Children's Hospital of Orange County
INSTITUTIONAL REVIEW BOARD

INFORMED CONSENT AGREEMENT

Exercise Aspects of Prader-Willi Syndrome and Childhood Obesity

You are being asked to allow your child to participate in a research study. Before you give your consent to allow your child to be a volunteer, it is important that you read the following information and ask as many questions as necessary to be sure that you understand what your child will be asked to do. If you don't understand something in this consent form, please be sure to ask your study doctor to explain.

Investigators and Sponsor

Principal Investigator:	Susan J. Clark MD
Co-Investigator(s):	Daniela Rubin PhD (CSUF), Daniel Judelson PhD (CSUF), Lien Trinh MD, Keirsten Montgomery FNP, Nancy Varni PNP, Joane Less RN BSN MBA, CCRC, Heather Speer MPH CCRC
Sponsor:	US Army Medical Research and Materiel Command (Department of Defense)

Purpose of this Study

Prader-Willi Syndrome (PWS) is the most common genetic cause of obesity in youth. PWS is a genetic disorder characterized by hypotonia (floppy muscles), obesity, and changed hormonal function. There are 2 nutritional stages in PWS: 1) failure to grow as a baby and 2) the inability to stop eating that can lead to being very overweight.

Exercise is a valuable tool for weight control in youth with PWS, as well as youth without PWS, because it results in positive hormonal and metabolic changes. In healthy, normal-weight youth, the hormonal and metabolic response to exercise leads to beneficial changes such as decreased body fat and increased lean mass. Excess body fat appears to alter these hormonal responses. Given the characteristics of PWS, the hormonal and metabolic responses to exercise in these youth are likely to be different.The purpose of this study is to examine how PWS and the amount of body fat affect the hormonal and metabolic responses to exercise.

Why this is a Research Study

This is a research study because it is important to know more about how the body responds to exercise training. The body's response may be different for children with PWS and that could change how these children should exercise. In youth with PWS, this is important in guiding the prescription for exercise. There are very few exercise studies looking at children with PWS. None of these studies have looked at how the body's hormones change during exercise.

This Exercise Study involves a resistance exercise where your child will do a bench stepping exercise while wearing a vest with weights. Your child may have previously participated in the bicycle riding

portion of this study but that part is now closed. Some basic information that may have been collected during the bicycle portion of the study may be used again. This information will be up to the investigator's discretion.

Number of Participants to be Enrolled and How Long You Will be in the Study

Number of Participants: A total of 60 children are being recruited to participate (30 children who have Prader-Willi Syndrome ages 8-18 years at CHOC, and 30 children who do not have this condition and are 8-11 years old at California State University Fullerton (CSUF).
There will be up to 30 children with PWS enrolled in the stepping exercise at CHOC.

Your child may be enrolled in the Exercise Study (stepping exercise) for up to 1 month.

Procedures to be Followed During the Exercise Study (stepping exercise)

This is what will happen if your child participates in this study:

- Your child will visit CHOC twice and will visit the CSUF campus once.

Visit 1 (at CHOC, about 2 hours long) for Exercise Study (stepping exercise):

- You will complete a medical and exercise history form.
- A physician will confirm the PWS status of your child based on your child's medical record
- The research team will conduct a physical screening (blood pressure, waist circumference, and body mass index) of your child.
- The pediatric endocrinologist, a doctor who takes care of children with hormone problems, will do a sexual development evaluation of your child. This will include briefly looking at the private parts (external genital area for both boys and girls and then breast tissue in girls). This will be done only when the parent is in the room at the same time.
- If no risk factors preventing your child to participate in an exercise test are found, then your child will do bench stepping with a weighted vest for about 20 minutes under the supervision of either Dr. Rubin or Dr. Judelson.
- While he or she is exercising, your child will wear a strap around the chest that measures heart rate (how many times the heart beats per minute).

Visit 2 (at CSUF, about 1 hour long) for the Exercise Study (stepping exercise)

- Your child will be evaluated for his/her body composition using a DEXA (dual energy X-ray absorptiometry) scan, a special X-ray that measures body fat, lean body mass and bone density. The DEXA scan will be done by a doctor licensed to perform these tests.
- Before the DEXA scan if your child is a girl and can become pregnant, the research team will do a urine pregnancy test. The pregnancy test is required by law in the State of California and it is done to ensure the safety of your child because the x-rays may be harmful to a fetus.
- If your child is pregnant, she will not have her body composition evaluated using x-rays and she will not be able to be in the study.
- During the DEXA scan, your child will lay still for a few minutes on a flat table while a machine takes a picture of her/his body using a very weak x-ray under the supervision of Dr. Rubin or Dr. Judelson.

Visit 3 (at CHOC, about 3 hours long, to be completed between 8 am-1pm) for the Exercise Study (stepping exercise)

- Your child will do the stepping exercise consisting of stepping on and off a bench a total of six times separated by 1 minute of rest. During each time your child will step up and down the step ten times with each leg. The total time of this exercise including breaks may be up to 30 minutes. The stepping exercise is done under the supervision of Dr. Rubin or Dr. Judelson.
- Before this exercise test, your child will eat only a pre-packaged breakfast that you will be provided during visit 1. Your child will not be allowed eat anything else until after the exercise test and the rest period are completed, for a total of 3.5-4 hours, but can drink plenty of water
- While exercising, your child will wear a strap around the chest that measures heart rate.
- After completing the exercise test, your child will rest, read a book, or watch TV or a movie for one hour.
- Rather than doing repeated blood draws, the nurse will place an intravenous catheter in a large vein to draw the blood. The catheter is a small, hollow, flexible Teflon tube. Once the catheter is in the vein, repeated blood samples can be easily obtained. The nurse will draw small blood samples (10 mL or approximately 2 teaspoons) from your child before exercise, immediately after exercise, and three times during the hour of rest. The total volume of blood drawn from your child during the study will be about 10 teaspoons (less than 2 fluid ounces).

	Medical screening (Bench Stepping)	**Exercise test (Bench Stepping)**	**DEXA**	**Blood test (Bench Stepping)**
Visit 1	✔	✔		
Visit 2 up to 3 weeks			✔	
Visit 3 up to 4 weeks		✔		✔

You will be informed of any significant new information regarding the study or of any changes in the procedures as described.

Would you be willing to be contacted about other future research opportunities for your child for which he/she may qualify?

Yes_____ No_____ Initials_____

Reproductive Risks

Because the x-rays produced by the DEXA scan may affect an unborn baby, a urine pregnancy test will be conducted for those girls who can become pregnant. If your daughter is pregnant, the DEXA scan will NOT be performed and she will not be able to be in the study.

Risks and Discomforts to This Study

There are some risks to participating in the exercise test in this study. During the exercise test or afterwards, your child may experience:

- An increase in how fast his/her heart is beating
- Increased sweating
- Pain or soreness in the legs
- Shortness of breath
- Fainting
- Headache
- Irritability
- Risk of soft tissue injuries (sprains, strains, and in very rare cases, tears)

These risks are not different from those your child may experience while playing outside during a physical education class or playing sports.

There are also risks involved in the blood drawing procedures that your child will undergo. Those risks are:

Catheter placement – This procedure may cause a little pain or a bruise at the site of catheter insertion. There is rarely any infection.

Blood Draw – This procedure may cause a little pain or bruising at the site of the draw. There is rarely any infection.

There are some risks involved with the DEXA scan.

- Your child's participation in this research study involves exposure to radiation from the DEXA scan. We are exposed to radiation every day of our lives from both natural and manmade sources. The effective dose from the DEXA scan is well below the levels that are thought to result in a significant risk of harmful effects.
- Your child may experience some discomfort while lying still on a flat table for a few minutes during the DEXA scan.

There may be some emotional discomfort that is involved with the physical and sexual development exam but this will not be different from when your child is normally examined at the pediatric endocrinologist's office.

These are the risks that we know about. There may be risks to being in this study that we don't know about now. You will be told of any changes in the way the study will be done and any additional identified risks to which your child may be exposed.

Benefits of the Study

We cannot promise that your child will benefit from this study. Others may benefit from the information gathered from this study. Throughout participation in this study, your child may learn about how her/his body reacts to exercise in a controlled environment. Moreover, if your child is not used to being physically active, she/he will be exposed to different exercises in an encouraging and nurturing environment.

Alternative Methods of Treatment

If you don't want your child to be in this research study, your child can receive information for his/her condition:

- A brief brochure including a series of exercises that your child can perform at home.

Removal From This Study

Your child's study doctor can remove your child from the study without your consent: A) based on the study doctor's judgment to improve your child's medical care, B) because you or your child has not followed the study procedures, or C) because the study sponsor decides to stop the study.

You are free to withdraw your consent and discontinue your child's participation in the study at any time. You should inform the physician of this decision immediately and your child will not further be tested.

Emergency, Side Effects, Illness, or Questions About the Study

If your child needs medical treatment, get treatment, and then let your study doctor know. If you or your child have any questions about the study, or need to talk to the study doctor, you may call:

Monday – Friday 8:00am – 4:30pm **Endocrinology 714-532-8634**
You may leave a message with the secretary and the doctor will call you back. Or you can call Dr. Daniela A. Rubin (657) 278-4704 or Dr. Daniel Judelson (657) 278-5423

Evenings, Weekends, & Holidays **CHOC Hospital 714-997-3000 or 800-992-2462 (CA. Only)**
Ask for the on-call physician for **Endocrinology*.*** You may be asked to leave a message with the page operator, and the physician on-call will return your call as soon as possible.

Compensation for Injury

You must notify the study doctor immediately of any injury or illness that you believe to be a result of participation in this study. If it is determined by the study sponsor Army Medical Research and Materiel Command (Department of Defense) that your child has been injured or become ill as a direct result of being involved in this research study, the sponsor agrees to pay all reasonable and necessary medical expenses to treat your child provided that:

A) All study directions provided to you by the study doctor were followed
B) That your insurance or third party payer, such as Medi-CAL, is not willing to cover the expenses.

Your study doctor will provide supporting information to the study sponsor but cannot guarantee reimbursement.

CHOC is not offering to provide financial compensation for lost wages, disability, or discomfort due to research-related injuries or illnesses. Should you require further information regarding research-

related injuries or illnesses you can contact you child's study doctor using the phone numbers provided on page 5 of this document.

If your child gets hurt or sick because of this research study, she or he can receive medical care at an Army hospital or clinic, free of charge. He or she will only be treated for injuries that are directly caused by the research study. The Army will not pay for transportation to and from the hospital or clinic. If you have questions about this medical care, please contact Dr. Daniela Rubin, at (657)278-4704 or Dr. Daniel Judelson at (657) 278- 5423. If you pay out-of pocket for medical care elsewhere for injuries caused to your child by this research study, contact the co-principal investigators Dr. Rubin or Dr. Judelson. If the issue cannot be resolved, contact the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of the Staff Judge Advocate (legal office) at (301)619-7663/2221.

Confidentiality

Information gathered about your child while participating in this study will be kept confidential according to applicable laws and regulations by the study principal investigator and his/her team, except that:

- The Sponsor of the study, **US Army Medical Research and Materiel Command (Department of Defense), California State University Fullerton (authorized CSUF personnel),** and their representatives will receive information concerning the study and will have access to your child's medical records as they relate to this study.
- Certain agencies, either Federal or State may require your child's medical information concerning this study.
- Representatives of the local IRB or the US Army Medical Research and Materiel Command (Department of Defense) are eligible to review records as part of their responsibility to protect human subjects in research.
- Certain legal actions may require disclosure of your child's medical information.
- Your child's medical information may be released to the CHOC Institutional Review Board or its legally authorized representative

By signing the informed consent, you authorize such access to your child's data. If the results of this study are published, your child's identity will be kept confidential.

Cost/Compensation

You and your child will be reimbursed to participate in this research study. Your child will receive a $10 gift for participating in the first exercise study (visit 1) and $25 for participating in the second test (Visit 3). These gifts can be gift certificates, board games, sports equipment, and/or crafts. You will be reimbursed for parking fees and gas mileage to both CHOC and CSUF, The parking reimbursement will be up to $8, and gas mileage at CSUF rates ($ 0.50 per mile) up to $60 for each roundtrip. No other compensation is available for participating in this research study. You will not be charged for any study required tests. No tests will be charged to your insurance and you The Principal Investigator of this study, Dr. Susan Clark and/or her designated CHOC co-investigators, will be reimbursed for their time and expense of doing this research.

The law requires that CHOC submit an IRS 1099 form for individuals to whom it provides compensation exceeding $600 per calendar year. Compensation provided by this research study will count toward the annual total for this purpose.

Participant Rights and Study Withdrawal

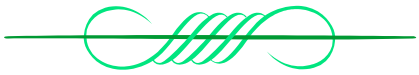
You and your child are agreeing to be in this research study by your own choice. You and your child can decide not to be in the study at all or you can decide to stop being in the study even after the study has started. No matter what you decide your child will still get your doctor's care and won't lose any other benefits you have now. You also won't be giving up any of your child's legal rights by signing this consent form.

It is important that you and your child understand the details about this study. If you or your child have any questions that haven't been answered, please be sure to ask your study doctor or research coordinator.

If you have any questions about your child's rights as a participant in a research study, please contact the CHOC Institutional Review Board for the protection of research participants through:

Office of Research Compliance
(714) 532-8869

This research project has been reviewed by an institutional review board for the protection of the rights of human participants in research projects, in accordance with federal regulations**. This informed consent is not valid without the CHOC Institutional Review Board stamp of approval.**



_____
Parent's Initials
CHOC form version: 12/12/08

Children's Hospital of Orange County
INSTITUTIONAL REVIEW BOARD

PEDIATRIC ASSENT FORM

NOTE: A Pediatric Assent Form is necessary for patients 7-11 years of age.

Study Title: Exercise Aspects of Prader-Willi Syndrome and Childhood Obesity

- I understand that I am being asked to be in this research study because my doctor and his/her helpers want to learn more about how exercise can be used as treatment for my Prader-Willi Syndrome.
- I understand that I will come to CHOC and exercise on two different days, and do a bench stepping exercise while wearing a weighted vest.
- I understand that bench stepping may make me feel tired, or may make my legs tired.
- I understand that at the second visit, the nurse will put a small plastic tube into one of my arm veins so blood can easily be drawn five times without having to poke me.
- I understand that on the second day that I do exercise, I will only have breakfast before exercising.
- I understand that after I exercise on the second day I will rest (sit) for 1 hour while watching a movie or reading a book.
- I understand that I will have x-rays. This is like having a picture taken. This will be at a different place on another day at the California State University Fullerton.
- I understand that I will need to lie still for a few minutes on a flat table while I am having the x-rays.
- I understand that the second study will also have blood draws during the second visit and that I may feel tired after the exercise.
- I understand that I may change my mind about being in this study and that nobody will be angry with me.
- I understand that I can ask questions about what my doctor and his/her helpers are doing and things will be explained to me in a way that I will understand.
- My doctors are Dr. Clark and Dr. Trinh and I can call them at 714-532-8634.
- If I have any exercise questions, I can call Dr. Rubin or Dr. Judelson at 657-278-4704/5423.

_____

Signature of 7 to 11 Year Old Participant Date

_____

Signature of Person Obtaining Consent (Principal or Co- Investigator) Printed Name Date

_____
Parent's Initials

Children's Hospital of Orange County
INSTITUTIONAL REVIEW BOARD

Human Research Participant's Bill of Rights

(For Medical Experiments)

Pursuant to the California Protection of Human Subjects in Medical Experimentation Act, any person who is asked to consent to become a participant in a research study involving a medical experiment or any person who is asked to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedure to be followed in the medical experiment and any drug or devices to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the participant reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the participant, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the participant after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the participant may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the participant's decision.

Signature and Consent

My signature below indicates that I am the parent/legal guardian of this child, and that he/she is not a ward of the state or other agency. I have read the above information about the study***, Exercise Aspects of Prader-Willi Syndrome and Childhood Obesity.*** I have had a chance to ask questions to help me understand what will be expected of my child in this study. I agree to allow my child to be in the study and I have been told that I can change my mind later if I want to. I have been told that by signing this consent form I am not giving up any of my child's legal rights. I have been informed that I will be given a signed and dated copy of this agreement which includes the Participant's Bill of Rights for my records.

Name of Participant (printed)	Age	
Signature of Parent/Legal Guardian or Participant if 18 Years of Age or Older		Date
Printed Name of Parent/Legal Guardian if Participant is under 18 Years of Age		Relationship
Signature of Witness	Printed Name	Date
Signature of Person Obtaining Consent (Principal or Co- Investigator)	Printed Name	Date
Signature of Translator (if used)	Printed Name	Date

Assent for Participants Ages 12 Through 17

My signature below means that I have read the above information about the study, ***Exercise Aspects of Prader-Willi Syndrome and Childhood Obesity.*** I have had a chance to ask questions to help me understand what will be expected of me in this study. I agree to be in the study and I have been told that I can change my mind later if I want to. I have been told that by signing this consent form I am not giving up any of my legal rights. I have been informed that I will be given a signed and dated copy of this agreement and of the Subject's Bill of Rights for my records.

Signature of Participant	Date

Children's Hospital of Orange County
COMITE DE REVISION INSTITUCIONAL

CONSENTIMIENTO PARA PARTICIPAR EN INVESTIGACIONES

Título del Estudio: Aspectos del Ejercicio en el Syndrome de Prader Willi y Obesidad en la Infancia

Estamos solicitando su permiso para que su hijo participe en este estudio de investigación. Antes de que usted acuerde hacerlo, el investigador deberá hablar con usted acerca de lo siguiente:

- El porqué de la investigación, propósito y duración del estudio, y cuántas personas participarán en él.
- Todos los procedimientos del estudio, incluyendo cualesquiera que estén en experimentación.
- Los posibles riesgos o beneficios provenientes del estudio para usted o para su hijo, y la posibilidad de otros riesgos desconocidos.
- La disponibilidad de algún otro tipo de tratamiento en lugar de participar en este estudio.
- El carácter confidencial de la información médica de su hijo y de quién puede tener acceso a ella.
- Cualquier compensación que pudiera estar disponible para ustedes.
- Qué pasará si su niño sufre lesiones/daños por tomar parte en este estudio.
- Cualesquier costos adicionales para usted.
- Las razones por las cuales el investigador podría cancelar la participación de su hijo en el estudio.
- Qué sucedería si no desea continuar en el estudio, y cuándo se le daría a conocer información nueva que pudiera hacerle cambiar de opinión acerca de su participación en el estudio.

Si usted está de acuerdo en permitir que su hijo participe en este estudio de investigación se le entregará una copia de este documento ya firmado y un resumen de la investigación por escrito.

Si su niño necesita atención médica, obténgala y hágaselo saber al doctor del estudio. Si usted o su niño tienen preguntas sobre el estudio, o si necesita hablar con el doctor del estudio, usted puede llamar:

Lunes - Viernes 8:00 am - 4:30 pm *Endocrinologia (714) 532 - 8634*
Puede dejar su mensaje con la secretaria y el doctor le devolverá la llamada.

Noches, Fines de semana y Días Festivos: Hospital CHOC (714) 997-3000
Pregunte por el médico de guardia de *Endocrinologia*. La operadora le pedirá que deje su mensaje, posteriormente el médico de guardia le llamará tan pronto como sea posible.

Si usted tiene preguntas sobre sus derechos como sujeto de estudio puede ponerse en contacto con el *CHOC Institutional Review Board* (Comité Institucional de Revisión de CHOC) al (714) 532-8869.

Su participación en esta investigación es voluntaria y sin importar cuál sea su decisión, su niño seguirá recibiendo atención médica sin perder ninguno de los beneficios que actualmente tenga. Usted tampoco estará renunciando a ninguno de los derechos de su hijo al firmar este consentimiento.

Firmar este documento significa que a usted se le ha descrito verbalmente el estudio de investigación, incluyendo la información arriba mencionada, y que su participación es voluntaria.

Children's Hospital of Orange County
INSTITUTIONAL REVIEW BOARD

Declaración de los Derechos de los Participantes en Investigaciones

(Para Experimentos Médicos)

De acuerdo con la California Protection of Human Subjects in Medical Experimentation Act (Ley de California de Protección a los Participantes en Experimentos Médicos), cualquier persona a la cual se le solicite participar en un estudio de investigación implicando un experimento médico, o de la cual se solicite que consienta a favor de otra, tiene derecho a:

1. Recibir información sobre la naturaleza y propósito del experimento.

2. Recibir una explicación del procedimiento que se seguirá en el experimento médico y cualquier fármaco o instrumento que será utilizado.

3. Recibir una descripción de cualquier riesgo y malestar que puede esperar tener quien participe en el experimento.

4. Recibir una explicación, si corresponde, de los beneficios del experimento al participante que razonablemente se pueden esperar.

5. Recibir información de otros tratamientos disponibles, fármacos o dispositivos que puedan ser ventajosos para el participante, y los riesgos y beneficios relacionados.

6. Ser informada de las alternativas de tratamiento médico, si las hubiese, disponibles para el participante después del experimento en caso que hubiesen complicaciones.

7. Tener la oportunidad de hacer preguntas acerca del experimento o los procedimientos que incluye.

8. Recibir explicación sobre cómo puede el consentimiento para participar en un experimento médico ser retirado en cualquier momento, y que el participante puede discontinuar participación en el experimento médico sin perjuicio.

9. Recibir una copia fechada y firmada del formulario de consentimiento usado en el experimento.

10. Tener la oportunidad de decidir a consentir o a no consentir a un experimento médico sin la intervención de ningún elemento de fuerza, fraude, engaño, coacción, coerción, o influencia excesiva en la decisión del participante.

_____

Nombre Completo del Participante (en letra de imprenta) Edad

_____

Firma del Padre/Madre/Tutor legal o del Participante si tiene por lo menos 18 años de edad Fecha

_____

Nombre Completo del Padre/Madre/Tutor legal (en letra de imprenta) Relación

_____

Firma del Traductor Nombre Completo (en letra de imprenta) Fecha

_____

Firma del Testigo (si no es la del Traductor) Nombre Completo (en letra de imprenta) Fecha

_____

Persona que Obtiene el Consentimiento Nombre Completo (en letra de imprenta) Fecha

CHILDREN'S HOSPITAL OF ORANGE COUNTY
INSTITUTIONAL REVIEW BOARD

Autorización para Usar, Establecer y Divulgar Información de Salud para Investigaciones

Título del Estudio: Aspectos del Ejercicio en el Syndrome de Prader Willi y Obesidad en la Infancia

En este formulario, la palabra "usted" se refiere tanto al participante en la investigación como a la persona que da permiso para participar en la investigación.

Propósito de esta Autorización

Le pedimos que participe en el estudio de investigación que se describe en el formulario de consentimiento del estudio cuyo título se anota anteriormente. Para realizar la investigación que se describe, el personal de investigación del CHOC necesita usar, establecer o divulgar su información de salud durante el transcurso de este estudio. La ley exige que le informemos cómo se hará y que obtengamos su permiso. Este formulario describe qué se hará con su información. Por favor léalo atentamente. Si usted está de acuerdo, por favor firme su nombre al final. Usted recibirá una copia de este formulario después de haberlo firmado.

Descripción de la Información de Salud que se Usará/ Divulgará

Con el permiso de usted, la información de salud que se usará, establecerá y compartirá incluye:

- Toda la información acerca de usted que se obtiene durante el estudio de investigación. Esto abarcaría los resultados de sus pruebas o exámenes de ejercicio y de composición corporal y de sangre que forman parte de los expedientes del estudio; los diarios y los cuestionarios que hay completado como parte del estudio y otros expedientes del estudio.
- Toda la información de salud que se encuentra en sus expedientes médicos que sea necesaria para este estudio de investigación. Esto podría incluir los resultados de sus exámenes físicos, análisis de sangre, procedimientos diagnósticos y de atención médica y su historial médico.

Personas / Organizaciones Autorizadas para Recibir su Información de Salud

Su información de salud podría compartirse con el personal de CHOC que asiste en esta investigación. Su información de salud también podría compartirse con ciertas personas y grupos fuera del CHOC. Estos podrían incluir:

- El patrocinador del estudio, **US Army Medical Research and Materiel Command (Department of Defense)**, **California State University – Fullerton (authorized CSUF personnel),** y sus representantes
- Agencias gubernamentales de Estados Unidos y en otros países, consejos de revisión y otros que supervisan la inocuidad, eficacia y gestión de la investigación
- Otros investigadores en caso de que un consejo de revisión apruebe que se comparta la divulgación de información de salud
- Su compañía de seguro médico si es la que paga por los servicios de salud que se proporcionan como parte del estudio de investigación

- Otros Investigadores en la Universidad del Estado de California en Fullerton (Dra. Daniela Rubin, Dr. Daniel Judelson)
- Otros, si lo requiere la ley

Vigencia de la Autorización y Uso Futuro de la Información de Salud
Este formulario de autorización vence en 50 años a partir de la fecha de la firma a no ser que revoque (cancele o retire) su autorización antes. Si usted firma este formulario, usaremos, estableceremos y compartiremos su información de salud hasta que la investigación haya concluido o hasta la fecha de vencimiento de su autorización, sea cual fuese primero.

Su información también podría ser de utilidad para otros estudios de investigación. Su información podría usarse de nuevo solo si el Institutional Review Board (Consejo de Revisión Institucional) del CHOC lo autoriza. Este consejo nos podría requerir que nos comuniquemos con usted antes de hacer la investigación. Pero el consejo también nos permitiría realizar la investigación sin comunicarnos de nuevo con usted si es que mantenemos su información de manera confidencial.

El Patrocinador del estudio usaría su información de salud para analizar y evaluar los resultados del estudio. Más adelante, el Patrocinador del estudio podría volver a analizar los resultados del estudio y combinarlos con los resultados de otros estudios. Sin embargo, su nombre jamás aparecerá en los formularios, informes o publicaciones del patrocinador, o en divulgaciones futuras del Patrocinador.

Sus Derechos a la Confidencialidad Durante una Investigación
Usted puede rehusar a firmar este formulario de autorización. Si usted no permite que usemos su información de salud protegida, no podrá participar en este estudio de investigación. Usted no podrá recibir ningún tratamiento relacionado con la investigación que se describe en ese formulario de consentimiento. Platicaremos con usted acerca de las alternativas que no estén relacionadas con la investigación y a su disposición. Sea cual fuese su decisión, usted recibirá la atención de su médico y no perderá ninguno de sus beneficios actuales.

Usted puede en cualquier momento revocar esta autorización mediante notificación por escrito al investigador principal a la dirección anotada a continuación. Si usted revoca su autorización, no se podrá retirar ninguna información que ya se haya divulgado. Una vez que la información suya se divulgue de acuerdo con esta autorización, el destinatario podría a su vez volver a divulgarla y la información no tendrá la protección de los reglamentos federales acerca de la confidencialidad. Sin embargo, el reglamento federal sobre la Confidencialidad de la Información acerca de Drogadicción (Federal Substance Abuse Confidentiality Requirements) puede prohibir que el destinatario divulgue información acerca de la drogadicción.

Si usted revoca su autorización, tal vez no podrá seguir participando en el estudio de investigación si aún no se ha recaudado toda la información necesaria. Le avisaremos si este es el caso. Aún así, nosotros podríamos usar la información que ya hayamos recaudado. Necesitamos saber qué sucede con todos los que empiezan un estudio de investigación, no tan solo con las personas que permanecen en el estudio.

Se le entregará una copia de la Nota de Prácticas de Intimidad de CHOC si usted la pide.

Acceso a la Información Protegida de Salud que se Recaude, Use o Divulgue de Acuerdo a esta Autorización
Usted tiene el derecho de ver y copiar la Información Personal de Salud suya que se relacione con el Estudio al comunicarse con el médico del estudio durante el tiempo que CHOC tenga la información. Sin embargo, para garantizar la integridad del Estudio, usted consiente que no podrá revisar parte de sus expedientes relacionados con el Estudio después de que éste haya terminado.

Preguntas acerca de esta Autorización
Si tiene cualquier pregunta, por favor comuníquese con la persona que dirige la investigación. Si tiene preguntas acerca del uso de su información de salud, puede también llamar a la persona encargada de la confidencialidad del CHOC al (714) 532-8466.

Firma y Fecha
Mi firma al calce significa que yo soy el padre/madre/tutor legal de este niño y que él/ella no es un pupilo bajo tutela del estado u otra agencia. He leído la información anterior sobre el estudio, **Aspectos del Ejercicio en el Syndrome de Prader Willi y Obesidad en la Infancia.**
Consiento en que se use, establezca y comparta la información de salud de mi niño para los propósitos descritos en este formulario y en el formulario de consentimiento del estudio.

Nombre Completo del Participante (en letra de imprenta)	Edad
Firma del Padre/Madre/Tutor legal o del Participante si tiene por lo menos 18 años de edad	Fecha
Nombre Completo del Padre/Madre/Tutor legal (en letra de imprenta)	Relación

Firma del Traductor	Nombre Completo (en letra de imprenta)	Fecha
Firma del Testigo (si no es la del Traductor)	Nombre Completo (en letra de imprenta)	Fecha
Persona que Obtiene el Consentimiento	Nombre Completo (en letra de imprenta)	Fecha