Document Coversheet

Study Title: Assessing the Impact of Illustrated Medication Labels on Medication Understanding Among Migrant and Seasonal Farmworkers in South Georgia

Institution/Site:	Emory University
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You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 200 people who are being studied at Emory Farmworker Project clinics.

Why is this study being done?

This study is being done to answer the question: does an illustrated medication label improve medication understanding among farmworkers? You are being asked to be in this research study because we want to make sure farmworkers have a deep understanding of their medications, retain the medication instructions, and take their medications safely and correctly.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate as part of your visit today. The researchers will ask you to do the following: learn about your medications through a verbal explanation or illustrated explanation, and complete two short surveys.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. Participating in this study may help you better understand any medications you are prescribed.

What are the risks or discomforts you should know about before deciding?

The study will take time. The procedure that is being tested may not work any better than regular care. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- Loss of time
- Loss of privacy
- Breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study. You will not be charged for any of the research activities.

There is more information in the "Costs" section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject

Title:
Assessing the Impact of Illustrated Medication Labels on Medication Understanding Among Migrant and Seasonal Farmworkers in South Georgia

IRB #:
STUDY00009062

Principal Investigator:
Jodie L. Guest, PhD, MPH
Rollins School of Public Health, Department of Epidemiology

Sponsor or Funding Source:
Centers for Disease Control and Prevention (CDC)

Introduction
You are being asked to be in a research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study. You can skip any questions that you do not wish to answer.**

Before making your decision:

- Please carefully read this form or have it read to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. By signing this form you will not give up any legal rights.

What is the purpose of this study?
The purpose of this study is to determine if an illustrated medication label improves medication understanding among farmworkers, and to assess the health literacy of farmworkers in South Georgia. You are being invited to participate in this study because you are a farmworker receiving care at the Emory Farmworker Project. You do not have to participate, and you will still receive medical care if you choose not to participate.

What will you be asked to do?
You will be asked to learn about your medications through a verbal explanation or illustrated explanation, and complete two short surveys.

Who owns your study data and samples?
If you join this study, you will be donating your data. Any identifying data or health information collected as part of your medical care are part of your health record and are separate from study data. You will not be paid if your data are used to make a new product. If you leave the study, the data that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the procedures that are not known at this time.

- The most common risks and discomforts expected in this study are: loss of time
- Rare but possible risks include: loss of privacy, loss of confidentiality

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?

You may not benefit from joining the study. You may experience the benefit of improved understanding and knowledge of your medication. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will not be compensated for being in this study.

What are your other options?

If you choose not to join this study, you can still receive free care at this clinic.

How will your private information be protected?

Your name and other identifying information will not be collected as part of this study. Study records will only contain demographic information like your age, sex, or ethnicity, and your responses to the questionnaires.

We will store the data that you provide. This data will not be linked to your name, initials, date of birth, or medical record. We will not allow any fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial medication label) that could be sold by a company. You will not receive money from the sale of any such product.

What is a Certificate of Confidentiality?

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy. The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases
- Giving law officials information about abuse of a child, elderly person, or disabled person
- Giving out information to prevent harm to you or others

- Giving the study sponsor or funders information about the study, including information for an audit or evaluation
- Storing and Sharing your Information

Costs
There are no costs, research or standard of care related, associated with the study.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Confidentiality
Ensuring the privacy of the information we collect about you is important to us. We will store the data that we collect securely. When possible, we will use a study number rather than your name on study records. Any personal information that could identify you will be removed before data is shared with other researchers or results are made public. However, absolute confidentiality cannot be guaranteed. Certain offices and people other than the researchers may look at study records to ensure the research is being done correctly. These offices and people may include the Office for Human Research Protections, the Centers for Disease Control and Prevention, the Emory Institutional Review Board, and other offices at Emory that help oversee studies.

People Who will Use/Disclose Your Information:
The following people and groups will use and disclose your information in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your information to conduct the study.
- Emory may use and disclose your information to run normal business operations.
- The Principal Investigator and research staff will share your information with other people and groups to help conduct the study or to provide oversight for the study.
- The following people and groups will use your information to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your information may be shared with that new institution and their oversight offices. Information will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent.

Contact Information

If you have questions about the study procedures or other questions or concerns about the research or your part in it, contact **Emi Grill** at **404-316-0268**.

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent

DOCUMENTATION OF VERBAL CONSENT - TO BE FILLED OUT BY STUDY TEAM ONLY

Participant agrees to participate: **Yes** **No**

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion **Date** **Time**