Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Kristin Archer, PhD **Revision Date:** May 8, 2018
Study Title: Spine Pain INtervention to Enhance Care quality And Reduce Expenditure (SPINE CARE)
Institution/Hospital: Vanderbilt University Medical Center

This informed consent document applies to adults.

Name of participant: _____ Age: _____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Your participation in this research study is voluntary. You may choose not to participate and receive alternative treatments without affecting your healthcare/services or other rights. You are also free to withdraw from this study at any time. In the event new information becomes available that may affect the risks or benefits associated with this research study or your willingness to participate in it, you will be notified so that you can make an informed decision whether or not to continue your participation in this study.

1. Purpose of the study:

The purpose of this study is to identify how best to care for individuals with back and neck pain. Approximately 3,000 patients at 30 primary care clinics across the US will be participating in this trial. As part of this trial, different clinics are using different approaches to care for patients like you. Patients in your clinic will continue to receive the treatments recommended by their doctor and medical team.

You are being asked to participate in a research study because you have been experiencing back and/or neck pain for less than 3 months.

2. Procedures to be followed and approximate duration of the study:

If you join the study, your participation will last 12 months. Like other patients from your clinic participating in this study, you will continue with the treatments recommended by your doctor and medical team. There will be no additional tests or treatments required as part of the study.

Before you leave the clinic today, you will be asked to complete baseline questionnaires that ask you about your pain and functioning. The questionnaires should take approximately 15 minutes to complete. All of these surveys will be completed electronically, with assistance available from study staff if necessary. You will be asked these same questions four (4) more times over the next 12 months. In addition, everyone (1) to two (2) months you will also be asked to complete a checklist that asks what healthcare services you used. These questionnaires will be used to estimate how much it costs to take care of patients with acute back and neck pain.

3. Expected costs:

There is no cost to you for this study. All care recommended by your Spine Care Team that is related to the research will be paid for by the study sponsor. Any charges related to your standard of care will be the responsibility of you or your insurance company.

4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

It is possible that your spine pain may be better controlled with other treatments that are not offered as part of this study. If you are concerned about symptoms you should speak with your primary care provider. There is a small risk that your health information may not be kept strictly confidential. We do our best to securely handle the information that we collect from you. If, during the study, any other risks become known, you will be told about them.

5. Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator with Sponsor input that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt or the Sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the Sponsor to give you money for the injury.

6. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study are that information from this study might help researchers to better understand spine pain or come up with new ways to help others in the future.

b) The benefits you might get from being in this study are that the study may also help you better manage your spine pain, but there is no guarantee that being in this study will help you. Your spine pain might not get better or may even get worse while you are in this study. Regardless of whether you choose to participate, your own primary care providers will continue to be closely involved in your care and can recommend additional treatments if necessary.

7. Alternative treatments available:

Whether or not you choose to take part in the study you will receive the same standard of care you would normally get for back and/or neck pain. Your provider and his/her staff will decide which treatments are best for you.

8. Compensation for participation:

All study subjects will be provided compensation for their time to participate in the study. Subjects will receive $20 after enrolling in the study (i.e., completing all questionnaires), $20 at 3 months, $20 at 6 months, $20 at 9 months and $20 at one year after enrollment for completing follow-up assessments, either in person, online, or by phone. The maximum total compensation per study subject will not exceed $100.

If you do not complete any of the required parts of this study, you will not be compensated for those parts.

9. Circumstances under which the Principal Investigator may withdraw you from study participation:

You may be withdrawn from the study if your medical condition changes so that staying in this study may risk your health or disqualify you for this research. The entire study could be stopped at any time if the safety of research participants is found to be at significant risk. If the study is stopped for any reason, you will be told that the study is being stopped. If you are taken out of the study, you will be told the reason why.

10. What happens if you choose to withdraw from study participation?

Taking part in this study is voluntary. You are free to choose not to take part in the study or to stop taking part at any time without any penalty or loss of benefits to which you would otherwise be entitled. You do not need to give a reason. If you decide to stop being part of the study, you must tell a member of the study staff. Deciding not to be part of the study will not change your regular medical care in any way.

11. Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact Dr. Archer or a member of the study staff at 615-936-3439.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

12. Confidentiality:

Your personal information, including the surveys that you complete, will be kept secure at all times, using an electronic data capture system called REDCap. This system allows your research team to collect your data on a secure, password protected platform. REDCap access is limited to the study staff only.

If information needs to be transmitted from your healthcare clinic it will be done using fax machines or your secure medical record used by your normal clinical providers.

A de-identified version of your information will be shared with the research team to analyze the overall results of the study. Your personal information will never be disclosed to other parties, unless a law enforcement, judicial, or governmental authority requires it for safety and public health reasons. If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

The following groups may see your study and medical records in order to verify the research was done properly: The Office for Human Research Protections (OHRP), the sponsor, or your doctor's Institutional Review Board (a group of people who review research studies to protect the rights and welfare of research participants).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

13. Privacy:

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked questionnaire data, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, and the study sponsor. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr Archer and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Archer in writing and let her know that you withdraw your consent. Her mailing address is 1215 21st Ave South, Suite 4200, Nashville, TN, 37232. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

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Principal Investigator: Kristin Archer, PhD **Revision Date:** ~~May 8, 2018~~April 2, 2019
Study Title: Spine Pain INtervention to Enhance Care quality And Reduce Expenditure (SPINE CARE)
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Name of participant: _____ Age: _____

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1. Purpose of the study:

The purpose of the study is to identify how best to care for individuals with back and neck pain. Approximately 3,000 patients at 30 primary care clinics across the US will be participating in this trial. As part of this trial, different clinics are using different approaches to care for patients like you. Your clinic is assigned to the Identify, Coordinated, Enhanced Decision Making (ICE) approach. As part of this approach your provider will manage your care and refer you to a physical therapist and a spine coach who will help you manage your pain.

You are being asked to participate in a research study because you have been experiencing back and/or neck pain for less than 3 months.

2. Procedures to be followed and approximate duration of the study:

If you join the study, your participation will last 12 months. Like other patients from your clinic, you will receive a referral to a specialized Spine Care Team. The team consists of three people: a physical therapist, a spine coach and a spine specialist physician. All participants in the study will have at least one in person session with the physical therapist, who will help you with strengthening and stretching exercises. All participants will also have a phone consultation with the spine coach who will provide you with skills to manage your pain and to overcome any challenges you are having doing your prescribed exercises. Patients with more severe symptoms will have additional physical therapy and spine coach visits as required, up to a maximum of three. If you have more severe symptoms, your spine related health records will be reviewed by a specialist spine physician, who will offer recommendations to your primary care provider about other treatments that might help you to improve your symptoms. The care you receive from the spine team will be paid for by the study. In addition to being referred to the spine care team, your doctor and medical team will still be available to you as usual.

Before you leave the clinic today, you will be asked to complete baseline questionnaires that ask you about your pain and functioning. The questionnaires should take approximately 15 minutes to complete. All of these surveys will be completed electronically, with assistance available from study staff if necessary. You will be asked these same questions four (4) more times over the next 12 months. In addition, everyone (1) to two (2) months you will also be asked to complete a checklist that asks what healthcare services you used. These questionnaires will be used to estimate how much it costs to take care of patients with acute back and neck pain.

If you drive to the Vanderbilt Physical Therapy clinic as part of this study, we will reimburse you for mileage at the current TN rate.

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1. Purpose of the study:

The purpose of this study is to identify how best to care for individuals with acute back and neck pain. Approximately 3,000 patients at 30 primary care clinics across the US will be participating in this trial. As part of this trial, different clinics are using different approaches to care for patients like you. Your clinic is assigned to the Individualized postural therapy (IPT) approach. As part of this approach your provider will manage your care and refer you to a trained postural therapy provider.

You are being asked to participate in a research study because you have been experiencing back and/or neck pain for less than 3 months.

2. Procedures to be followed and approximate duration of the study:

If you join the study, your participation will last 12 months. Like other patients from your clinic, you will be referred to a treatment program that uses exercises to correct imbalances in your posture that cause back or neck pain. This way of caring for patients is called “Individualized Postural Therapy” and for the purpose of this study will be delivered by therapies at the Egoscue Method clinic. Your visits to the Egoscue clinics will be paid for by the study. The Egoscue therapists will provide you with a postural assessment and recommend exercises to improve your pain and functioning. A typical course of treatment will include 8 visits over two months. Egoscue therapists will work with you to ensure exercises are done properly and you progress adequately. This method does not involve the use of prescription medications, surgery, or manipulation. The first visit must be done in person but follow-up visits can be done by video conference (for example, using Skype).

In addition to being referred to the Egoscue Method clinic, your doctor and medical team will still be available to you as usual.

Before you leave the clinic today, you will be asked to complete baseline questionnaires that ask you about your pain and functioning. The questionnaires should take approximately 15 minutes to complete. All of these surveys will be completed electronically, with assistance available from study staff if necessary. You will be asked these same questions four (4) more times over the next 12 months. In addition, everyone (1) to two (2) months you will also be asked to complete a checklist that asks what healthcare services you used. These questionnaires will be used to estimate how much it costs to take care of patients with acute back and neck pain.

If you drive to the Egoscue Method clinic as part of this study, we will reimburse you for mileage at the current TN rate.

3. Expected costs:

There is no cost to you for this study. All care recommended by your Spine Care Team that is related to the research will be paid for by the study sponsor. Any charges related to your standard of care will be the responsibility of you or your insurance company.

4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

It is possible that your spine pain may be better controlled with other treatments that are not offered as part of this study. If you are concerned about symptoms you should speak with your primary care provider. There is a small risk that your health information may not be kept strictly confidential. We do our best to securely handle the information that we collect from you. If, during the study, any other risks become known, you will be told about them.

5. Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator with Sponsor input that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury. There are no plans for Vanderbilt or the Sponsor to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or the Sponsor to give you money for the injury.

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7. Alternative treatments available:

Whether or not you choose to take part in the study you will receive the same standard of care you would normally get for back and/or neck pain. Your provider and his/her staff will decide which treatments are best for you.

8. Compensation for participation:

All study subjects will be provided compensation for their time to participate in the study. Subjects will receive $20 after enrolling in the study (i.e., completing all questionnaires), $20 at 3 months, $20 at 6 months, $20 at 9 months and $20 at one year after enrollment for completing follow-up assessments, either in person, online, or by phone. The maximum total compensation per study subject will not exceed $100.

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10. What happens if you choose to withdraw from study participation?

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11. Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact Dr. Archer or a member of the study staff at 615-936-3439.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

12. Confidentiality:

Your personal information, including the surveys that you complete, will be kept secure at all times, using an electronic data capture system called REDCap. This system allows your research team to collect your data on a secure, password protected platform. REDCap access is limited to the study staff only.

If information needs to be transmitted from your healthcare clinic it will be done using fax machines or your secure medical record used by your normal clinical providers.

A de-identified version of your information will be shared with the research team to analyze the overall results of the study. Your personal information will never be disclosed to other parties, unless a law enforcement, judicial, or governmental authority requires it for safety and public health reasons. If you leave the study, the study doctor and study staff will still be able to use your information that they have already collected.

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13. Privacy:

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Principal Investigator: Kristin Archer, PhD **Revision Date: April 2, 2019**
Study Title: Spine Pain INtervention to Enhance Care quality And Reduce Expenditure (SPINE CARE)
Institution/Hospital: Vanderbilt University Medical Center

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked questionnaire data, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, the study sponsor, and your postural therapist. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr Archer and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Archer in writing and let her know that you withdraw your consent. Her mailing address is 1215 21st Ave South, Suite 4200, Nashville, TN, 37232. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title

3. Expected costs:

There is no cost to you for this study. All care recommended by your Spine Care Team that is related to the research will be paid for by the study sponsor. Any charges related to your standard of care will be the responsibility of you or your insurance company.

4. Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

During the study, you will be seen by a licensed physical therapist who will help you with strengthening and stretching exercises. It is possible that you may experience soreness in your muscles after exercising. It is also possible that your spine pain may be better controlled with other treatments that are not offered as part of this study. If you are concerned about symptoms you should speak with your primary care provider. There is a small risk that your health information may not be kept strictly confidential. We do our best to securely handle the information that we collect from you. If, during the study, any other risks become known, you will be told about them.

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7. Alternative treatments available:

Whether or not you choose to take part in the study you will receive the same standard of care you would normally get for back and/or neck pain. Your provider and his/her staff will decide which treatments are best for you.

8. Compensation for participation:

All study subjects will be provided compensation for their time to participate in the study. Subjects will receive $20 after enrolling in the study (i.e., completing all questionnaires), $20 at 3 months, $20 at 6 months, $20 at 9 months and $20 at one year after enrollment for completing follow-up assessments, either in person, online, or by phone. The maximum total compensation per study subject will not exceed $100.

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Date	Signature of patient/volunteer

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Date Signature

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Printed Name and Title