The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	Implementation of Multidisciplinary Assessments for Geriatric Patients in an ED Observation Unit
Principal Investigator:	Lauren Southerland, MD
Sponsor:	National Institutes of Health (NIH)

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This study is being conducted to evaluate the effect of screening Emergency Department patients for problems that are common in older adults. If you choose to participate we will ask you a series of questions during your visit today and during two follow-up phone calls. The research activities should take no longer than 20 minutes today and 10 minutes for each follow-up phone call.

1. Why is this study being done?

This study is being done so we can determine if screening Emergency Department patients for problems that are common in older adults and then providing help for problems that are found can impact a person's quality of life and recovery from an illness or injury.

2. How many people will take part in this study?

A total of 380 patients will take part in this study.

3. What will happen if I take part in this study?

If you agree to participate, we will ask you questions about your medical, physical, and social well-being, as well as demographic questions during this visit. The questions include whether or not you need help at home and which activities can be difficult for you. It will take about 20 minutes. The questions will be interrupted should you need attention by a healthcare provider, if you are in pain or any other distress, or if you just need a break.

We will also review your medical records to gather information about this visit. We will call you to repeat some of the questions and check how you have been recovering in about 1 month and 3 months from this visit. These questions will be similar to the ones asked during today's visit and should take about 10 minutes to complete.

4. How long will I be in the study?

You will be in the study for three months, however the total time you will be participating in the study today will be about 40 minutes. We will ask you questions today and conduct two follow-up phone calls with you. The first follow-up call will be in one month and second follow-up call will be in three months. These calls will take about 10 minutes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There is a risk that the confidentiality of your personal information will be compromised. In order to lower this risk, you will be identified by only a study number. All study-related information will be stored securely. Psychological risks and discomforts may arise from answering personal and sensitive questions. You can decline to answer any question, or skip questions you don't want to answer. We will take all measures necessary to minimize these risks. As with all research, this study may involve risks that are currently unforeseeable.

7. What benefits can I expect from being in the study?

Your clinical care will not change whether you are in the study or not. However, answering some of the study questions may make you realize needs you have for your care or recovery. If that happens and you wish to speak with your doctor or the case manager, the research team can contact them for you. Future patients may benefit from the study findings.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

Your care in the emergency department and hospital will not be affected by this study, and your health insurance will be billed as usual for the costs of medical care during this study as these expenses would have happened even if you were not in the study. There is no additional cost to you for participation in this study.

10. Will I be paid for taking part in this study?

You will be given a $25 Target gift card upon completion of the questions during your visit today.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. Will my de-identified information be used or shared for future research?

Yes, the study data may be used or shared for future research.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Will my study-related information be kept confidential?

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (blood, tissue, etc.). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples.

However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the NIH requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

Study information that has health implications may be placed in your medical record where authorized employees may see the information. Further, authorized requests for your records (medical record release for continuity of care) may result in research-related information being released.

Please talk to your study team, or contact the Office of Responsible Research Practices at 614-688-8641, if you have questions.

You may also visit the NIH website at https://humansubjects.nih.gov/coc/faqs to learn more.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Internet/Email Data Collection:
If you elect to schedule times for the follow-up phone calls over email, your email address is subject to the same protections as the rest of your personally identifiable information and will not be released by us to companies. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you as being a part of this study.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Recommendations from your physicians and healthcare providers
  Questionnaires
  Your medical charts.

II. Who may use and give out information about you?

- Researchers and study staff.

III. Who might get this information?

- The sponsor of this research, which is the NIH.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic or physician's office record.

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

- There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

- Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

- Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

- There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

- Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

- For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Dr. Lauren Southerland and the EM Research team at 614-293-8305.

- For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the HIPAA Privacy Officer at 614-293-4477.

- For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

- If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Lauren Southerland at 614-293-8305.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
Relationship to the subject	**AM/PM**
	Date and time

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time