NYU Langone MEDICAL CENTER

# RESEARCH SUBJECT INFORMED CONSENT FORM

**Protocol Title**: Evaluating the Impact of Reining in Anxiety™ on Childhood Anxiety.

**Protocol #**:
**Sponsor**: N/A
**Principal Investigator**: Kimberly Hoagwood, PhD
**Institution**: New York University School of Medicine
**Address**: One Park Avenue, 8th Floor, New York, NY. 10016
**Telephone**: (240) 401-4289

## Key Information Statement

The purpose of this study is to evaluate Reining in Anxiety™, an equine assisted therapy for childhood anxiety. Study subjects (your child) will participate in 10 weekly group sessions lasting 45 minutes each week, and answer questionnaires about their knowledge about anxiety and their relationship with the horse. You will also answer questionnaires about your child's symptoms of anxiety and emotional regulation. You and your child's participation will last for no more than three months. Participation is completely voluntary. There is the risk of loss of confidentiality of your (you and your child's) personal information collected for this study. You and your child may also feel uncomfortable answering some of the questions, and your child may find the saliva collection uncomfortable.

**If you are interested in learning more about this study, please continue to read below, where you will find additional information related to this study such as the risks, benefits, procedures, alternatives, and contact information.**

## KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a subject in a research study because you are the caregiver of a child between the ages of six and 17 who has symptoms of anxiety.

**The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.**

| | |
|---|---|
| **Purpose** | This is a research study to evaluate the effectiveness of Reining in Anxiety™, an equine treatment for childhood anxiety. You are being asked to participate in this study because you are the primary caregiver of a child between six and 17 years of age who has symptoms of anxiety. This study is being delivered at Fieldstone Farm Therapeutic Riding Center. |
| **Voluntary Participation** | Your decision to be in this study is voluntary. |
| **Withdrawal** | If you decide to be in this study and then change your mind, you can leave the study at any time without penalty. |
| **Length of Participation** | Your participation is expected to last for about three months. During that time, you and your child will have about 10 study visits at Fieldstone Farm Therapeutic Riding Center. |

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| **Procedures** | Your child will receive Reining in Anxiety™ at Fieldstone Farm. This therapy consists of a 10-week riding group that meets weekly for 45 minutes each week. Your child will attend the group sessions and complete three questionnaires: two (which will assess whether your child feels in control when they feel anxious and their knowledge about anxiety) will be collected at baseline (before the first session) and posttest (after the eighth session). The third will be collected four times (after the child's first, fourth, seventh, and tenth group sessions).and will assess your child's feelings towards their horse. Your child will also provide a saliva sample eight times (before and after their first, fourth, seventh, and tenth group sessions).<br>You will also answer seven questionnaires; two will be collected at baseline (before your child's first session) and will ask for information about you and your child; one will be collected at baseline only and ask about any traumatic events your child has had in your life, and three will be collected both at baseline and posttest (after your child's last session) about any symptoms of anxiety your child has had, whether they are in control when they feel anxious, and your child's relationships with others. You will also be asked to complete a satisfaction questionnaire at the end of your participation. Finally, you will join the last 10 minutes of each group session to learn about anxiety and ways to help your child manage it. |
| **Risks** | There are not expected to be any physical risks to you as part of this study. However, you may find some of the questions uncomfortable. Your child may also find some of the questions, or collecting their saliva uncomfortable. You do not have to answer any questions that make you feel uncomfortable, and your child does not have to answer any questions or have their saliva collected. There is also the risk of a loss of your and your child's confidentiality due to your participation in this study. All data will be coded with ID numbers and stored on computerized, password-protected computers. All electronic records will be kept on REDCap, a secure online server at New York University. Privacy will be protected through the use of codes. |
| **Benefit** | There is no guarantee that you or your child will benefit as a result of your participation in this study, however the study results may help people in the future. |
| **Alternative(s) to Study Participation** | The other option for treatment is a group therapeutic riding intervention that is already being delivered at Fieldstone Farm Therapeutic Riding Center. |
| **Costs** | There are no costs associated with this study. |

**This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.**

## INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

### DISCLOSURE OF FINANCIAL INTERESTS

There is no funding for this research.

### PURPOSE OF THE STUDY

The purpose of this study is to examine the impact of an equine-facilitated group intervention called Reining in Anxiety™ for children with anxiety and their caregivers.

### NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION

About 80 children/teens and their caregivers are expected to participate in this study at Fieldstone Farm Therapeutic Riding Center, which has provided therapeutic riding to children with mental health problems for over 40 years. Your participation in this study is expected to last no longer than three months.

### STUDY PROCEDURES

If you agree to participate in this study, you and your child will receive Reining in Anxiety,™ a 10 week group that meets weekly for 45 minutes each week for your child. You will join the last 10 minutes of each group session to learn about anxiety and the treatment your child is receiving. Your child will answer three questionnaires: two will assess whether your child feels in control when they feel anxious and their knowledge about anxiety and will be collected at baseline (before the first session) and posttest (after the eighth session). These questionnaires will take about 30 minutes to complete. The third questionnaire will be collected four times (after your child's first, fourth, seventh, and tenth group sessions) about your child's feelings towards their horse. This will take about 10 minutes to complete. Your child will also provide a saliva sample eight times (before and after their child's first, first, fourth, seventh, and tenth group sessions). This will take approximately five minutes to complete at each time point.

You will also answer seven questionnaires; two will be collected at baseline (before your child's first session) and will ask for information about you and your child; one will be collected at baseline only and ask about any traumatic events you have had in your life, three will be collected both at baseline and posttest (after your child's last session) about any symptoms of anxiety your child has had, whether they are in control when they feel anxious, and your child's relationships with others. The final questionnaire will ask about your satisfaction with the program. The questionnaires will take approximately 30 minutes to complete at each timepoint.

### RISKS AND DISCOMFORTS

There are no physical, social or economic risks associated with participation. However, you or your child may find some of the questions uncomfortable. You or your child do not have to answer

any questions that make you feel uncomfortable. Your child may also find the saliva collection uncomfortable. Your child does not have to provide a saliva sample if they feel uncomfortable. There is also the risk of a loss of you/your child's confidentiality due to your participation in this study. To protect your confidentiality, all data will be coded with ID numbers and stored on computerized, password-protected computers. Tracking information also will be kept in password protected computer files. The master list will only be used to coordinate data collection. All other data, including consent forms and questionnaires, will be kept on REDCap, a secure web platform at New York University. And all staff will be required to receive training on confidentiality issues. In addition, research staff will be required to complete a computer-based training related to human subjects data collection offered through New York University.

Further, your responses will be kept confidential by the researcher, but the researcher cannot guarantee that others in the group will do the same.

Additionally, there is a potential risk that your child's symptoms may worsen as a consequence of the progression of a serious mental health issue or response to a service provided. If this occurs, your study participation will be halted and your instructor will provide appropriate care in accordance with clinic procedure immediately.

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Clinically Relevant Research Results
The overall results of this study may or may not be available to you at the end of the study. The study doctor will also explain if and when you will receive individual research results that may have clinical significance.

**BENEFITS**
In a prior study, children who received Reining in Anxiety™ experienced benefits including reduced symptoms of anxiety and emotional regulation. There is no guarantee that your child's anxiety will improve as a result of your participation in this study. It may stay the same or worsen. However, the information learned from this study may help other people with anxiety in the future.

**ALTERNATIVES TO STUDY PARTICIPATION**
You do not have to participate in this study to receive treatment for your child's anxiety. condition. Fieldstone Farm offers therapeutic riding lessons for children with mental health problems.

**COSTS OF PARTICIPATION**
There is no cost associated with participation in this study.

**REIMBURSEMENT**
You will receive $25 gift card at the beginning of the study after completing the first set of questionnaires before your child's first session, and $25 gift card after completing the questionnaires after your child's final session.

Tax law may require the payer (e.g. research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you

received from the study.

## CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

**Collection of Identifiable Private Information**:
Your information collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research studies.

## VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor's office for a final study visit for your safety.

## CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Kimberly Hoagwood at (240) 401-4289.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

**STATEMENT OF CONSENT - SIGNATURES**

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

| | | |
|---|---|---|
| **Subject**: Name (Print) | Signature | Date |
| **Person Obtaining Consent**: Name (Print) | Signature | Date |

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**COSTS OF PARTICIPATION**
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**REIMBURSEMENT**
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**Collection of Identifiable Private Information**:
Your information collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research studies.

## VOLUNTARY PARTICIPATION AND WITHDRAWAL

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- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

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| **Person Obtaining Consent**: Name (Print) | Signature | Date |