. The level of risk of injury for you is considered to be minimal and should not be greater than what you would routinely experience in your daily life and activities. The potential exists for

muscle overexertion with related muscle stiffness and soreness.

If you have any comment about the tests/procedures, you should contact:
David Hard, Research Health Scientist
Telephone: 304-285-6068

3. There are no alternative test procedures
4. Injury or harm from this project is unlikely. But if it results, medical care is not provided, other than emergency treatment. If you are injured through negligence of a NIOSH employee you may be able to obtain compensation under Federal Law. If you want to file a claim against the Federal government your contact point is: Public Health Service Claims Office: (301) 443-1904. If you are injured or harmed through the negligence of a NIOSH contractor, your claim would be against the contractor, not the federal government. If an injury or harm should occur to you as the result of your participation, you also should contact:

David Hard
Research Health Scientist
304-285-6068

OR

Cheryl F. Estill
Chair NIOSH HSRB
513-533-8591

5. If you have questions about this research, contact David Hard, Research Health Scientist, 304-285-6068. If you have questions about your rights as a member of this study, contact Cheryl F. Estill, Chair NIOSH Human Subjects Review Board, 513-533-8591
6. Your participation is voluntary and you may withdraw your consent and your participation in this study at any time without penalty or loss of benefits to which you are otherwise entitled.

At the completion of the CROPS demonstration retrofit, you will be allowed to keep the CROPS you have just installed on your tractor, an estimated value of \$800.00.
7. There will be about 18 CROPS farm tractor owner/operator demonstrators in your state with a total of around 36 CROPS demonstrators in the study.
8. The CROPS should fit on your model of tractor without major alteration and the original equipment (i.e., tractor fenders) should be able to continue to be used with the CROPS. If aftermarket equipment has been added (i.e., front-end loader, sprayer tank, etc.), these may have to be removed. There should be no new parts needed in order to retrofit the CROPS, other than what NIOSH provides.
9. NIOSH reserves the right to terminate participation if the owner/operator demonstrator uses mechanical/fabrication procedures which would put him/her or bystanders at undue risk.
10. If the CROPS retrofit installation is not completed at the initial demonstration, through no fault of the farm tractor owner/operator, he/she will be allowed to keep the CROPS. If the CROPS demonstration retrofit installation is not completed due to the failure of the farm tractor owner/operator to adequately or successfully follow directions or accept

NIOSH
the farm
operating

assistance, then NIOSH reserves the right to retain the CROPS and it will be tractor owner/operator's responsibility to return the tractor to its original condition.

11. You will be told of any significant new findings which are found out during the research study which might effect whether you wish to continue with the study.

III. USE OF INFORMATION

This study is being done by The National Institute for Occupational Safety and Health (NIOSH). NIOSH is part of the Centers for Disease Control (CDC), a government agency in the Department of Health and Human Services. We collect this information in order to learn about various kinds of work hazards that may influence the health of the American worker.

NIOSH is allowed to collect and keep information about you, including your results from this study, because of three laws passed by Congress. These laws are:

1. The Public Health Service Act (42 U.S.C 241)
2. The Occupational Safety and Health Act (29 U.S.C. 669)
3. The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

You will decide whether you want to provide us with this information by being in this study. You are free to choose not to be in this study. It is up to you. If the information we are collecting is maintained and retrieved by personal identifiers, such as your name, it will become part of the CDC record system and we will protect it to the extent allowed by law. You should know, however, that there are conditions under the Privacy Act when we could be authorized to release this information to outside sources. These conditions under which we might release this information are listed in Attachment A (the Privacy Act).

IV. SIGNATURES

I have read this consent form and received a copy of the conditions for data release under the Privacy Act (Attachment A). I agree to participate in this study.

PARTICIPANT _____ Date _____
(signature)

I, the NIOSH representative, have accurately described this study to the participant.

REPRESENTATIVE _____ Date _____
(signature)

Attachment A

The Information you provide will become part of the CDC Privacy Act System, 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems" and may be disclosed to

- Appropriate state or local health departments to report communicable diseases;
- Private contractors assisting NIOSH;
- Collaborating researchers under certain circumstances to conduct further investigations;
- One or more potential sources of vital statistics to make determinations of death, health status or to find last known address;
- The Department of Justice or the Department of Labor in the event of litigation;
- Congressional offices assisting an individual in locating his or her records;

You may request an accounting of the disclosures made by NIOSH.

Except for these and other permissible disclosures authorized by the Privacy Act, or in limited circumstances required by the Freedom of Information Act, no other disclosures may be made without your written consent.