Appendix B
Consent Forms

FAMILY LETTER OF INTRODUCTION
(by postal mail)

Dear Mr./Mrs. (name):

(Name of facility) is participating in a project on falls risk in assisted living facilities. All residents who meet eligibility criteria will be invited to participate, and will be assessed for falls risk at three points in time. This is an important area of care for our residents and we are excited to participate in the project. It is funded by The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina.

(Name), a member of the UNC team would like to call you in the next few days, to discuss the project and explain what participation involves. She will discuss the enclosed pamphlet and consent forms with you, and if you are interested, explain the next steps. If you do not want her to contact you to tell you about the project, please feel free to call the project coordinator at 966-6074. You also can ask to speak with Drs. Zimmerman or Sloane, if you have questions about the project in advance.

Thank you for your time and consideration.

Sincerely,

(Name of Administrator), Administrator
(Name of Facility)

Sheryl Zimmerman, PhD
Principal Investigator and Co-Director
Program on Aging, Disability & Long-Term Care
Sheps Center for Health Services Research
University of North Carolina at Chapel Hill

Philip D. Sloane, MD, MPH
Co-Principal Investigator and Co-Director
Program on Aging, Disability and Long-Term Care
Sheps Center for Health Services Research
University of North Carolina at Chapel Hill

PHYSICIAN LETTER OF INTRODUCTION
(via fax)

Dear Dr (name of physician):

(Name of facility) is participating in a project on falls risk in assisted living facilities. All residents who meet eligibility criteria will be invited to participate, and will be assessed for falls risk at three points in time. This is an important area of care for our residents and we are excited to participate in the project. It is funded by The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina.

As a physician providing primary care for one or more patients who reside at (name of facility), your participation in the project is also requested. Your involvement would be minimal, and would consist of a 30 minute in-person interview now and one year from now about matters related to falls prevention. Within a few days, you will be contacted by Kirsten Nyrop (a doctoral student who is a member of the project team), who will explain the project in more detail, and if you are interested, arrange a time for the interview. If you do not want her to contact you to tell you about the project, please feel free to call the project coordinator at 966-6074. You also can ask to speak with Drs. Zimmerman or Sloane, if you have questions about the project in advance.

Thank you for your time and consideration.

Sincerely,

(Name of Administrator), Administrator
(Name of Facility)

Sheryl Zimmerman, PhD
Principal Investigator and Co-Director
Program on Aging, Disability & Long-Term Care
Sheps Center for Health Services Research
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Philip D. Sloane, MD, MPH
Co-Principal Investigator and Co-Director
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University of North Carolina at Chapel Hill

Scripts to Introduce the Evaluation and Obtain Consent
I. RESIDENT (IN PERSON)

Introductions

- Hi, I'm (name) from the University of North Carolina. You're Mr./Mrs./Ms. (name) right? How are you today?
- I'm here to tell you about a project that the University is doing with (facility name).
- Is it okay if we sit and talk for a few minutes?

Pamphlet

- **[Hand resident pamphlet.]** This pamphlet describes the study. (*If applicable, say, "We also sent one to your [family relation"].) Let me tell you what it says.*

  - The project is called "Preventing Falls in Assisted Living", and it's about what puts people at risk for falling. You probably know that falls can be a serious problem and sometimes result in injuries. We want to learn about what puts people at risk for falls, and how that changes over time.

  - We'd like you to join in this project. It's really simple to do. I will be visiting (facility name) today and two more times over the next year to conduct a basic, everyday assessment of the people who live here. I will observe and measure your strength and balance, and examine some other things like your shoes. In total, it will take about 40 minutes. I also will review your (facility name) chart and information from your health care providers, and talk to (facility name) staff about what might put you at risk for falls. Also, at the end of the study, you may be offered the opportunity to answer a few questions about your participation in the study.

  - This is a really important project, because more than half of older adults fall. Therefore, it is really important to understand what puts people at risk for falls, and how that changes over time.

  - If you're willing, I'd like to give you a few more details, and ask if you'll participate and sign this consent form. **[Hand resident consent form.]** Let me point out what it says:

Consent Form

- This first section lists the names of the University investigators and their telephone numbers. It also says that research studies are meant to provide scientific information, and that you do not have to participate.

- This next section talks about the purpose of the study, which I already explained. It's to assess assisted living residents for risk of falls and changes in risk of falls over time.

- You are eligible to participate if you are 65 or older, speak English, and are not bed bound or receiving Hospice.

- All together, we expect that approximately 270 residents who live here and in other assisted living facilities will participate.

- As I said, you will complete a performance assessment of everyday abilities (such as rising from a chair and walking), and participate in a brief interview about your medical history and general well-being, including cognition. This will occur once at the start of the study and then again six and twelve months later. By participating in this study, you also grant permission for researchers talk with assisted living staff about your falls risk at those three times, and to review your assisted living medical chart and communications received from your health care providers related to your medical history, medication, diagnoses, and activities throughout the one year. We'll do this over the course of one year, so I expect you'll see me a lot around here!

- We will be asking you common questions and to perform everyday activities, but if you want to skip some questions or activities or stop completely, then that will be fine.

- We hope that this study will help us gain new knowledge and improve staff training, practice, policy, and resident well-being in assisted living. If we find that you are high risk of a fall, we will let you know, and recommend that you see a physical therapist.

- I also need to let you know that there may be some risk connected to the physical assessments we will ask you to do. You may lose your balance or fall. However, during the assessment you can always rest when you need to. You will be guarded by one or two trained testers to help reduce the chance that you might fall. These trainers are able to anticipate and prevent loss of balance. Therefore, this risk is small.

- Of course, if we ever learn of a reason to not participate in this study, we will tell you.

- Also, I guarantee that your privacy will be protected. We will give you an ID number, and never link your name to information you provide or name you in any way. This information is only being used for research.

  There is no payment for participating in this study, and no cost to you for participating. (If they ask, it is being funded by The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina.)

- Once you start, you may withdraw at anytime.

- If you have questions about this study, I should be able to answer them. Also, you may contact the investigators directly. Their contact information is listed on the front of this consent form. If you have questions or concerns about your rights as a research subject, you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

- This is where you sign, if your questions have been answered and you agree to participate.

  - It says that I've explained the form or you read it, and you agree to participate. I should mention that I'll be helping to organize everything in this study, so you and I will get to know each other, and I'll be sure everything goes smoothly. Can I sign you up?

  - *If yes:*
    - Wonderful ! Here's where you sign. I'll put on the date, so you don't need to worry about that. You can keep this blank copy, for your records.

  - *If no:*
    - Sometimes people have more questions. Can I answer those for you? Since in this study we are aren't doing much more than asking you to answer a few questions and do simple physical performance assessments for short periods of time, we really don't expect it to be a bother.

    - *Other; ad-lib as indicated*

HIPAA Form

- There's one more form that needs to be signed, called the HIPAA form. You have probably signed this type of form for other reasons. The purpose is to get your permission to use the information from your chart, which will include your medical history, medications and some basic descriptive information, such as your age. This information will be used to assess and better understand your falls risk. All the same points about refusing to participate and protecting your privacy, that we just discussed, apply to this, also.

- Here's where you sign this one, and you can keep this blank one, for your records.

Next Steps

- How about if we begin right now? If this isn't a good time, what time would be better?

Script to Introduce the Evaluation and Obtain Consent
II. FAMILY (TELEPHONE)

Introductions

- Hi, I'm (name) from the University of North Carolina. May I speak with Mrs./Ms. (name)? How are you today?
- I'm calling to tell you about a project that the University is doing with (facility name). I expect that you received the letter and pamphlet that we sent to you?
- Are you free to talk for a few minutes about the project?

  - The project is called "Preventing Falls in Assisted Living", and it's about what puts people at risk for falling. You probably know that falls can be a serious problem and sometimes result in injuries. We want to learn about what puts people at risk for falls, and how that changes over time.

  - We'd like your (family relation) to join in this project. It's really simple to do. I will be visiting (facility name) soon and two more times over the next year to conduct a basic, everyday assessment of the people who live there. I will observe and measure the residents' strength and balance, and examine some other things like their shoes. In total, it will take about 40 minutes. I also will review charts and information from health care providers, and talk to (facility name) staff about what might put residents at risk for falls. Also, at the end of the study, your relative may be offered the opportunity to answer a few questions about her/his participation in the study.
  -

  - This is a really important project, because more than half of older adults fall. Therefore, it is really important to understand what puts people at risk for falls, and how that changes over time.

  - If you're willing, I'd like to give you a few more details, and ask if you'll agree to have (family relation) participate. Of course, if you do, your (family relation) can still refuse to participate at any time.

Consent Form

- I'm going to summarize the consent form for you. If you have it in front of you, you will be able to read along.

- The first section lists the names of the University investigators and their telephone numbers. It also says that research studies are meant to provide scientific information, and that your (family member) does not have to participate.

- This next section talks about the purpose of the study, which I already explained. It's to assess assisted living residents for risk of falls and changes in risk of falls over time.

- Your (family relation) is eligible to participate is if he/she is 65 or older, speaks English, and is not bed bound or receiving Hospice.

- All together, we expect that approximately 270 residents who live in assisted living facilities will participate.

- As I said, your (family relation) will complete a performance assessment of everyday abilities (such as rising from a chair and walking), and participate in a brief interview about your (family relation's) medical history and general well-being, including cognition. This will occur once at the start of the study and then again six and twelve months later. By participating in this study, you also grant permission for researchers talk with the assisted living staff about falls risk at those three times, and to review your (family relation's) assisted living medical chart and communications received from his/her health care providers related to medical history, medication, diagnoses, and activities throughout the one year. We'll do this over the course of one year, so I'll get to know him/her pretty well!

- We will be asking him/her common questions and to perform everyday activities, but he/she wants to skip some questions or activities or stop completely, then that will be fine.

- We hope that this study will help us gain new knowledge and improve staff training, practice, policy, and resident well-being in assisted living. If we find that your (family relation) is at high risk of a fall, we will let you know, and recommend that he/she sees a physical therapist.

- I also need to let you know that there may be some risk connected to the physical assessments. Your (family relation) may lose his/her balance or fall. However, during the assessment he/she can always rest, and he/she will be guarded by one or two trained testers to help reduce the chance of a fall. These trainers are able to anticipate and prevent loss of balance. Therefore, this risk is small.

- Of course, if we ever learn of a reason to not participate in this study, we will tell you.

- Also, I guarantee that your (family relation's) privacy will be protected. We will give him/her an ID number, and never link his/her name to information in any way. This information is only being used for research.

  There is no payment for participating in this study, and no cost for participating. (If they ask, it is being funded by The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina.)

- Once your (family relation) starts, he/she may withdraw at anytime.

- If you or your (family relation) have questions about this study, I should be able to answer them. Also, you or your (family relation) may contact the investigators directly. Their contact information is listed on the front of this consent form. If you your (family relation) have questions or concerns about your (family relation) rights as a research subject, you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

- The consent form asks you to sign, if your questions have been answered and you agree for the resident to participate.

  - It says that I've explained the form or you read it, and you agree for your (family relation) to participate. Can I sign him/her up?

  - *If yes:*
    - Wonderful ! If you would sign it and send one of the signed copies to me in the enclosed envelope, I'd really appreciate it.

  - *If no:*
    - Sometimes people have more questions. Can I answer those for you? Since in this study we are aren't doing much more than asking a few questions and doing everyday activities for short periods of time, we really don't expect it to be a bother.

    - *Other; ad-lib as indicated*

HIPAA Form

- There's one more form that needs to be signed, called the HIPAA form. You have probably signed this type of form for other reasons. The purpose is to get your permission to use the information from your (family relation's) chart and information from your (family relation's) health care provider, which will include medical history, medications and some basic descriptive information, such as age. This information will be used to assess and better understand your (family relation's) falls risk. All the same points about refusing to participate and protecting privacy, that we just discussed, apply to this, also.

- Can you sign and send one signed copy of that one to me, as well?

Thank you very much !

Script to Introduce the Evaluation and Obtain Consent
III. PHYSICIAN (TELEPHONE)

Introductions

- Hello, Dr. (name). I'm (name) from the University of North Carolina. How are you today?
- I trust you received the letter that we sent, about the falls risk prevention project we're doing with (facility name).
- I'd like to tell you about the project, and if you're willing, arrange a time to interview you.

  - The project is called "Preventing Falls in Assisted Living", and it's about what puts people at risk for falling. We'll be interviewing residents and staff, and reviewing charts and observing resident performance, in four assisted living facilities. We'd also like to interview the physicians who care for patients who live in the participating facilities, to learn more about your own thoughts and practices related to falls prevention.

  - The interview will take about 30 minutes, and I can conduct whenever and wherever it is convenient for you. I'd like to interview you once soon, and than again in one year. Can we set up an appointment?

  - *If yes:*
    - Wonderful ! I'll see you then.

  - *If no:*
    - If you prefer, we can wait to schedule the interview for a later date, or our project physician, Dr. Philip Sloane, can talk with you directly. This is work he's been doing for quite some time, and I know he would appreciate the opportunity to talk to you about it.

    - *Other; ad-lib as indicated*

Consent Form

- This first section lists the names of the University investigators and their telephone numbers. It also says that research studies are meant to provide scientific information, and that you do not have to participate.

- This next section talks about the purpose of the study, which is to learn physician perspectives on the risk of falls among older adults who live in assisted living residences. Specifically, we are interested in your perspectives on the importance of falls prevention, your ability to help prevent falls, the ability of others to help prevent falls, expected outcomes of falls prevention efforts, and your need for additional information on falls prevention.

- You are being asked to participate because you provide care for one or more people living in that facility.

- All together, we expect 30-40 physicians will participate.

- As I said, you will complete an interview now and again in one year. It will be in a place of your choosing, and will take about 30 minutes.

- There are no risks or benefits to you, although you may enjoy the opportunity to talk about falls prevention.

- Also, I guarantee that your privacy will be protected. We will give you an ID number, and never link your name to information you provide or name you in any way. This information is only being used for research.

- There is no payment for participating in this study, and no cost to you for participating. If you are a UNC employee, participating will have no effect on your job, and isn't related to your job.

- The project is being funded by the Agency for Healthcare Research and Quality (AHRQ).

- Once you start, you may withdraw at anytime.

- If you have questions about this study, I should be able to answer them. Also, you may contact the investigators directly. Their contact information is listed on the front of this consent form. If you have questions or concerns about your rights as a research subject, you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

- This is where you sign, if your questions have been answered and you agree to participate.

  - It says that I've explained the form or you read it, and you agree to participate. Can I sign you up?

  - *If yes:*
    - Wonderful ! Here's where you sign. I'll put on the date, so you don't need to worry about that. You can keep this blank copy, for your records.

  - *If no:*
    - If you prefer, we can wait to schedule the interview for a later date, or our project physician, Dr. Philip Sloane, can talk with you directly. This is work he's been doing for quite some time, and I know he would appreciate the opportunity to talk to you about it.

    - *Other; ad-lib as indicated*

Next Steps

- How about if we begin right now? If this isn't a good time, what time would be better?

Thank you very much !

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Physician Subjects
Biomedical Form

IRB Study #_____ **Consent Form Version Date:** 2/25/07

Title of Study: Preventing Falls in Assisted Living Facilities

Principal Investigator: Sheryl Zimmerman, PhD
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-962-6417

Co-Investigators: Phillip D. Sloane, MD, MPH
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-966-5818

Project Director: Edith G. Walsh, PhD
Mailing Address: RTI International, Research Triangle Park, NC
Phone number: 781-434-1754

Funding Source: The Agency for Health Care Quality and Research through a contract to RTI International) and a subcontract to the University of North Carolina.

Study Project Manager: Madeline Mitchell
Study Contact telephone number: 919-966-6074
Study Contact email: Madeline_Mitchell@unc.edu

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

What are some general things you should know about research studies?

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There may also be risks to being in research studies.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this study is to learn about physician perspectives on the risk of falls among older adults who live in assisted living residences. Specifically, we are interested in your perspectives on the importance of falls prevention, your ability to help prevent falls, the ability of others to help prevent falls, expected outcomes of falls prevention efforts, and your need for additional information on falls prevention.

You are being asked to participate in the study because you are the primary care physician for one or more patients living in a participating assisted living residence.

How many people will take part in this study?
You will be one of approximately 30-40 primary care physicians participating in this project.

How long will your participation last?
You will be interviewed once now, and once one year from now; thus, your involvement will be one year.

What will happen if you take part in the study?
If you agree to participate in this study, you will be interviewed at your office or other location of your choosing. This interview will take approximately 30 minutes. You will be contacted again in one year, to participate in a similar interview.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. While there are no direct benefits for you, you may enjoy the opportunity to talk about falls risk and fall prevention.

What are the possible risks or discomforts involved with being in this study?
We do not anticipate any immediate or long-term physical, psychological, or social risks/discomforts associated with your involvement in this study. However, there could be uncommon or previously unknown risks and you should report any problems to the researcher.

How will your privacy be protected?
Participants will not be identified in any report or publication about this study. Your answers will be coded with identification numbers, not names, and the list linking numbers and names will be kept in a separate file. The forms will be kept in the research offices of UNC-CH, and will be locked when not in use. The only people who will use the information will be research staff who are working on the project.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

Will you be paid for participating?
You will not be paid for taking part in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study.

What if you are a UNC employee?
Taking part in this research is not a part of your University duties and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Who is sponsoring this study?
This research is funded by The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

- -

Subject's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_______________________________________ __________________
Signature of Research Subject Date

____
Printed Name of Research Subject

_______________________________________ __________________
Signature of Person Obtaining Consent Date

____
Printed Name of Person Obtaining Consent

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Legally Authorized Representative

IRB Study #_____ **Consent Form Version Date:** 2/25/07

Title of Study: Preventing Falls in Assisted Living Facilities

Principal Investigator: Sheryl Zimmerman, PhD
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-962-6417

Co-Investigators: Phillip D. Sloane, MD, MPH
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-966-5818

Project Director: Edith G. Walsh, PhD
Mailing Address: RTI International, Research Triangle Park, NC
Phone number: 781-434-1754

Funding Source: The Agency for Health Care Quality and Research through a contract to RTI International) and a subcontract to the University of North Carolina

Study Project Manager: Madeline Mitchell
Study Contact telephone number: 919-966-6074
Study Contact email: Madeline_Mitchell@unc.edu

Your family member is being asked to take part in a research study. To join the study is voluntary. The investigators listed above are in charge of the study; other professional persons may help them or act for them.

What are some general things you should know about research studies?

Research studies are designed to obtain new gain scientific knowledge that may help other people in the future. Your family member may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

You may refuse to have your family member participate, or may withdraw your consent at any time, and for any reason, without jeopardizing his or her future care at this assisted living residence, or his or her relationship with the health care provider, University of North Carolina-Chapel Hill or the Research Triangle Institute International. If he/she is a patient with an illness, he/she does not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about whether you want your family member to be in the research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this project is to assess assisted living residents for risk of falls and changes in risk of falls over time. Your family member is being asked to be in the study because he/she is a resident of an assisted living facility.

Are there any reasons your family member should not be in this study?
Your family member should not participate if he/she is younger than 65 years old, does not speak English, is bed bound, or receiving hospice care.

How many people will take part in this study?
Your family member will be one of approximately 270 people at four assisted living facilities who will take part in this study. All eligible residents in your family member's facility will be asked to participate.

How long will his/her participation last?
Your family member will participate for one year. Over that year, we will meet with him/her three times, once now, and once six and twelve months from now. We will meet with him/her for about 40 minutes at each time. Also, at the end of the study, your relative may be offered the opportunity to answer a few questions about his/her participation in the study.

What will happen if he/she takes part in the study?
If you family member takes part in this project, he/she will be assessed for falls risk. He/she will be asked to perform everyday abilities such as rising from a chair and walking, and participate in a brief interview about his/her medical history and general well-being, including cognition. This will occur once at the start of the study and then again six and twelve months later. Your family member may choose not to answer questions or perform physical tasks for any reason. By participating in this study, you also grant permission for researchers talk with assisted living staff about your family member's falls risk at those three times, and to review his/her assisted living medical chart and communications received from health care providers related to medications, diagnoses, and activities throughout the one year.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge and what is learned from this study could potentially have implications for staff training, practice, policy, and resident well-being in assisted living. If we find that your family member is at high risk for a fall, we will tell you and recommend that you contact a physical therapist.

What are the possible risks or discomforts involved with being in this study?
There is some risk that your family member may lose balance or fall during performance testing. To reduce the risk, he/she will be able to rest if needed and will be guarded by one or two trained testers to prevent loss of balance. In addition, there may be uncommon or previously unknown risks that might occur. Your family member should report any problems to the researchers.

What if we learn about new findings or information during the study?
You and your family member will be given any new information gained during the course of the study that might affect your willingness to continue participation.

How will your family member's privacy be protected?
Your family member will not be identified in any report or publication about this study. His/her answers will be coded with identification numbers, not names, and the list linking numbers and names will be kept in a separate file. The forms will be kept in the research offices of UNC-Chapel Hill, and will be locked when not in use. The only people who will use the information will be research staff who are working on the project.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your family member's information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

What will happen if your family member is injured by this research?
All research involves a chance that something bad might happen to participants. This may include the risk of personal injury. In spite of all safety measures, your family member might develop an injury from being in this study. If such problems occur, the researchers will help your family member get medical care, but any costs for the medical care will be billed to your family member and/or his/her insurance company. UNC-Chapel Hill has not set aside funds to pay your family member for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any legal rights.

What if you want to stop before your family member's part in the study is complete?
You can withdraw your family member from this study at any time, without penalty. He/she may also choose to stop participation. The investigators also have the right to stop his/her participation at any time. This could be because he/she had an unexpected reaction or failed to follow instructions, or because the entire study has been stopped.

Will your family member be paid for participating?
Your family member will not be paid for taking part in this study.

Will it cost anything if your family member is in the study?
There will be no costs to your family member for being in this study.

Who is sponsoring this study?
This research is funded by The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your family member's rights as a research subject?
All research on human volunteers is reviewed by a committee that works to protect your family member's rights and welfare. If you have questions or concerns about your family member's rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Subject's Agreement:

I have read or had explained to me the information provided above. I have asked all the questions I have at this time. I voluntarily agree to have my family member participate in this study.

_____

Printed Name of Research Subject

_____

Printed Name of Authorized Representative/Relationship

_____ _____

Signature of Authorized Representative Date

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Interviewer Signature Verifying Verbal Consent Date

University of North Carolina-Chapel Hill
Consent to Participate in a Research Study
Adult Subjects

IRB Study #_____ **Consent Form Version Date:** 2/25/07

Title of Study: Preventing Falls in Assisted Living Facilities

Principal Investigator: Sheryl Zimmerman, PhD
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-962-6417

Co-Investigators: Phillip D. Sloane, MD, MPH
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-966-5818

Project Director: Edith G. Walsh, PhD
Mailing Address: RTI International, Research Triangle Park, NC
Phone number: 781-434-1754

Funding Source: The Agency for Health Care Quality and Research through a contract to RTI International) and a subcontract to the University of North Carolina

Study Project Manager: Madeline Mitchell
Study Contact telephone number: 919-966-6074
Study Contact email: Madeline_Mitchell@unc.edu

You are being asked to take part in a research study. To join the study is voluntary. The investigators listed above are in charge of the study; other professional persons may help them or act for them.

What are some general things you should know about research studies?

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

You may refuse to participate, or may withdraw your consent at any time, and for any reason, without jeopardizing your future care at this assisted living residence, or your relationship with the health care provider, University of North Carolina-Chapel Hill or the Research Triangle Institute International. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this project is to assess assisted living residents for risk of falls and changes in risk of falls over time. You are being asked to be in the study because you are a resident of an assisted living facility.

Are there any reasons you should not be in this study?
You should not participate in the study if you are younger than 65 years old, do not speak English, are bed bound, or receiving Hospice care.

How many people will take part in this study?
Approximately 270 people at four assisted living facilities will take part in this study. All eligible residents in your facility will be asked to participate.

How long will your participation last?
You will participate for one year. Over that year, we will meet with you three times, once now, and once six and twelve months from now. We will meet with you for about 40 minutes at each time. Also, at the end of the study, you may be offered the opportunity to answer a few questions about your participation in the study.

What will happen if you take part in the study?

If you take part in this project, you will be assessed for falls risk. You will be asked to perform everyday activities such as rising from a chair and walking, and participate in an interview about your medical history and general well-being, including cognition. This will occur once at the start of the study and then again six and twelve months later. You may choose not to answer questions or perform daily activities for any reason. By participating in this study, you also grant permission for researchers to talk with assisted living staff about your health status and falls risk, and to review your assisted living medical chart and communications received from your health care providers related to your medical history, medications, diagnoses, and activities throughout the year.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge and what is learned from this study could potentially have implications for staff training, practice, policy, and resident well-being in assisted living. If we find you are at high risk for a fall, we will tell you or your family member, and recommend that you contact a physical therapist.

What are the possible risks or discomforts involved with being in this study?
There is some risk that you may lose your balance or fall during performance testing. To reduce the risk you will be able to rest if needed and will be guarded by one or two trained testers to prevent loss of balance. In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue participation.

How will your privacy be protected?
No subjects will be identified in any report or publication about this study. Your answers will be coded with identification numbers, not names, and the list linking numbers and names will be kept in a separate file. The forms will be kept in the research offices of UNC-Chapel Hill, and will be locked when not in use. The only people who will use the information will be research staff who are working on the project.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies for purposes such as quality control or safety.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop an injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. UNC-Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. However, by signing this form, you do not give up any of your legal rights.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you be paid for participating?

You will not be paid for taking part in this study.

Will it cost you anything to be in this study?

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

Who is sponsoring this study?

This research is funded by The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

- -

Subject's Agreement:

I have read or had explained to me the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____ _____

Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent

Preventing Falls In Assisted Living Facilities

Administrator Consent Form

What is the purpose of this study? The project we want you to join is a research study being sponsored by the Agency for Healthcare Research and Quality (AHRQ) and conducted by Research Triangle Institute (RTI) and its subcontractor, the University of North Carolina. The purpose of this project is to design, implement, and evaluate an intervention program to prevent injurious falls in assisted living facilities. To help us accomplish our goal, four assisted living facilities in NC are scheduled to participate in the project.

Why was I chosen? Your living facility agreed to partner with the RTI-UNC team to implement a program to help reduce injurious falls in assisted living facilities.

What will happen during the interview? The interview will last 60 minutes. With your permission, the discussion will be tape recorded. The tapes will help us get everything you have to say. During the interview we will talk about how well the activities fit into your operation, the benefits of the program, what worked well, and what changes you would recommend to the approach. We also ask about whether you are planning to continue the program. There are no costs to you for participating.

Will I be contacted again? You may be contacted again to provide clarification to questions, but we do not expect to interview you again about the intervention program.

Are there risks? We do not expect any risks to you from being in this study; however you may choose not to answer any question that makes you uncomfortable. If you decide later that you do not want to be included, we will not use your comments.

Are there benefits? There is no direct benefit to you for being part of this study except the satisfaction of helping us to develop a protocol that may be used nationally to implement falls prevention programs in assisted living facilities.

Will I be paid for participating? You will not be paid for taking part in this interview. However, your facility will receive $2,000 as appreciation for participating in the project.

Do I have to take part? Your participation is voluntary and you can leave the discussion at any time. You can refuse to answer any question.

Will this be kept private? We will keep the tapes and the transcriptions in a secure computer file and will delete the recordings and the transcriptions after the project is over. We will summarize what we learn and prepare a report, but your name will not be used in any of our reports. Only project team members will be allowed to use them and they will keep your information private.

Whom do I call if I have questions? If you have any questions about the study, you can call the project director, Edith Walsh, PhD at 1-800-334-8571, x 21754. You can also call her if you decide later that you don't want to be in this study. If you have any questions about your rights in taking part of this study, or if you feel you have been harmed, you can call RTI's Office of Research Protection and Ethics at 1-866-214-2043 (a toll-free number).

I have read this form and I agree to be a part of this study. I have received a copy of the consent form. I asked questions about anything that was not clear to me.

_____ _____

Signature Date

Preventing Falls in Assisted Living Facilities

Exercise Program Staff Consent Form

What is the purpose of this study? The project we want you to join is a research study being sponsored by the Agency for Healthcare Research and Quality (AHRQ) and conducted by Research Triangle Institute (RTI). The purpose of this project is to design, implement, and evaluate an intervention program to prevent injurious falls in assisted living facilities. To help us accomplish our goal, four assisted living facilities in NC are scheduled to participate in the project.

Why was I chosen? Your assisted living facility agreed to implement a falls intervention program and you are the person the administrator identified as leading the exercise program. Exercise program staff or volunteers will also be interviewed at one other facility to help us understand how such programs work in assisted living facilities and how residents at risk for falls benefit from them.

What will happen during the interview? The interview will last 45 minutes. With your permission, the discussion will be tape recorded. The tapes will help us get everything you have to say. During the interview we will talk about who participated in the exercise program; what worked well; what did not work well; and what barriers to participation were identified. We also ask about the changes you observed in the participants and any recommendations you have for changes to the program. There are no costs to you for participating and you will not be paid for your participation.

Will I be contacted again? We may contact you again to clarify your responses to questions, but we do not expect to interview you again as past of the falls intervention project.

Are there risks? We do not expect any risks to you from being in this study. It is possible that some of the things we discuss could make you uneasy; however you may choose not to answer any question that makes you uncomfortable. If you decide later that you do not want to be included, we will not use your comments.

Are there benefits? There is no direct benefit to you for being part of this study except the satisfaction of helping us to develop a protocol that may be used nationally to implement falls intervention programs.

Do I have to take part? Your participation is voluntary and you can leave the discussion at any time. You can refuse to answer any question.

Will this be kept private? We will keep the tapes and the transcriptions in a secure computer file and will delete the recordings and the transcriptions after the project is over. We will summarize what we learn and prepare a report, but your name will not be used in any of our reports. Only project team members will be allowed to use them and they will keep your information private.

Whom do I call if I have questions? If you have any questions about the study, you can call the project director, Edie Walsh, PhD at 1-800-334-8571, x21754. You can also call her if you decide later that you don't want to be in this study. If you have any questions about your rights in taking part of this study, or if you feel you have been harmed, you can call RTI's Office of Research Protection and Ethics at 1-866-214-2043 (a toll-free number).

I have read this form and I agree to be a part of this study. I have received a copy of the consent form. I asked questions about anything that was not clear to me.

_____ _____

Signature Date

Preventing Falls in Assisted Living Facilities

Medication Review Staff Consent Form

What is the purpose of this study? The project we want you to join is a research study being sponsored by the Agency for Healthcare Research and Quality (AHRQ) and conducted by Research Triangle Institute (RTI). The purpose of this project is to design, implement, and evaluate an intervention program to prevent injurious falls in assisted living facilities. To help us accomplish our goal, four assisted living facilities in NC are scheduled to participate in the project.

Why was I chosen? Your assisted living facility agreed to implement a falls intervention program and you are responsible for the medication reviews and follow-up with the physicians. We are interviewing the person primarily responsible for implementing the medication reviews in two facilities to understand how the process works.

What will happen during the interview? The interview will last 60 minutes. With your permission, the discussion will be tape recorded. The tapes will help us get everything you have to say. During the interview we will talk about how well the materials you received worked; and about the process for following up with physicians about possible medication changes. We also ask about what worked well and what did not work particularly well. There are no costs to you for participating and you will not be paid for participating in the interview.

Will I be contacted again? We do not expect to contact you again to interview you about the falls prevention project.

Are there risks? We do not expect any risks to you from being in this study. It is possible that some of the things we discuss could make you uneasy; however you may choose not to answer any question that makes you uncomfortable. If you decide later that you do not want to be included, we will not use your comments.

Are there benefits? There is no direct benefit to you for being part of this study except the satisfaction of helping us to develop a protocol that may be used nationally to implement falls intervention programs.

Do I have to take part? Your participation is voluntary and you can leave the discussion at any time. You can also refuse to answer any questions that make you uneasy.

Will this be kept private? We will keep the tapes and the transcriptions in a secure computer file and will delete the recordings and the transcriptions after the project is over. We will summarize what we learn and prepare a report, but your name will not be used in any of our reports. Only project team members will be allowed to use them and they will keep your information private.

Whom do I call if I have questions? If you have any questions about the study, you can call the project director, Edie Walsh, PhD at 1-800-334-8571, x21754. You can also call her if you decide later that you don't want to be in this part of the study. If you have any questions about your rights in taking part of this study, or if you feel you have been harmed, you can call RTI's Office of Research Protection and Ethics at 1-866-214-2043 (a toll-free number).

I have read this form and I agree to be a part of this study. I have received a copy of the consent form. I asked questions about anything that was not clear to me.

_____ _____

Signature Date

Preventing Falls in Assisted Living Facilities

Resident Consent Form

What is the purpose of this study? The project we want you to join is a research study being sponsored by the Agency for Healthcare Research and Quality (AHRQ) and conducted by Research Triangle Institute (RTI) and its subcontractor, the University of North Carolina. The purpose of this project is to design, implement, and evaluate an intervention program to prevent injurious falls in assisted living facilities. To help us accomplish our goal, four assisted living facilities in NC are scheduled to participate in the project.

Why was I chosen? You participated in the exercise program at your facility during the last year. Approximately 200 residents across the four assisted living facilities in North Carolina are participating in the project. We will be interviewing approximately six residents in two of these facilities about their participation in the falls Prevention project.

What will happen during the interview? The interview will last approximately 30 minutes. With your permission, the discussion will be tape recorded. The tapes will help us get everything you have to say. During the interview we will talk about your thoughts about the exercise program, the impact the program had on you and how you liked participating in the falls prevention project overall. We also ask about any recommendations for improvements. There are no costs to you for participating and you will not be paid for participating in the interview.

Will I be contacted again? We do not expect to contact you again to participate in interviews about the falls prevention project.

Are there risks? We do not expect any risks to you from participating in this study; however you may choose not to answer any question that makes you uncomfortable. If you decide later that you do not want to be included, we will not use your comments.

Are there benefits? There is no direct benefit to you for being part of this study except the satisfaction of helping us to develop a protocol that may be used nationally to implement falls prevention programs in assisted living facilities.

Do I have to take part? Your participation is voluntary and you can leave the discussion at any time. You can refuse to answer any question. Your choice to take part will not have any impact on your relationship with facility staff.

Will this be kept private? We will keep the tapes and the transcriptions in a secure computer file and will delete the recordings and the transcriptions after the project is over. We will summarize what we learn and prepare a report, but your name will not be used in any of our reports. Only project team members will be allowed to use them and they will keep your information private.

Whom do I call if I have questions? If you have any questions about the study, you can call the project director, Edie Walsh, PhD at 1-800-334-8571, x21754. You can also call her if you decide later that you don't want to be in this study. If you have any questions about your rights in taking part of this study, or if you feel you have been harmed, you can call RTI's Office of Research Protection and Ethics at 1-866-214-2043 (a toll-free number).

I have read this form and I agree to be a part of this study. I have received a copy of the consent form. I asked questions about anything that was not clear to me.

_____ _____

Signature Date

HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

UNIVERSITY OF NORTH CAROLINA-CHAPEL HILL

IRB Study #_____ **HIPAA Form Version Date:** 2/25/07

Title of Study: Preventing Falls in Assisted Living Facilities

Principal Investigator: Sheryl Zimmerman, PhD
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-962-6417

Co-Investigators: Phillip D. Sloane, MD, MPH
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-966-5818

Project Director: Edith G. Walsh, PhD
Mailing Address: RTI International, Research Triangle Park, NC
Phone number: 781-434-1754

Funding Source: The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina

Study Contact telephone number: 919-966-6074
Study Contact email: Madeline_Mitchell@unc.edu

This is a permission called a "HIPAA authorization." It is required by "The Health Insurance Portability an4d Accountability Act of 1996" (known as "HIPAA") for us to get information from your medical records or health insurance records to use in this research study.

1. If you sign this HIPAA authorization form you are giving your permission for the following people or groups to give the researchers certain information (described in #2 below) about you:

The assisted living provider where you currently reside.

2. If you sign this HIPAA authorization form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Medical information related to your falls risk, such as your cognitive status, diagnoses, or medications. This information will be used to assess and better understand your falls risk.

3. The people or groups listed in #1 on this form may give this health information to the researcher listed at the top of this form (UNC-Chapel Hill Principal Investigator) or to another researcher working on this research

study. This information may also be shared with, used by or seen by the sponsor of the research study, the sponsor's representatives, officials of the IRB, and certain employees of the university or government agencies if needed to oversee the research study.

4. The HIPAA rules that apply to your medical records will not apply to your information in the research study records. The informed consent document describes the procedures in this research study to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2 on this form. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study but not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. HIPAA rules are that if you want to stop this HIPAA authorization, you must do that in writing. You may give your written stop of this HIPAA authorization directly to the people or groups listed in #1 on this form or you may give it to the researcher and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____
Signature of Research Subject Date

_____
Print Name of Research Subject

For Personal Representative of the Research Participant (<u>if applicable</u>)

Print Name of Personal Representative: _____
Please explain your authority to act on behalf of this Research Subject:

_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Subject.

_____ _____
Signature of Personal Representative Date

HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

UNIVERSITY OF NORTH CAROLINA-CHAPEL HILL

Legally Authorized Representative

IRB Study #_____ **HIPAA Form Version Date:** 2/25/07

Title of Study: Preventing Falls in Assisted Living Facilities

Principal Investigator: Sheryl Zimmerman, PhD
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-962-6417

Co-Investigators: Phillip D. Sloane, MD, MPH
UNC-Chapel Hill Department: Cecil G. Sheps Center for Health Services Research
Mailing Address: CB 7590, 725 Martin Luther King Jr. Blvd., Chapel Hill, NC 27599
UNC-Chapel Hill Phone Number: 919-966-5818

Project Director: Edith G. Walsh, PhD
Mailing Address: RTI International, Research Triangle Park, NC
Phone number: 781-434-1754

Funding Source: The Agency for Health Care Quality and Research through a contract to RTI International and a subcontract to the University of North Carolina

Study Contact telephone number: 919-966-6074
Study Contact email: Madeline_Mitchell@unc.edu

This is a permission called a "HIPAA authorization." It is required by "The Health Insurance Portability an4d Accountability Act of 1996" (known as "HIPAA") for us to get information from your (family relation's) medical records or health insurance records to use in this research study.

1. If you sign this HIPAA authorization form you are giving your permission for the following people or groups to give the researchers certain information (described in #2 below) about your (family relation):

The assisted living provider where you currently reside.

2. If you sign this HIPAA authorization form, this is the health information about your (family relation) that the people or groups listed in #1 may give to the researchers to use in this research study:

Medical information related to your falls risk, such as your cognitive status, diagnoses, or medications. This information will be used to assess and better understand your (family relation's) falls risk.

3. The people or groups listed in #1 on this form may give this health information to the researcher listed at the top of this form (UNC-Chapel Hill Principal Investigator) or to another researcher working on this research study. This information may also be shared with, used by or seen by the sponsor of the research study, the sponsor's representatives, officials of the IRB, and certain employees of the university or government agencies if needed to oversee the research study.

4. The HIPAA rules that apply to your (family relation's) medical records will not apply to your information in the research study records. The informed consent document describes the procedures in this research study to protect your (family relation's) personal information. You can also ask the researchers any questions about what they will do with your (family relation's) personal information and how they will protect your (family relation's) personal information in this research study.

5. If you want your (family relation) to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about your (family relation) that is listed in #2 on this form. If you do not want to sign this HIPAA authorization form, your (family relation) cannot participate in this research study but not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will not stop unless you stop it in writing.

7. You have the right to stop this HIPAA authorization at any time. HIPAA rules are that if you want to stop this HIPAA authorization, you must do that in writing. You may give your written stop of this HIPAA authorization directly to the people or groups listed in #1 on this form or you may give it to the researcher and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____ _____
Signature of Research Subject Date

_____
Print Name of Research Subject

For Personal Representative of the Research Participant (<u>if applicable</u>)

Print Name of Personal Representative: _____
Please explain your authority to act on behalf of this Research Subject:

_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Subject.

_____ _____
Signature of Personal Representative Date