Brain Changes in Pediatric Obstructive Sleep Apnea

Principal Investigator-Rajesh Kumar, PhD

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UNIVERSITY OF CALIFORNIA LOS ANGELES

ASSENT TO PARTICIPATE IN RESEARCH

Brain Changes in Pediatric Obstructive Sleep Apnea - Control

1. My name is_____.

2. We are asking you to take part in a research study because we are trying to learn more about the brain of children with OSA and how it compares before and after surgery to remove the tonsils and/or adenoids.

3. If you agree to be in this study you will be asked to come to UCLA one time. When you get here, you will fill out some tests that will ask about your mood and test how you think. You will then be put inside an MRI machine and asked to lay still for about an hour and then you will be done.

4. There are some small risks that come with being in this study. You may feel uncomfortable in the MRI machine or answering questions about your mood. Remember you do not have to answer any questions you do not want to and we can take you out of the MRI machine at any time and you will not get in trouble.

5. You will not directly benefit from participating in this study. But this study may benefit society by increasing our knowledge about OSA in children and the effect of surgery to remove the adenoids and/or tonsils.

6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes” you can still decide not to do this.

7. If you don’t want to be in this study, you don’t have to participate. Remember, being in this study is up to you and no one will be upset if you don’t want to participate or even if you change your mind later and want to stop.

8. If you agree to be in this study you will be asked to refrain from caffeine, nicotine, and alcohol at least 24 hours before to study.

9. You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, you can call me at 310-825-1808 or ask me next time.

10. Signing your name at the bottom means that you agree to be in this study. You and your parents will be given a copy of this form after you have signed it.

_____ _____

Name of Subject Date

UNIVERSITY OF CALIFORNIA LOS ANGELES

ASSENT TO PARTICIPATE IN RESEARCH

Brain Changes in Pediatric Obstructive Sleep Apnea

1. My name is_____.

2. We are asking you to take part in a research study because we are trying to learn more about the brain of children with OSA and how it compares before and after surgery to remove the tonsils and/or adenoids.

3. If you agree to be in this study you will be asked to come to UCLA about one week before your surgery. When you get here, you will fill out some tests that will ask about your mood and test how you think. You will then be put inside an MRI machine and asked to lay still for about an hour and then you will be done. You will be asked to come back to UCLA and do these exact same things about 6 months after your surgery.

4. There are some small risks that come with being in this study. You may feel uncomfortable in the MRI machine or answering questions about your mood. Remember you do not have to answer any questions you do not want to and we can take you out of the MRI machine at any time and you will not get in trouble.

5. You will not directly benefit from participating in this study. But this study may benefit society by increasing our knowledge about OSA in children and the effect of surgery to remove the adenoids and/or tonsils.

6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes” you can still decide not to do this.

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9. You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, you can call me at 310-825-1808 or ask me next time.

Signing your name at the bottom means that you agree to be in this study. You and your parents will be given a copy of this form after you have signed it.

_____ _____

Name of Subject Date

UNIVERSITY OF CALIFORNIA, LOS ANGELES

PARENT PERMISSION FOR MINOR TO PARTICIPATE IN RESEARCH

Brain Changes in Pediatric Obstructive Sleep Apnea

Dr. Rajesh Kumar, PhD, and associates from the Department of Anesthesiology, at the University of California, Los Angeles (UCLA) are conducting a research study. Your child was selected as a possible participant in this study because your child is between the ages of 7-12, have been diagnosed with obstructive sleep apnea and is undergoing an adenoidectomy and/or tonsillectomy. Your child's participation in this research study is voluntary.

Why is this study being done?

Obstructive Sleep Apnea (OSA) in children is often associated with decreased academic performance and mood issues, suggesting the brain changes due to the condition. Removal of the adenoids and/or tonsillectomy is the most common treatment of OSA in children and often leads to improved academic performance and mood, suggesting brain changes due to treatment This study is being done to examine the connections between cognition, mood, brain changes and treatment in pediatric OSA.

What will happen if my child takes part in this research study?

If you agree to allow your child to participate in this study, we would ask him/her to do and understand the following:

One week before adenoidectomy and/or tonsillectomy:

Your child will be asked to arrive at the Department of Radiological Sciences, MRI suite (Ronald Reagan Hospital or 300 Medical Plaza, UCLA) at your scheduled time and be met by the Principal investigator (Dr. Kumar), who will review the procedures and obtain your permission. We will perform various non-invasive MR procedures during the same visit, and your child will require usually two visits to UCLA to complete the study. Your child will not have any caffeine (coffee, soda etc) or alcohol 24 hours prior to the day of visit. Your child may opt out at any time, even if they have not completed all the procedures. Prior to the study, Dr. Kumar or a research team member will review your child's medical history relevant to the current study (e.g., any previous cardiac disease, stroke, vascular congenital anomalies, or any other brain disorders). Dr. Kumar or a research team member will also review the MRI safety questionnaire to ensure your child can safely participate in a MRI scan. If we determine that your child cannot safely enter into the scanner, your child will be excluded from the study.

Procedure 1, medical history and cognition and mood assessment: You will complete a questionnaire regarding your child's safety and provide permission to participate in this study. Your child will then complete a number of questionnaires regarding his/ her mood, feelings of anxiousness and other emotions, and general health and well-being, and cognitive tests.

Procedure 2, MRI scanning: After completing the medical history and assessments, we will take your child in the MRI suite to familiarize him/ her with the scanner environment. Your child will have a device attached to his/ her finger to measure oxygen saturation levels in the blood (no needles required), electrodes attached to his/ her chest to record his/ her heart activity, a band placed around his/ her chest to record

breathing, and be given ear plugs to decrease the MRI scanner sounds and protect his/ her hearing. Your child will then be placed in the MRI scanner, lying flat and as still as possible. Your child will lie without doing anything for about 60 minutes while we obtain MRI scans. If your child wish to come out from the scanner, he/ she may do so at any time by signaling the scanner operator, who will be talking with him/ her regularly. The following magnetic resonance scans will be collected while your child is inside the scanner (your child will not receive any injections of contrast agents):

1. Anatomical T1-weighted MRI scans: 13 minutes
2. Diffusion tensor imaging (DTI) and diffusional kurtosis imaging (DKI) scans, which show brain connections: 40 minutes
3. Proton-density and T2-weighted scans, which are helpful for verifying the absence of brain injury: 5 minutes
4. Magnetic resonance spectroscopy (MRS) scan, which looks at brain metabolites: 10 minutes
5. Arterial spin labeling (ASL) scan, which looks at blood flow in your brain: 5 minutes
6. ASL-based diffusion-weighted scan, which is helpful to examine blood brain barrier function: 15 minutes
7. BOLD baseline scan, which is helpful to assess regional brain connectivity: 7 minutes

After the scanning session, we will remove recording devices and answer any questions you/ your child may have, which will take approximately 10 minutes.

These brain scans are for research purposes only. If your child participate in this study, his/ her brain images will not become part of his/ her medical record, they will not be used for diagnostic purposes, and they will not be looked at by a physician. The imaging examination(s) performed as part of this research will not be reviewed by a UCLA radiologist and no formal interpretation will be rendered. All questions concerning the findings from this exam should be referred to the principal investigator. However, if we notice any serious abnormality in your child's brain images, our research team will communicate to your child's appropriate providing physician with your consent. Since these scans do not include any identifying information (such as your child's name or patient ID), they will also not be stored in the Department of Radiological Sciences or UCLA Health System records.

<u>6 Months After Adenoidectomy and/or Tonsillectomy:</u>

Your child will be asked to return to the Department of Radiological Sciences, MRI suite (Ronald Reagan Hospital or 300 Medical Plaza, UCLA) at your scheduled time and be met by the Principal investigator (Dr. Kumar).

Your child will review the procedures and then repeat the same exact procedures he/ she completed at his/ her visit 1 week before surgery.

How long will my child be in the research study?

Participation in the study will involve two visits to UCLA—one a week before surgery and one 6 months after. Each visit will take approximately 2 hours, with a total participation time of approximately 4 hours.

Are there any potential risks or discomforts that my child can expect from this study?

The device attached to your child's finger to record blood oxygen levels may cause a slight pressure on his/ her finger; however, it should not cause long-lasting discomfort. Rarely, children develop an itchy skin rash at the places where the electrodes are attached to the body. Such reactions can be treated with a cortisone-type cream, but frequently disappear without treatment.

Being asked about your child's medical history or health-related issues may bring up feelings of sadness, anxiety, despair or tiredness. Your child only need to answer questions that he/ she is comfortable with, and your child will be free to stop the procedures at any time. If we believe your child is unduly distressed or otherwise uncomfortable, we will stop the experiment.

While lying in the MRI scanner, your child may feel anxious because of the close confines of the space. However, your child will be in communication with the operators at all times while in the scanner, and if he/ she wishes to be removed from the scanner, he/ she will be taken out instantly. There are no known additional risks from the MRI scanner; however, the procedure may involve risks that are currently unforeseeable.

The imaging examination(s) performed as part of this study will not be reviewed by a UCLA radiologist and no formal interpretation will be rendered. Because of this, there is a small chance that clinical findings on the images would not be identified or communicated to you.

Are there any potential benefits to my child if he or she participates?

Your child will not directly benefit from his/ her participation in the research.

The results of the research may have benefits to humanity that include better understanding regarding the possible cause for mood and cognitive issues in pediatric OSA subjects and the effect of adenotonsillectomy. Such knowledge may suggest ways to better treat or mitigate effects of the disease.

Will my child be paid for participating?

Your child will receive up to $300 for this study, $150 for the first visit and $150 for the second visit, and will be reimbursed for parking costs. If your child finish the questionnaires and medical history and are not eligible for the remaining MRI procedures, or if your child wish to terminate the study before completion, your child will be paid for the parts of the study completed according to the following schedule:

- Procedure 1- Questionnaires, medical history, cognitive test $50
- Procedure 2- MRI Scanning $100

If the investigators stop your child's participation during the MRI scanning procedures because of study inclusion/exclusion protocol (such as significant changes in heart rate, oxygen saturation, or blood pressure) your child will receive full payment of $150.

You will receive your child's payment as a check in the mail from UCLA, typically within 1-2 months of the study date.

You will be required to provide your social security number (SSN) or individual tax payer identification number (ITIN) and mailing address in order to be paid for your child's participation. Your SSN/ITIN will be retained in a locked cabinet behind locked doors

under the control of the investigator. Your SSN will be destroyed once you have cashed your child's payment check.

If you are a non-resident alien, you will be required to register with the UCLA GLACIER system in order for payments to be processed. As a non-resident alien, you may be subject to tax withholdings.

Will information about my child's participation be kept confidential?

The researchers will do their best to make sure that your child's private information is kept confidential. Information about your child will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Confidentiality will be maintained as best possible by means of storing cognitive and mood evaluations data and any medical history using a code number (instead of your name), with no personal information, and only authorized researchers will have access to the code sheets (that link the code with your name). The information from the MRI studies is of two kinds, 1) the signals that tell the oxygen level in your body, heart rate and breathing rate, and 2) the brain images which show brain structural integrity. All of this information is stored with only numbers (not with your child's name) to identify them. All other information collected about your child has only a code.

It is possible that other investigators conducting other research might request that data collected for this study be shared for further research. Even if you agree that your child's data may be shared with other investigators, your child's name or other personal identifying information would not be revealed. Though your child's privacy is very important to us and we will use many safety measures to protect your child's privacy, it is possible that there may be unforeseen privacy risks. For example, although we would not put any personal identifying information about your child in a shared database, someone in the future might find some way to link your child's medical information or other information collected for this study back to your child even in the absence of his/ her name or other personal identifying information. Alternatively, there could be violations to the security of the separate computer systems used to store the codes linking your child information to him/ her.

All codes and code sheets will be kept in a locked file cabinet in one of the PIs' office (56-132 CHS) so that your privacy is protected. Also, all brain MRI and physiology data (oxygen level in your body, heart rate and breathing rate) will be stored in a computer protected with password, with access to authorize personal only.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your child's identity. Only the investigators listed in this consent form will have access to the results of the research; no information will be included that would reveal your child's identity.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

How information about you may be used for future research?

The identifiers attached to the data/ information will be removed and, after such removal, the information/ data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Withdrawal of participation by the investigator

The investigator may withdraw your child from participating in this research if circumstances arise which warrant doing so. If your child cannot safely be in the MRI machine, he/ she may have to drop out, even if he/ she would like to continue. The investigator will make the decision and let you and your child know if it is not possible for your child to continue. The decision may be made to protect your child's health and safety, or to make sure the study follows protocol.

What are my and my child's rights if he or she takes part in this study?

You may withdraw your permission at any time and discontinue your child's participation without penalty or loss of benefits to which your child was otherwise entitled.

You can choose whether or not you want your child to be in this study. If your child volunteer to be in this study, he/ she may leave the study at any time without consequences of any kind. You and your child are not waiving any of your legal rights if you choose to be in this research study. Your child may refuse to answer any questions that he/ she do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

The research team member:

If you have any questions, comments or concerns about the research, you can talk to the study's principal investigators. Please contact:

Rajesh Kumar, PhD, Principal Investigator
Professor In-Residence
Department of Anesthesiology
Room 56-141, Center for the Health Sciences
University of California at Los Angeles
Los Angeles, CA 90095-1763
Tel: 310.206.1679; 310.206.6133

Email: rkumar@mednet.ucla.edu

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

You will be given a copy of this information to keep for your records.

SIGNATURE OF PARENT OR LEGAL GUARDIAN

_____
Name of Child

_____
Name of Parent or Legal Guardian

_____ _____
Signature of Parent or Legal Guardian Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

UNIVERSITY OF CALIFORNIA, LOS ANGELES

PARENT PERMISSION FOR MINOR TO PARTICIPATE IN RESEARCH

Brain Changes in Pediatric Obstructive Sleep Apnea – **Healthy Control**

Dr. Rajesh Kumar, PhD, and associates from the Department of Anesthesiology, at the University of California, Los Angeles (UCLA) are conducting a research study. Your child was selected as a possible participant in this study because your child is between the ages of 7-12, do not have obstructive sleep apnea and are healthy. Your child's participation in this research study is voluntary.

Why is this study being done?

Obstructive Sleep Apnea (OSA) in children is often associated with decreased academic performance and mood issues, suggesting the brain changes due to the condition. Removal of the adenoids and/or tonsillectomy is the most common treatment of OSA in children and often leads to improved academic performance and mood, suggesting brain changes due to treatment. This study is being done to examine the connections between cognition, mood, brain changes and treatment in pediatric OSA.

What will happen if my child takes part in this research study?

If you agree to allow your child to participate in this study, we would ask him/her to do and understand the following:

Your child will be asked to arrive at the Department of Radiological Sciences, MRI suite (Ronald Reagan Hospital or 300 Medical Plaza, UCLA) at your scheduled time and be met by the Principal investigator (Dr. Kumar), who will review the procedures and obtain your permission. We will perform various non-invasive MR procedures during the same visit, and your child will require usually one visit to UCLA to complete the study. Your child will not have any caffeine (coffee, soda etc) or alcohol 24 hours prior to the day of visit. Your child may opt out at any time, even if they have not completed all the procedures. Prior to the study, Dr. Kumar or a research team member will review your child's medical history relevant to the current study (e.g., any previous cardiac disease, stroke, vascular congenital anomalies, or any other brain disorders). Dr. Kumar or a research team member will also review the MRI safety questionnaire to ensure your child can safely participate in a MRI scan. If we determine that your child cannot safely enter into the scanner, your child will be excluded from the study.

Procedure 1, medical history and cognition and mood assessment: You will complete a questionnaire regarding your child's safety and provide permission to participate in this study. Your child will then complete a number of questionnaires regarding his/ her mood, feelings of anxiousness and other emotions, and general health and well-being, and cognitive tests.

Procedure 2, MRI scanning: After completing the medical history and assessments, we will take your child in the MRI suite to familiarize him/ her with the scanner environment. Your child will have a device attached to his/ her finger to measure oxygen saturation levels in the blood (no needles required), electrodes attached to his/ her chest to record his/ her heart activity, a band placed around his/ her chest to record breathing, and be given ear plugs to decrease the MRI scanner sounds and protect his/ her hearing. Your child will then be placed in the MRI scanner, lying flat and as still as

possible. Your child will lie without doing anything for about 60 minutes while we obtain MRI scans. If your child wish to come out from the scanner, he/ she may do so at any time by signaling the scanner operator, who will be talking with him/ her regularly. The following magnetic resonance scans will be collected while your child is inside the scanner (your child will not receive any injections of contrast agents):

1. Anatomical T1-weighted MRI scans: 13 minutes
2. Diffusion tensor imaging (DTI) and diffusional kurtosis imaging (DKI) scans, which show brain connections: 40 minutes
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4. Magnetic resonance spectroscopy (MRS) scan, which looks at brain metabolites: 10 minutes
5. Arterial spin labeling (ASL) scan, which looks at blood flow in your brain: 5 minutes
6. ASL-based diffusion-weighted scan, which is helpful to examine blood brain barrier function: 15 minutes
7. BOLD baseline scan, which is helpful to assess regional brain connectivity: 7 minutes

After the scanning session, we will remove recording devices and answer any questions you/ your child may have, which will take approximately 10 minutes.

These brain scans are for research purposes only. If your child participate in this study, his/ her brain images will not become part of his/ her medical record, they will not be used for diagnostic purposes, and they will not be looked at by a physician. The imaging examination(s) performed as part of this research will not be reviewed by a UCLA radiologist and no formal interpretation will be rendered. All questions concerning the findings from this exam should be referred to the principal investigator. However, if we notice any serious abnormality in your child's brain images, our research team will communicate to your child's appropriate providing physician with your consent. Since these scans do not include any identifying information (such as your child's name or patient ID), they will also not be stored in the Department of Radiological Sciences or UCLA Health System records.

How long will my child be in the research study?

Participation in the study will involve one visit to UCLA. The visit will take approximately 2 hours, with a total participation time of approximately 2 hours.

Are there any potential risks or discomforts that my child can expect from this study?

The device attached to your child's finger to record blood oxygen levels may cause a slight pressure on his/ her finger; however, it should not cause long-lasting discomfort. Rarely, children develop an itchy skin rash at the places where the electrodes are attached to the body. Such reactions can be treated with a cortisone-type cream, but frequently disappear without treatment.

Being asked about your child's medical history or health-related issues may bring up feelings of sadness, anxiety, despair or tiredness. Your child only need to answer questions that he/ she is comfortable with, and your child will be free to stop the

procedures at any time. If we believe your child is unduly distressed or otherwise uncomfortable, we will stop the experiment.

While lying in the MRI scanner, your child may feel anxious because of the close confines of the space. However, your child will be in communication with the operators at all times while in the scanner, and if he/ she wishes to be removed from the scanner, he/ she will be taken out instantly. There are no known additional risks from the MRI scanner; however, the procedure may involve risks that are currently unforeseeable.

The imaging examination(s) performed as part of this study will not be reviewed by a UCLA radiologist and no formal interpretation will be rendered. Because of this, there is a small chance that clinical findings on the images would not be identified or communicated to you.

Are there any potential benefits to my child if he or she participates?

Your child will not directly benefit from his/ her participation in the research.

The results of the research may have benefits to humanity that include better understanding regarding the possible cause for mood and cognitive issues in pediatric OSA subjects and the effect of adenotonsillectomy. Such knowledge may suggest ways to better treat or mitigate effects of the disease.

Will my child be paid for participating?

Your child will receive $150 for this visit, and will be reimbursed for parking costs. If your child finish the questionnaires and medical history and are not eligible for the remaining MRI procedures, or if your child wish to terminate the study before completion, your child will be paid for the parts of the study completed according to the following schedule:

- Procedure 1- Questionnaires, medical history, cognitive test $50
- Procedure 2- MRI Scanning $100

If the investigators stop your child's participation during the MRI scanning procedures because of study inclusion/exclusion protocol (such as significant changes in heart rate, oxygen saturation, or blood pressure) your child will receive full payment of $150.

You will receive your child's payment as a check in the mail from UCLA, typically within 1-2 months of the study date.

You will be required to provide your social security number (SSN) or individual tax payer identification number (ITIN) and mailing address in order to be paid for your child's participation. Your SSN/ITIN will be retained in a locked cabinet behind locked doors under the control of the investigator. Your SSN will be destroyed once you have cashed your child's payment check.

If you are a non-resident alien, you will be required to register with the UCLA GLACIER system in order for payments to be processed. As a non-resident alien, you may be subject to tax withholdings.

Will information about my child's participation be kept confidential?

The researchers will do their best to make sure that your child's private information is kept confidential. Information about your child will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As

with any use of electronic means to store data, there is a risk of breach of data security. Confidentiality will be maintained as best possible by means of storing cognitive and mood evaluations data and any medical history using a code number (instead of your name), with no personal information, and only authorized researchers will have access to the code sheets (that link the code with your name). The information from the MRI studies is of two kinds, 1) the signals that tell the oxygen level in your body, heart rate and breathing rate, and 2) the brain images which show brain structural integrity. All of this information is stored with only numbers (not with your child's name) to identify them. All other information collected about your child has only a code.

It is possible that other investigators conducting other research might request that data collected for this study be shared for further research. Even if you agree that your child's data may be shared with other investigators, your child's name or other personal identifying information would not be revealed. Though your child's privacy is very important to us and we will use many safety measures to protect your child's privacy, it is possible that there may be unforeseen privacy risks. For example, although we would not put any personal identifying information about your child in a shared database, someone in the future might find some way to link your child's medical information or other information collected for this study back to your child even in the absence of his/ her name or other personal identifying information. Alternatively, there could be violations to the security of the separate computer systems used to store the codes linking your child information to him/ her.

All codes and code sheets will be kept in a locked file cabinet in one of the PIs' office (56-132 CHS) so that your privacy is protected. Also, all brain MRI and physiology data (oxygen level in your body, heart rate and breathing rate) will be stored in a computer protected with password, with access to authorize personal only.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your child's identity. Only the investigators listed in this consent form will have access to the results of the research; no information will be included that would reveal your child's identity.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality

does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

How information about you may be used for future research?

The identifiers attached to the data/ information will be removed and, after such removal, the information/ data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative.

Withdrawal of participation by the investigator

The investigator may withdraw your child from participating in this research if circumstances arise which warrant doing so. If your child cannot safely be in the MRI machine, he/ she may have to drop out, even if he/ she would like to continue. The investigator will make the decision and let you and your child know if it is not possible for your child to continue. The decision may be made to protect your child's health and safety, or to make sure the study follows protocol.

What are my and my child's rights if he or she takes part in this study?

You may withdraw your permission at any time and discontinue your child's participation without penalty or loss of benefits to which your child was otherwise entitled.

You can choose whether or not you want your child to be in this study. If your child volunteer to be in this study, he/ she may leave the study at any time without consequences of any kind. You and your child are not waiving any of your legal rights if you choose to be in this research study. Your child may refuse to answer any questions that he/ she do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

The research team member:

If you have any questions, comments or concerns about the research, you can talk to the study's principal investigators. Please contact:

Rajesh Kumar, PhD, Principal Investigator
Professor In-Residence
Department of Anesthesiology
Room 56-141, Center for the Health Sciences
University of California at Los Angeles
Los Angeles, CA 90095-1763
Tel: 310.206.1679; 310.206.6133
Email: rkumar@mednet.ucla.edu

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

You will be given a copy of this information to keep for your records.

SIGNATURE OF PARENT OR LEGAL GUARDIAN

Name of Child

Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian | Date

SIGNATURE OF PERSON OBTAINING CONSENT

Name of Person Obtaining Consent | Contact Number

Signature of Person Obtaining Consent | Date