

(THIS FORM IS FOR RRB USE ONLY)

RRB RESEARCH REVIEW DETERMINATION

- Exempt from Review (Chair RRB)
- Expedited Review (RRB Subcommittee)
- Full RRB Review (Full RRB Committee)

RRB RESEARCH APPROVAL DETERMINATION

- Disapproval
- Full Approval
- Conditional Approval* (circle A or B)
 - A. Approval, subject to minor change
 - B. Approval in general but requiring major alterations, clarifications or assurances

(* Data collection cannot begin until Full Approval is given by the RRB Chair)

COMMENTS:

Chair, Research Review Board

Date

**APPLICATION FOR RESEARCH INVOLVING HUMAN SUBJECTS
IN BIOMEDICAL OR BEHAVIORAL RESEARCH**

Please Type

1. Principal Investigator's Name: Tom Sneed, PT, DPT

Co-Investigator: Amanda Coblentz, Tara Hargrove, Erin Kirsch, Jana McNulty,
and Robin Miller

Department: Physical Therapy

Phone: 328-1672/1911

2. If you are a student, provide the following:

Faculty Sponsor: N/A

Department:

Phone:

Is this your thesis research? Yes _____ No _____

3. Title of Project: Effect of Therapeutic Exercise on Idiopathic Scoliosis

4. Has this project previously been considered by the RRB? Yes _____ No X

If yes, give approximate date of review:

5. Is a proposal for external support being submitted? Yes _____ No X

If yes, you must submit one copy of that proposal as soon as it is available and complete the following:

a. Is notification of Human Subject approval required? Yes _____ No _____

b. Is this a renewal application? Yes _____ No _____

c. Sponsor's Name:

d. Total project period: From: _____ To: _____

6. In your judgment, does your research fall under one of the EXEMPT categories listed in the RRB Guidelines and Application for Research Involving Human Subjects, section II2IA1-4? Yes _____ No X

If you believe it does, indicate the number of the category under which you are claiming an exemption:

7. Does your project fall under one of the categories eligible for EXPEDITED REVIEW as listed in the RRB Guidelines and Application for Research Involving Human Subjects, section IIIB1-5?

Yes _____ No X

8. Have you included copies of all pertinent attachments including, but not limited to: questionnaire instruments, informed consent(s), letters of approval from cooperating institutions, copy of external support proposal, etc.?

Yes X No _____

Proposed Research Project: Please type your answers to the following questions and provide supporting documents in appendices.

- A. Provide a brief description of the proposed research. Include major hypotheses (or research question), research design and a brief review of the literature supporting your position.

Scoliosis is the term given to describe a lateral curvature of the spine measuring greater than 10° according to the Cobb angle of measurement.^{1,7,12} Scoliosis also involves a rotational deformity of the vertebrae in the spinal column. Coupling of the lateral and rotational curvatures leads to a deformity of the ribcage/trunk causing an associated body asymmetry.² The spinal deformity scoliosis has many known causes but the vast majority, 70-90%, has an unknown origin thus designating it as idiopathic scoliosis.^{7,17} Prevalence of an idiopathic scoliosis of around 10° is somewhere between 2-4% of children ages 10-16 years and it is equally divided between females and males.^{9,12} Prevalence drops as the severity of the curvature increases but with an increased ratio of females to males of 4-5:1.^{7,9,12} Curvature prevalence between 20-30 $^{\circ}$ is approximately 0.3-0.5% while curves between 30-40 $^{\circ}$ is approximately 0.1-0.3%.^{7,9} Finally, prevalence of curves greater than 40 $^{\circ}$ is about 0.1%.^{7,9} In light of the majority of scoliosis deformities being idiopathic and the noted prevalence, it becomes important to identify the spinal deformity as early as possible.

Identifying idiopathic scoliosis typically relies on screening of spinal, trunk, or postural asymmetries in a basic physical examination typically performed in public school settings. A positive finding on the screening exam in turn leads to a physician referral for evaluation. The diagnosis of idiopathic scoliosis is made by eliminating all other causes of a lateral curvature of the spine. Physician evaluation typically consists of a medical history, physical examination, and standing radiographs of the entire spine whereby the type and severity of curve is documented.^{7,9} Once a diagnosis of idiopathic scoliosis is made, current standard of care measures that follow include observation of curves less than 20 $^{\circ}$, bracing for curves with 5 $^{\circ}$ progression and move beyond 20-25 $^{\circ}$, and surgery for curvatures beyond 40 $^{\circ}$.^{12,17} Risk factors of progression include age, gender, curvature magnitude at the time of detection, skeletal maturity as it relates to growth potential, and puberty.^{7,9,12,17} The more skeletally immature, pre-menarche female with a larger curve noted at detection is at greatest risk of curvature progression. The end result of idiopathic scoliosis leads to the impairments of pain, spinal deformity, decreased spinal range of motion, curvature progression, psychological distress, and potential cardiac and pulmonary dysfunction.^{9,12,16}

It should be noted from above that the mainstays of intervention for idiopathic scoliosis have been observation, bracing, and surgery. The intervention of therapeutic exercise was not mentioned as a treatment option in the standard of care for the natural history and progression of the disease. However, there is a growing body of research giving evidence to the positive effect a variety of exercises have on idiopathic scoliosis. A variety of studies have looked at the effect of what appears to be postural correction and awareness through motor control and movement re-education.^{3,6,8,13,15,18,19,20} These exercise studies used various approaches to improve scoliosis curvature emphasizing posture correction via a side shift therapy,^{3,8} a specific therapeutic maneuver,⁶ and an in-patient hospital stay.^{15,18,19,20} A few studies have specifically looked at strength training of trunk musculature.^{10,11,14} One study focused on strengthening muscles controlling the pelvis¹⁴ while two other studies focused

specifically on paraspinal muscle strengthening.^{10,11} Still other studies report improved effects of exercise on scoliotic curvatures but were less specific in descriptions of exercises.^{4,5,13} These last few studies hint around about stretching and posture correction activities as the exercises utilized. Unfortunately, no consistent set of exercises or program have been used in all studies. Collectively though, it appears the exercise approach to utilize for idiopathic scoliosis should incorporate posture correction/awareness, strengthening, and stretching. This leads to a research question of what are the effects of therapeutic exercise on progression and/or reduction of spinal curvature in idiopathic scoliosis using some combination of posture correction, strengthening, and stretching? More evidence of the positive effect therapeutic exercise has on idiopathic scoliosis is needed.

The purpose of this proposal is to perform a single-subject pre-test, post-test design study measuring the effect of a therapeutic exercise program using posture correction, strengthening, and stretching on spinal curvature in an idiopathic scoliosis subject.

Reference List:

1. Ahn UM, et al. The etiology of adolescent idiopathic scoliosis. *Am J Orthop* 2002; 31(7): 387-95.
2. Dangerfield PH. The classification of spinal deformities. *Ped Rehab* 2003; 6(3-4): 133-36.
3. den Boer WA, Anderson PG, Limbeek Jv, Kooijman MAP. Treatment of idiopathic scoliosis with side-shift therapy: an initial comparison with a brace treatment historical cohort. *Eur Spine J* 1999; 8(5): 406-10.
4. Dobosiewicz K, Durmala J, Czernicki K, Jendrzewek H. *Pathomechanic basics of conservative treatment of progressive idiopathic scoliosis according to Dobosiewicz method based upon radiologic evaluation*. Stud Health Technol Inform. 2002; 91:336-41.
5. El-Sayyad M, Conine TA. Effect of exercise, bracing and electrical surface stimulation on idiopathic scoliosis: a preliminary study. *Intern J Rehab Research* 1994; 17(1): 70-4.
6. Golembiewski GV, Catanzaro DJ. Scoliosis reduction utilizing an exercise. *J Vertebral Sublux Research* 2001; 4(2): 31-6.
7. Hawes MC. Scoliosis and the human spine. Tucson, AZ: West Press; 2003. p. 4-34.
8. Mamyama T, Kitagawal T, Katsushi T, Nakainura K. *Side shift exercise for idiopathic scoliosis after skeletal maturity*. Stud Health Technol Inform. 2002; 91: 361-4.
9. Miller NH. Cause and natural history of adolescent idiopathic scoliosis. In: Stanitski DF, editor. *The orthopedic clinics of north america: disorders of the pediatric spine*. Philadelphia, PA: WB Saunders; 1999. p.343-52.
10. Mooney V, Brigham A. The role of measured resistance exercises in adolescent scoliosis. *Orthopedics* 2003; 26(2): 167-71.
11. Mooney V, Gulick J, Pozos R. A preliminary report on the effect of measured strength training in adolescent idiopathic scoliosis. *J Spinal Disord* 2000; 13(2): 102-7.
12. Roach JW. Adolescent idiopathic scoliosis. In: Stanitski DF, editor. *The orthopedic clinics of north america: disorders of the pediatric spine*. Philadelphia, PA: WB Saunders; 1999. p. 353-65.
13. Solberg G. Scoliosis: plastic changes in spinal function of pre-pubescent scoliotic children engaged in an exercise therapy programme. *South Afric J Physiother* 1996;

52(1): 19-22, 24.

14. Stone B, et al. The effect of an exercise program on change in curve in adolescents with minimal idiopathic scoliosis: a preliminary study. *Phys Ther* 1979; 59(6): 759-63.

15. Weiss HR, Lohschmidt K, El-Obeidi N, Verres CH. Preliminary results and worst-case analysis of in patient scoliosis rehabilitation. *Ped Rehab* 1997; 1(1): 35-40.

16. Weiss HR. Guest editorial. *Ped Rehab* 2003; 6(3-4): 131-32.

17. Weiss HR. Rehabilitation of adolescent patients with scoliosis-what do we know?: a review of the literature. *Ped Rehab* 2003; 6(3-4): 183-94.

18. Weiss HR. The progression of idiopathic scoliosis under the influence of a physiotherapy rehabilitation programme. *Physiotherapy* 1992; 78(11): 815-21.

19. Weiss HR, Weiss G, Petermann F. Incidence of curvature progression in idiopathic scoliosis patients treated with scoliosis in-patient rehabilitation (SIR): an age- and sex-matched controlled study. *Pediatric Rehab*. 2003;6:23-30.

20. Weiss HR. Influence of an in-patient exercise program on scoliotic curve. *Italian Journal of Orthopaedics and Traumatology*. 1992;3:395-406.

B. Describe the source(s) of subjects and the selection criteria. Specifically where will you obtain the names of potential subjects and how will you contact them?

The Southwest Baptist University PT program maintains relationships with a number of primary health care physicians in Polk County. These physicians will be contacted requesting their assistance in identifying potential subjects. The PT program also maintains a relationship with the area schools in assisting with scoliosis screening exams. The school nurses will be contacted to inform them of the study and the need for their assistance in identifying potential subjects.

The potential subjects will be selected using the following criteria:

- 1) must have a diagnosis of idiopathic scoliosis from a primary care physician,
- 2) no prior history of physical therapy intervention of therapeutic exercises, use of a brace, or surgery for their scoliosis,
- 3) curve magnitude (less than) $< 40^\circ$ according to the Cobb angle measurement,
- 4) be skeletally immature, and
- 5) pre-menarche or pre-pubescent.

Each physician or school nurse identifying a potential subject will inform the subject and his/her guardian of the research study and ask for permission to allow the research team to contact him/her. Once the potential subject agrees to being contacted, the principal investigator or one of the co-investigators will contact the potential subject by phone to discuss the research study and verify that the subject meets the selection criteria.

C. Informed Consent: Describe the consent process and attach all consent documents.

Once a physician or school nurse has identified a potential subject, the research team will contact the potential subject and subject's guardian by phone to determine the level of interest in participating in the study and answer any preliminary questions. Once the interest level determined is sufficiently high enough, an 'in-person' meeting will be established wherein the potential subject and the subject's guardian will review the consent form while a member of the research team clearly explains the study and all its requirements and expectations. Once the study has been explained and the

subject has been given the opportunity to ask any questions, the subject will be asked to sign the consent form. (See Attachment A)

- D. Procedures: Provide a step-by-step description of each procedure, including the frequency, duration, and location of each procedure. Attach copies of surveys or other research materials as appropriate.
(note: additions or changes in procedures involving human subjects as well as any problems connected with the use of human subjects once the project has begun must be brought to the attention of the RRB).

The initial day will involve pretest measurement procedures to include:

- taking a history of the subject
- sagittal, frontal, and transverse plane thoracic spine, lumbar spine, and thoracolumbar spine range of motion measurements using a gravity inclinometer
- spinal rotation and extension strength measurements using Holten's diagram of percent of one repetition maximum
- anterior, posterior, left and right lateral Polaroid pictures on grid film.

The subject will then go through a predetermined exercise program for 26 weeks. There are two distinct components of the exercise program. The first component involves in-house performance of exercises under the supervision of the research team at the SBU Meyer Wellness Center on a three time per week basis. The second component involves performance of a home exercise program (HEP) daily, excluding the exercise days at the SBU Wellness Center. The pretest strength measurements will determine the amount of weight or resistance to be used initially for the in-house strength training exercise program.

The Wellness Center exercise component program includes several types of exercises to include stretching, strength training, and posture awareness/ correction. The stretching exercise consists of side-bending opposite the curvature deformity (3 repetitions of 30-60secs) and a manual contract-relax stretch (3 repetitions of 5-7sec contraction holds) into rotation opposite the curvature deformity. The strength training portion of the Wellness Center exercise program will follow a progressive resistance exercise format (PRE). In a PRE regimen, the participant adds repetitions of a specific weight or resistance level until the participant is able to perform three sets of a predetermined number of repetitions with relative ease. Once this is accomplished, the weight or resistance level is raised and progression of repetitions starts over again. For this study, weight or resistance levels will be progressed in 5% increments once the subject is able to perform 3 sets of 20 repetitions. The strength training exercises include seated pulley trunk rotations left and right, and sagittal plane back extension using a Back Extension Machine. The posture awareness/correction exercise includes a side shift maneuver wherein the subject is taught to shift the trunk over their pelvis in a direction opposite the convexity curvature deformity. This maneuver is an active self correction or overcorrection by muscle contraction. Repetitions and durations held of this exercise will vary over the course of the study with the goal of the exercise being that the subject can hold this corrected posture for long periods of time, even to the point of adapting to the corrected posture as their normal.

The HEP component includes exercises that mimic the in-house exercise program. The same type of exercise is included such as stretching, strengthening, and posture correction. The stretching exercise utilizes the side-bending stretch adapted to

be performed at home independently. The strength training exercises utilize seated rotations with theraband as the resistance in place of the pulley and prone back extension over a physioball in place of the Back Extension Machine. Finally, the posture awareness/correction exercise is exactly the same as the in-house exercise but performed completely independently using the approach taught in the in-house program.

Following the 26 week predetermined exercise program, the subject will be re-measured using the same pretest measurements of spinal range of motion, spinal rotation and extension strength, and Polaroid grid film posture pictures.

E. How will confidentiality of the data be maintained?

Confidentiality of the subject will be maintained by designating an alphanumeric code for the subject and storing the electronic data on password protected computer disk by the principal investigator. Hard copy of subject data will be maintained in a folder placed in a locked file cabinet found in the principal investigator's office. Any external reporting of this data will be made in such a manner that the subject's identity is concealed.

F. Describe all known and anticipated risks to the subject including side effects, risks of placebo, risks of normal treatment delay, etc.

Known and anticipated risks from being involved in the study are few and are essentially the same that may occur for anyone starting a new exercise routine. Minor anticipated risks include: strain/sprain on muscle and/or joint tissues and delayed onset muscle soreness (DOMS). These minor anticipated risks will be minimized by educating and encouraging the subject to use proper technique during exercise performance.

The most significant risk from being involved in the study relates to the spinal curvature. The spinal curve could simply remain the same or potentially get worse. However, it should be noted that the natural history of idiopathic scoliosis curves of less than a 20° curvature have been shown to progress as well, so the subject is at no greater risk by participating in the study than by not participating.

G. Describe the anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result.

Direct anticipated benefits to subjects being involved in this study include improved spinal range of motion, increased spinal muscle strength, and improved posture. These benefits result from a more primary benefit of decreased (improved) spinal curvature, thus preventing progression of the curvature deformity. Related direct benefits beyond the physical improvements listed include psychological benefit. The subject may experience a higher level of self-confidence and/or body image as a result of the physical changes/improvements. Further indirect benefits include avoiding the need for brace and/or surgical correction of the spine. The knowledge gained from this research will help to build the evidence of the effect of therapeutic exercise on spinal curvature in idiopathic scoliosis. Furthermore, the exercises required to have any effect will be more narrowed and simplified for potential application to large numbers of patients or subjects with debilitating spinal curvature deformity.

(Attachment A)
SOUTHWEST BAPTIST UNIVERSITY
CONSENT TO PARTICIPATE IN
BIOMEDICAL RESEARCH

PARENT PERMISSION FORM

PROJECT TITLE:

Effect of Therapeutic Exercise on Spinal Curvature in Idiopathic Scoliosis

INVESTIGATORS:

Tom Sneed, PT, DPT (Principal Investigator) Assistant Professor, Department of Physical Therapy, Southwest Baptist University, Bolivar MO, 65613, 417/328-1672 or 417/328-1911.

Amanda Coblentz, SPT (Co-Investigator) Doctor of Physical Therapy Student, Department of Physical Therapy, Southwest Baptist University, Bolivar MO, 65613, 417/328-1672

Tara Hargrove, SPT (Co-Investigator) Doctor of Physical Therapy Student, Department of Physical Therapy, Southwest Baptist University, Bolivar MO, 65613, 417/328-1672

Erin Kirsch, SPT (Co-Investigator) Doctor of Physical Therapy Student, Department of Physical Therapy, Southwest Baptist University, Bolivar MO, 65613, 417/328-1672

Jana McNulty, SPT (Co-Investigator) Doctor of Physical Therapy Student, Department of Physical Therapy, Southwest Baptist University, Bolivar MO, 65613, 417/328-1672

Robin Miller, SPT (Co-Investigator) Doctor of Physical Therapy Student, Department of Physical Therapy, Southwest Baptist University, Bolivar MO, 65613, 417/328-1672

COOPERATING INSTITUTIONS:

Department of Physical Therapy
Southwest Baptist University
1600 University Avenue
Bolivar, Missouri 65613

DESCRIPTION OF RESEARCH PROJECT:

Scoliosis is an irregular curvature of the spine with many possible causes. The vast majority of scoliosis curvatures, 70-90%, have no known cause designating them as idiopathic scoliosis. Idiopathic scoliosis is usually identified through school screenings followed by a referral to a family physician for more extensive evaluation. The current standard of care for an individual with an idiopathic scoliosis is observation of curves less than 20°, bracing for curves with 5° progression and move beyond 20-25°, and surgery for curvatures beyond 40°. Risk factors of progression include age, gender, curvature magnitude at the time of detection, skeletal maturity as it relates to growth potential, and puberty. The more skeletal immature, pre-menarche female with a larger curve noted at detection is at greatest risk of curvature progression. The end result of idiopathic scoliosis leads to the impairments of pain, spinal deformity, decreased spinal range of motion, curvature progression, psychological distress, and potential cardiac and pulmonary dysfunction. It should be noted from above that the

intervention of therapeutic exercise was not mentioned as a treatment option in the standard of care for the natural history and progression of the disease. However, there is a growing body of research giving evidence to the positive effect a variety of exercises have on idiopathic scoliosis. The purpose of this study is to add to that body of knowledge by evaluating the effects of an exercise program including stretching, strengthening, and posture awareness/correction on spinal curvature.

Your child's participation in this study will possibly help physical therapists and other health care providers in appropriately managing idiopathic scoliosis patients, helping to prevent the need for bracing and/or surgery in these individuals.

ELIGIBILITY TO PARTICIPATE IN THE STUDY: Your child is required to have:

1. Diagnosis of idiopathic scoliosis from a primary care physician.
2. No prior history of physical therapy intervention of therapeutic exercises, use of a brace, or surgery for their scoliosis.
3. Curve magnitude (less than) $< 40^\circ$ according to the Cobb angle measurement,
4. Be skeletally immature.
5. Be pre-menarche or pre-pubescent.
6. Signed Parent Permission and Child Assent Forms.

PROCEDURES:

The initial day will involve pretest measurement procedures to include:

- taking a history of the subject;
- sagittal, frontal, and transverse plane thoracic spine, lumbar spine, and thoracolumbar spine range of motion measurements using a gravity inclinometer;
- spinal rotation and extension strength measurements using Holten's diagram of percent of one repetition maximum;
- anterior, posterior, left and right lateral Polaroid pictures on grid film.

Your child will then go through a predetermined exercise program for 26 weeks. There are two distinct components of the exercise program. The first component involves in-house performance of exercises under the supervision of the research team at the SBU Meyer Wellness Center, Bolivar, Missouri, on a three time per week basis. The second component involves performance of a home exercise program (HEP) daily, excluding the exercise days at the SBU Wellness Center. The pretest strength measurements will determine the amount of weight or resistance to be used initially for the in-house strength training exercise program.

The Wellness Center exercise component program includes several types of exercises to include stretching, strength training, and posture awareness/correction. The stretching exercise consists of side-bending opposite the curvature deformity (3 repetitions of 30-60secs) and a manual contract-relax stretch (3 repetitions of 5-7sec contraction holds) into rotation opposite the curvature deformity. The strength training portion of the Wellness Center exercise program will follow a progressive resistance exercise format (PRE). In a PRE regimen, the participant progresses repetitions of a specific weight or resistance level until the participant is able to perform three sets of a pre-determined number of repetitions with relative ease. Once this is accomplished, the weight or resistance level is raised and progression of repetitions starts over again.

For this study, weight or resistance levels will be progressed in 5% increments once the subject is able to perform 3 sets of 20 repetitions. The strength training exercises include seated pulley trunk rotations left and right, and sagittal plane back extension using a Back Extension Machine. The posture awareness/correction exercise includes a side shift maneuver wherein your child is taught to shift the trunk over their pelvis in a direction opposite the convexity curvature deformity. This maneuver is an active self correction or overcorrection by muscle contraction. Repetitions and durations held of this exercise will vary over the course of the study with the goal of the exercise being that the subject can hold this corrected posture for long periods of time, even to the point of adapting to the corrected posture as their normal.

The HEP component includes exercises that mimic the in-house exercise program. The same type of exercise is included such as stretching, strengthening, and posture correction. The stretching exercise utilizes the side-bending stretch adapted to be performed at home independently. The strength training exercises utilize seated rotations with theraband as the resistance in place of the pulley and prone back extension over a physioball in place of the Back Extension Machine. Finally, the posture awareness/correction exercise is exactly the same as the in-house exercise but performed completely independently using the approach taught in the in-house program.

All services provided are done so free of charge to your child. This include the issuing of theraband and the physioball as well as admission into the SBU Wellness Center for use of the equipment for this study.

Following the 26 week predetermined exercise program, your child will be re-measured using the same pretest measurements of spinal range of motion, spinal rotation and extension strength, and Polaroid grid film posture pictures.

CONFIDENTIALITY OF DATA:

Confidentiality of the subject will be maintained by designating an alphanumeric code for the subject and storing the electronic data on password protected computer disk by the principal investigator. Hard copy of subject data will be maintained in a folder placed in a locked file cabinet found in the principal investigator's office. Any external reporting of this data will be made in such a manner that the subject's identity is concealed. This includes the written information collected and the pictures taken of your child's posture. Typically the final pictures published will be cropped to show as little of your child's face or head as needed to depict the head and neck posture.

RISKS:

Known and anticipated risks from being involved in the study are few and are essentially the same that may occur for anyone starting a new exercise routine. Minor anticipated risks include: strain/sprain on muscle and/or joint tissues and delayed onset muscle soreness (DOMS). These minor anticipated risks will be minimized by educating and encouraging the subject to use proper technique during exercise performance.

The most significant risk from being involved in the study relates to the spinal curvature. The spinal curve could simply remain the same or potentially get worse. However, it

should be noted that the natural history of idiopathic scoliosis curves of less than a 20° curvature have been shown to progress as well, so the subject is at no greater risk participating in the study than by not participating.

ANTICIPATED BENEFITS:

Direct anticipated benefits to subjects being involved in this study include improved spinal range of motion, increased spinal muscle strength, and improved posture. These benefits result from a more primary benefit of decreased (improved) spinal curvature, thus preventing progression of the curvature deformity. Related direct benefits beyond the physical improvements listed include psychological benefit. Your child may experience a higher level of self-confidence and/or positive body image as a result of the physical changes/improvements. Further indirect benefits include avoiding the need for brace and/or surgical correction of the spine.

I have discussed with the parents the procedure(s) described above and the risks involved; I believe she/he understands the contents of the permission form, and is competent to give legally effective and informed consent.

Signature of Investigator

Date Signed

I understand what you are asking of my child and hereby give permission for _____ to participate in the SBU Scoliosis study of the Effects of Therapeutic Exercise on Spinal Curvature in Idiopathic Scoliosis. I understand that I am free to refuse to participate in this research project or to withdraw my consent and discontinue participation in the project at any time without prejudice to me or my child and there will be effect on my child's medical care.

All my questions regarding this project have been answered. I agree to allow my child to participate in the project as described above.

Signature of Parent

Date Signed

Signature of Witness

Date Signed

If you are not satisfied with the manner in which this study is being conducted, you may report (anonymously if you so choose) any complaints to the Research Review Board at Southwest Baptist University (SBU) at (417) 328-1735 (Dr. Kilpatrick, Chair RRB), (417) 328-1659 (Dr. Gary O. Gray, Dean, College of Sciences and Mathematics, or (417) 328-1672 (Dr. Lesh, Chair of Physical Therapy Program).

A COPY OF THIS FORM HAS BEEN GIVEN TO ME. _____ Parent's Initials

(Attachment B)
SOUTHWEST BAPTIST UNIVERSITY
CONSENT TO PARTICIPATE IN BIOMEDICAL RESEARCH

CHILD ASSENT FORM

Why am I here?

We want you to be in a research study on how exercise affects someone with scoliosis. Your parents said it is OK for you to be in this study, but only if you want to be in it. The rest of this paper tells you more about the study. Someone will go over all this with you and answer any questions you have. Then you can decide if you want to be part of the study.

What is Scoliosis?

Scoliosis is a bad curve of the back. It happens in people before they are fully grown. Things like your age, if you are a boy or girl, how bad the curve is at the beginning, and if your bones and body are growing will tell if the curve might get worse. We want to see if exercise will help keep the curve from getting worse.

How was I selected?

We have asked doctors in your town to help us find someone who has a small curve but who has never had treatment. We also need the person to not be fully grown. You meet all of these needs but we must have your parent's permission and your permission before we begin.

What will I need to do?

You will need to do 3 things. 1) On the first day we will just talk to you and your parents. We will also take some measurements. The measurements will be of your back motion and strength. The last thing we will do on that day is take some pictures of you with a special camera and film. We will also show you the exercises you will be doing. 2) You will be doing exercises three times per week. The exercises include stretching, posture, and strengthening. You will have to do exercise at home on days you are not working with us. The exercises will go on for 6 months. 3) At the end of 6 months, we will take the same measurements we did on the first day. That will end your part of the study.

Will you tell anyone about me?

We will only show the measurements we collect and pictures we take in a paper we write to share the results of the study. No, we will not tell anyone about you. We will not tell anyone your name or who you are. The picture will not show your face.

What if I don't want to do the exercise?

You do not have to do any of the exercises if you don't want to be in the study. You can stop doing the exercises at any point if you want to. Stopping the exercises will take you out of the study.

Will any of the exercises hurt me?

The exercises might cause some soreness. This soreness is the same thing you feel when you have played hard.

How will the exercises help me or anyone else?

The exercises might help keep the small curve you have from getting worse. If it helps you, then we think it might help others as well.

I have discussed with this child the various parts of the study. I believe she/he understands the study and can give permission to be apart of the study.

Signature of Investigator

Date

I understand what you are asking me to do. All of my questions have been answered. I give my permission to be in the study on exercise in scoliosis.

Signature of Child

Date

Signature of Witness

Date

A copy of this form has been given to me. _____ Child's Initials