Study Title: Engaging disadvantaged patients in sharing patient generated health data and patient reported outcomes through health information technology

NCT #: NCT03386773

Version Date: 11/12/2018

Principal Investigator: Susan L. Moore
COMIRB No: TBD
Version Date: June 8, 2017

Study Title: Engaging disadvantaged patients in sharing patient generated health data and patient reported outcomes through health information technology

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about collecting patient generated, patient provided health information and answers to questions about patient reported outcomes through using off-the-shelf technology like smartphones, mobile apps, and fitness trackers. This will help us learn about how to obtain and use this kind of information to make health care better, especially care for patients who have chronic conditions like diabetes. We are planning to ask for information about weight loss and weight management to test whether or not using technology like this is a good way to collect information from patients.

We are especially interested in learning about how people who have challenges that may make it harder for them to get health care could use technology like this to share health information. Many Denver Health patients have these kinds of challenges, such as low income. You are being asked to be in this research study because you are a Denver Health patient who is at least 18 years old and who is overweight or obese.

Up to 400 people will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to use an app on your phone or a fitness tracker, like a Fitbit, to track information about your weight, what you eat, and your physical activity. You will be asked to let members of the study team be able to see

your information through the app and by sending messages back and forth. You will also be asked to answer questions about your health and how you are feeling. Some people may also be asked to join focus groups to share what you think about using technology like to share information about your health.

You will be asked to keep track and share information for 16 weeks, or 4 months.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include feeling uneasy about sharing your health information with other people.

Other possible risks include the chance that someone who you did not mean to share your health information with could see your information. This could happen if someone uses your account on your phone or on someone else's phone, or if someone were to hack into the computer database where your information is stored. We do not think that this is likely to happen, and will do everything that we can to keep your information safe.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how to help patients better manage chronic conditions like diabetes by using technology to share health information with their doctors and care providers. This can help make it easier to get access to health care. This can also help patients and providers communicate between clinic visits, and can help patients to be more empowered by knowing more about their own health and how to be more engaged in their own care.

Who is paying for this study?

This research is being paid for by the Agency for Healthcare Research and Quality, which is a federal agency.

Will I be paid for being in the study? Will I have to pay for anything?

We will give every patient a fitness tracker, if they want one. You can keep the fitness tracker after the study is over. Also, if you are one of the patients who participates in a focus group, you will receive a $25 gift card.

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Who do I call if I have questions?

The researcher carrying out this study is Susan Moore, PhD. You may ask any questions you have now. If you have questions later, you may call Dr. Moore at 303-602-2744.

You may have questions about your rights as someone in this study. You can call Dr. Moore with questions. You can also call the Colorado Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

Who will see my research information?

The University of Colorado Denver and the hospital(s) it works with have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- Denver Health and Hospital Authority

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, Dr. Susan Moore, at the name and address listed below. If you

do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Susan L. Moore, PhD
Center for Health Systems Research
Denver Health
777 Bannock St.
MC 6551
Denver, CO 80204

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- The Agency for Healthcare Research and Quality, who is the company paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

If you participate in a focus group, we will make an audio recording of the group discussion. Focus group recordings and electronic transcriptions will be kept on a secure network computer that can only be accessed by members of the research team with Denver Health network logins. We will keep recordings and study data for at least 7 years after the study is over, and then will make sure to securely destroy it.

You have the right to request access to your personal health information for this study from the Principal Investigator, Dr. Moore.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, and procedure results
- Information about your health insurance.
- Research Visit and Research Test records
- Any information that you share with the study team through your smartphone mobile apps and fitness trackers.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator: _____ Date: _____
Investigator must sign within 30 days

Witness (if applicable):_____ Date_____

Print Name: _____

Witness of Signature ☐

Witness of consent process ☐

Initials_____

Principal Investigator: Susan L. Moore
COMIRB No: 17-1082
Version Date: 05/02/2018

Study Title: Engaging disadvantaged patients in sharing patient generated health data and patient reported outcomes through health information technology

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You are being asked to participate in an interview for a study. This form gives you information about the study. Please read the information below and ask us questions about anything you don't understand before deciding whether or not to take part. A member of the research team will tell you about the study and answer all of your questions.

Why is this study being done?
This study plans to learn more about collecting health information from patients by using off-the-shelf technology like smartphones, mobile apps, and fitness trackers. This will help us learn about how to obtain and use this kind of information to make health care better, especially care for patients who have chronic conditions like diabetes.

You are being asked to participate in a interview to help us learn about how people like Denver Health patients could use technology like this to share health information with their care providers. You are being asked to participate in this interview because you have been identified by your peers as someone who has particular knowledge or expertise that is important for understanding how technology like this could be used to improve health care.

How many people will be in the study?
Up to 30 people will be asked to participate in interviews.

What happens if I join this study?
If you agree, we will ask you to participate in an interview. We are interested in your opinions about what sorts of things are important to you in terms of using technology, and we want to know what you think might be important for us to know about collecting information from patients through technology.

Each interview will last from 30 minutes to 1 hour. You will only be asked to participate in 1 interview. The interview will be audio-recorded. We will listen to the recording and type out word for word what is said in each session. No personal information will be connected to this written version of the audio recording.

What are the possible discomforts and/or risks?
Questions that we ask should not cause discomfort or embarrassment, but if you feel uncomfortable, you can refuse to answer any questions we ask. You are also free to leave the interview at any time. We will do our best to make the interview comfortable for you.

Initials_____

It is possible that the study may include risks that are unknown at this time.

What are the possible benefits of the study?
This study is designed for the research team to learn more about whether or not patients can and will use technology to share health information with their doctors and other care providers. This can help patients and providers communicate between clinic visits, and can also help patients to be more empowered by knowing more about their own health and how to be more engaged in their own care.

Will I have to pay for anything?
There is no cost to you for being in this study.

Will I be paid for being in the study?
You will not receive anything for being a part of this study.

Who is paying for this study?
This study is being paid for by a grant from the Agency for Healthcare Research and Quality, which is a federal agency.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I cancel my permission?
You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator, Dr. Susan Moore, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Susan L. Moore, PhD
Center for Health Systems Research
Denver Health
777 Bannock St., MC 6551
Denver, CO 80204

Whom do I call if I have questions?
The researcher carrying out this study is Susan Moore, PhD. You may ask any questions you have now. If you have questions later, you may call Dr. Moore at 303-602-2744.

You may have questions about your rights as someone in this study. You can call Dr. Moore with questions. You can also call the Colorado Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

It is important for you to know that being in this study does not take the place of your regular medical care. You should always keep doing what your doctor or nurse has suggested you do to manage your medical problems. Being in this study does not replace talking to your doctor or to a nurse when you need to. If you have any questions about your medical care, you should call your regular doctor or clinic during business hours. You can also call the NurseLine for advice, 24 hours a day, 7 days a week. The NurseLine is (303) 739-1211. In case of an emergency, you should call 911.

Who will see my research information?
The University of Colorado Denver and the hospital(s) and health care systems it works with, like Denver Health, have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- Denver Health and Hospital Authority

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University of Colorado Denver and its affiliate hospitals may not be covered by this promise.

We will do everything we can to keep your records a secret. It cannot be guaranteed.

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information. These include:

- Federal offices such as the Food and Drug Administration (FDA) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study doctor and the rest of the study team.
- The Agency for Healthcare Research and Quality, who is the company paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

If you participate in an interview, we will make an audio recording of the conversation. Recordings and electronic transcripts will be kept on a secure network computer that can only be accessed by members of the research team with Denver Health network logins. Your name will not be associated with the focus group recording or the electronic transcripts of what is said in the interview. We will

keep recordings and study data for at least 7 years after the study is over, and then will make sure to securely destroy it.

You have the right to request access to your personal health information for this study from the Principal Investigator, Dr. Moore.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.

Some things we cannot keep private. If you give us any information about child abuse or neglect we have to report that to Social Services. Also, if we get a court order to turn over your study records, we will have to do that.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that my participation in this study is voluntary. I agree to participate in this study. I know I can stop being in the study at any time. I will get a copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator: _____ Date: _____

Investigator must sign within 30 days

Principal Investigator: Susan L. Moore
COMIRB No: 17-1082
Version Date: 01/26/2018

Study Title: Engaging disadvantaged patients in sharing patient generated health data and patient reported outcomes through health information technology

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You are being asked to participate in a focus group for a study. This form gives you information about the study. Please read the information below and ask us questions about anything you don't understand before deciding whether or not to take part. A member of the research team will tell you about the study and answer all of your questions.

Why is this study being done?
This study plans to learn more about collecting health information from patients by using off-the-shelf technology like smartphones, mobile apps, and fitness trackers. This will help us learn about how to obtain and use this kind of information to make health care better, especially care for patients who have chronic conditions like diabetes.

You are being asked to participate in a focus group to help us learn about how people like you could use technology like this to share health information with their care providers. A focus group is a conversation with 6-10 people at one time. You are being asked to be in this focus group because you are a Denver Health patient who is at least 18 years old and who is overweight or obese.

How many people will be in the study?
Up to 64 people will be asked to participate in focus groups.

What happens if I join this study?
If you agree, we will ask you to participate in a focus group. We are interested in your opinions about what sorts of things are important to you in terms of using technology, and we want to know what you think might be important for us to know about collecting information from patients through technology.

Each focus group will last 60 to 90 minutes. You will only be asked to participate in 1 focus group. The focus groups will be audio-recorded. We will listen to the recording and type out word for word what is said in each session. No personal information will be connected to this written version of the audio recording.

What are the possible discomforts and/or risks?
Questions that we ask should not cause discomfort or embarrassment, but if you feel uncomfortable, you can refuse to answer any questions we ask. You are also free to leave the focus group at any time. We will do our best to make the focus group comfortable for you.

It is possible that the study may include risks that are unknown at this time.

What are the possible benefits of the study?
This study is designed for the research team to learn more about whether or not patients can and will use technology to share health information with their doctors and other care providers. This can help patients and providers communicate between clinic visits, and can also help patients to be more empowered by knowing more about their own health and how to be more engaged in their own care.

Will I have to pay for anything?
There is no cost to you for being in this study.

Will I be paid for being in the study?
You will receive a $25.00 gift card for your time and participation in the focus group.

Who is paying for this study?
This study is being paid for by a grant from the Agency for Healthcare Research and Quality, which is a federal agency.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I cancel my permission?
You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator, Dr. Susan Moore, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Susan L. Moore, PhD
Center for Health Systems Research
Denver Health
777 Bannock St., MC 6551
Denver, CO 80204

Whom do I call if I have questions?
The researcher carrying out this study is Susan Moore, PhD. You may ask any questions you have now. If you have questions later, you may call Dr. Moore at 303-602-2744.

You may have questions about your rights as someone in this study. You can call Dr. Moore with questions. You can also call the Colorado Multiple Institutional Review Board (IRB). You can call them at 303-724-1055.

It is important for you to know that being in this study does not take the place of your regular medical care. You should always keep doing what your doctor or nurse has suggested you do to manage

your medical problems. Being in this study does not replace talking to your doctor or to a nurse when you need to. If you have any questions about your medical care, you should call your regular doctor or clinic during business hours. You can also call the NurseLine for advice, 24 hours a day, 7 days a week. The NurseLine is (303) 739-1211. In case of an emergency, you should call 911.

Who will see my research information?
The University of Colorado Denver and the hospital(s) and health care systems it works with, like Denver Health, have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- Denver Health and Hospital Authority

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- People at the Colorado Multiple Institutional Review Board (COMIRB).
- The study doctor and the rest of the study team.
- The Agency for Healthcare Research and Quality, who is the company paying for this research study.
- Officials at the institution where the research is being conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research.

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

If you participate in a focus group, we will make an audio recording of the group discussion. Focus group recordings and electronic transcripts will be kept on a secure network computer that can only be accessed by members of the research team with Denver Health network logins. Your name will not be associated with the focus group recording or the electronic transcripts of what is said in the focus group. We will keep recordings and study data for at least 7 years after the study is over, and then will make sure to securely destroy it.

You have the right to request access to your personal health information for this study from the Principal Investigator, Dr. Moore.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, and procedure results.
- Information about your health insurance.
- Any information that you share with the study team through your smartphone mobile apps and fitness trackers.

Some things we cannot keep private. If you give us any information about child abuse or neglect we have to report that to Social Services. Also, if we get a court order to turn over your study records, we will have to do that.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that my participation in this study is voluntary. I agree to participate in this study. I know I can stop being in the study at any time. I will get a copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

Investigator: _____ Date: _____
Investigator must sign within 30 days

Investigador Principal: Susan L. Moore
COMIRB No: 17-1082
Versión Fecha: Enero 26, 2018

Título del estudio: Pacientes desfavorecidos participando en el intercambio de datos de salud generaros del paciente y reportando resultados del paciente a través de la tecnología informativa de salud

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A usted se la ha preguntado si desea participar en un Grupo de Conversación de un estudio. Este documento le proveerá información sobre el estudio. Lea por favor la información a continuación y preguntemos acerca de cualquier cosa que usted no comprenda antes de decidir si desea o no ser parte de este grupo de conversación. Un miembro del equipo de investigación le va a describir el estudio y va a responder todas sus preguntas.

¿Por qué se está haciendo este estudio?
Este estudio planea aprender más acerca de la recopilación de información sobre la salud de los pacientes mediante el uso de una tecnología estándar como teléfonos inteligentes "smartphones", aplicaciones móviles y seguidores de fitness. Esto nos ayudará a aprender acerca de cómo obtener y utilizar este tipo de información para mejorar la atención de la salud, específicamente para pacientes que tienen condiciones crónicas como la diabetes.

Usted está invitado a participar en este grupo de conversación para ayudarnos a aprender acerca de cómo la gente como usted podría utilizar la tecnología como esta para compartir información de salud con sus proveedores de cuidado. Un grupo de conversación es un grupo de 6-10 personas que se reúne a conversar. Se les pide estar en este grupo de conversación porque usted es un paciente de Denver Health mayor de18 años de edad y tiene sobrepeso o es obeso.

¿Cuántas personas estarán en el estudio?
Hasta 64 personas serán invitadas a participar en los Encuentros de Conversación.

¿Qué pasa si decido participar en este estudio?
Si está de acuerdo, le pediremos participar en un grupo de conversación. Estamos interesados en su opinión sobre qué tipo de cosas son importantes para usted en relación con el uso de la tecnología, y queremos saber qué piensa usted que sería importante que nosotros sepamos acerca de la recopilación de información de los pacientes a través de la tecnología.

Cada uno de los grupos de conversación durará de 60 a 90 minutos. Usted sólo tendrá que participar en 1 grupos de conversación. Los grupos de conversaciones serán grabados en audio. Vamos a escuchar las grabaciones y escribiremos palabra por palabra lo que se dice en cada sesión. Ninguna información personal será conectada a la versión escrita de la grabación de audio.

¿Cuáles son las posibles molestias y/o los posibles riesgos?
Las preguntas que hacemos no deberían causar molestias ni pena; sin embargo, si usted se siente incómodo, puede negarse a contestar cualquier pregunta que hacemos. También usted está libre de dejar el grupo de conversación en cualquier momento. Nosotros haremos lo posible para que usted se sienta cómodo/a en el grupo de conversación.

Es posible que en el estudio pueda haber riesgos que son desconocidos en este momento.

¿Cuáles son los posibles beneficios del estudio?
Este estudio está diseñado para que el equipo de investigación aprenda más acerca de que si es posible o no que los pacientes puedan utilizar la tecnología para compartir información de salud con sus médicos y otros proveedores de cuidados. Esto puede ayudar a que los pacientes y los proveedores se comuniquen entre las visitas de la clínica, y también puede ayudar a los pacientes a estar más preparados para saber más acerca de su propia salud y cómo participar más activamente en su propio cuidado.

¿Tendré que pagar por algo?
Para usted No hay ningún costo por estar en este estudio.

¿Me pagarán por ser parte de este estudio?
Usted recibirá una tarjeta de regalo por $25,00 por su tiempo y participación en el grupo de conversación.

¿Quién está pagando por este estudio?
Este estudio está siendo pagado por la agencia federal "Agency for Healthcare Reasearch and Quality"

¿Es mi participación voluntaria?
Tomar parte en este estudio es voluntario. Usted tiene el derecho de escoger no participar en este estudio. Si usted decide participar, usted tiene el derecho de salirse del estudio en cualquier momento. Si decide no participar o deciden retirarse más adelante, usted no perderá ningún beneficio o derechos con los que cuenta.

¿Puedo cancelar mi permiso?
Usted puede cancelar su permiso para usar o divulgar su información en cualquier momento escribiendo al investigador principal del estudio la Dra. Susan Moore, su nombre y dirección aparece a continuación. Si usted cancela su permiso para usar o divulgar su información, su parte en este estudio finalizará y ninguna otra información sobre usted será recopilada. Su cancelación no afectara la información ya recolectada en este estudio.

Susan L. Moore, PhD
Center for Health Systems Research
Denver Health
777 Bannock St., MC 6551
Denver, CO 80204

¿A quién llamo yo si tengo preguntas?
La investigadora principal que está realizando este estudio es Susan Moore, PhD. Usted puede hacer cualquier pregunta en este momento. Si usted tienes preguntas más adelante, puede llamar a Dr. Moore al 303-602-2744.

Usted puede tener preguntas sobre sus derechos como persona que está en este estudio. Usted puede llamar a Dr. Moore con preguntas. También puede llamar al "Colorado Multiple Institutional Review Board (IRB)" Usted puede llamarlos al 303-724-1055.

Es importante que usted sepa que este estudio no toma el lugar de su atención médica regular. Uno debe de siempre hacer lo que su médico o enfermera ha sugerido que haga para controlar sus problemas médicos. Este estudio no sustituye el hablar con su médico o con una enfermera cuando usted necesite. Si usted tiene alguna pregunta sobre su atención médica, debe llamar a su médico o su clínica durante el horario de trabajo. También puede llamar a la línea de enfermeras "NurseLine" para asesoramiento, 24 horas al día, 7 días a la semana. El número de "NurseLine" es 303-739-1211. En el caso de una emergencia, usted debe llamar 911.

¿Quién verá mi información de investigación?
The University of Colorado Denver y los hospitales trabajan conjuntamente para tener reglas para proteger la información acerca de usted. Leyes federales y estatales, entre ellos el "Health Insurance Portability y Accountability Act (HIPAA)" que también protege su privacidad. En esta parte del documento de consentimiento le dice a usted qué información es la que se puede recolectar en este estudio y quien pueda verla o utilizarla.

Las instituciones involucradas en este estudio incluyen
- Denver Health and Hospital Authority

Vamos a ver, usar y revelar su información sólo como se describe en este formulario y en nuestro Aviso de Prácticas de Privacidad; sin embargo, las personas ajenas a la Universidad de Colorado en Denver y sus hospitales afiliados no pueden ser cubiertos por esta promesa.

Haremos todo lo que podamos para mantener sus registros un secreto. No puede ser garantizada.

Tanto los registros de investigación que identifican al usuario y el documento de consentimiento firmado por usted podrá ser vista por otras personas que tienen derecho a ver esa información.

- Oficinas federales como la Food Drug Administration (FDA) que protegen a los sujetos de investigación como tú.
- Las personas de Colorado Multiple Institutional Review Board (COMIRB)
- El médico del estudio y el resto del equipo del estudio.
- La Agencia "Healthcare Research and Quality", que es la empresa que paga por este estudio de investigación.
- Funcionarios en la institución donde la investigación está siendo realizada y funcionarios de otras instituciones involucradas en este estudio que están a cargo de asegurarse de seguir todas las reglas para la investigación

Podríamos hablar de este estudio de investigación en las reuniones. También podemos imprimir los resultados de este estudio de investigación en revistas pertinentes. Pero siempre mantendremos privado los nombres de los participantes, como usted, que estuvieron en la investigación.

Si usted participa en un grupo de conversación, vamos a realizar una grabación de audio de la conversación en grupo. Las grabaciones y transcripciones electrónicas del grupo de conversación serán guardadas en un ordenador de red segura que sólo pueden acceder los miembros del equipo de investigación con la contraseña de Denver Health. Mantendremos las grabaciones y los datos del estudio durante al menos 7 años después de que termine el estudio, y luego se destruirá de forma segura.

Usted tiene el derecho a solicitar acceso a su información de salud personal de este estudio a la Investigadora Principal, la Dr. Moore.

Información acerca de usted que será visto, recopilada, utilizada y divulgada en este estudio:

- Nombre y Datos demográficos (edad, sexo, etnia, dirección, número de teléfono, etc.
- porciones de sus registros médicos previos y actuales que son pertinentes a este estudio, incluyendo pero no limitado al diagnóstico(es), la historia y la física, laboratorio o estudios de tejidos, estudios radiológicos y resultados del procedimiento
- Información acerca de su seguro de salud.
- Visita de investigación y registros de prueba de investigación
- Cualquier información que comparta con el equipo de estudio a través de las aplicaciones de sus teléfonos inteligentes "Smartphone" y rastreadores de fitness.

Algunas cosas nosotros no podemos mantenerlo en privado. Si usted nos da cualquier información sobre mal tratos a niños o descuido, nosotros tenemos la obligación de informar a Servicios Sociales. También, si recibimos una orden judicial para entregar sus registros del estudio, nosotros tenemos que hacer lo que nos piden.

Acuerdo de estar en este estudio y utilizar mis datos

He leído este documento de consentimiento acerca del estudio o este se me ha leído. Comprendo los posibles riesgos y beneficios de este estudio. Sé que mi participación en este estudio es voluntaria. Yo he elegido tomar parte en este estudio. Sé que puedo dejar de ser parte de este estudio en cualquier momento. Recibiré una copia de este documento de consentimiento.

_____

Nombre Impreso del Participante de Estudia

_____ _____

Firma Fecha

_____ _____

Firma de Persona que Realizó la Explicación del Consentimiento Fecha

_____ _____

Firma del Investigador (Investigator must sign within 30 days) Fecha