

(SAMPLE INFORMED CONSENT)

FAMILY STUDY OF WHOLE BLOOD SEROTONIN

Informed Consent Form

1. **PURPOSE:**
The purpose of this research project is to learn whether your blood level of serotonin (an important chemical in the body) is similar to the blood level of serotonin in other members of your family.
2. **PROCEDURE:**
Approximately 10ml (two teaspoons) of blood will be drawn from your vein upon agreement to participate in this study. This blood sample will be drawn by trained personnel using a sterile technique. The blood will be used to determine blood serotonin levels and platelet count.
3. **DURATION:**
Shortly after the blood sample is taken, you will be asked to fill out a data form and may be asked to participate in a family history interview.
4. **EXPERIMENTAL PROCEDURES:**
No experimental procedures are involved.
5. **RISKS OR DISCOMFORTS:**
Some discomfort may be experienced when the blood is being withdrawn from the vein. This discomfort is usually due to puncturing the skin by a needle designed for withdrawing blood. However, minimal risk is involved in drawing blood, and trained personnel will be glad to discuss this procedure with you.
6. **BENEFITS:**
There will be no direct benefit received from participating in this study above or beyond any heretofore published or recognized treatment. However, your participation in this study may enhance the understanding of treatment for autism.
7. **ALTERNATIVE PROCEDURES:**
Participation in this research project is not intended to be a substitute for any treatment program. Therefore, no alternative procedures are offered.
8. **CONFIDENTIALITY:**
Your participation in this study and any information obtained from the analysis of your blood sample will be treated with the utmost confidentiality as prescribed by state law. The Department of Health and Human Services and/or the Federal Food and Drug Administration has the right to review the research records.

Any data derived from your participation in this study may be published for scientific use, but your name will not appear with such publication.

Initials _____

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9. COMPENSATION:

You will be provided, within the capability of the facility of the South Carolina Department of Mental Health at which this project is being conducted, medical assistance that may be necessary for any physical injury that may result from your participation in this study. No other financial compensation is available in case of injury.

10. CONTACT PERSON:

The research investigator will be happy to answer any questions that you may have about this study. You may contact the Principal investigator, _____, at (803 _____ or P.O. Box _____, Columbia, S.C. 29202.

11. VOLUNTARY PARTICIPATION:

Participation in this study is completely voluntary. You may withdraw at any time and it will not be held against you.

12. REMOVAL OF SUBJECT FROM PARTICIPATION:

Your physician may at any time withdraw you from this study if in his best judgment and experience he thinks that your participation may not be in your best interest.

Your signature below indicates your willingness to participate in this study. A copy of this informed consent will be given to you.

Signature

Date

Witness

Signature of Other
Consenting Person, if necessary

Date