

Name of Institution
Informed Consent Agreement for
Home-Based Multisystemic Therapy (MST)
vs.
Parent Group

I, _____ agree to the participation of my child, _____
 (Name of Parent/Legal Guardian) (Name of Child)
 in a research project studying ways to help families with children who have been physically abused. Researcher _____ has explained to me the information described below.

- A. **Purpose:** This study will compare which of two treatments is better at (1) improving a child's behavior and ability to get along with other children, (2) improving parents ability to manage their anger, discipline their child, and handle stress, (3) reducing a parent's physical abuse of their child, and (4) improving family relationships.
- B. **Procedures:** Families who participate in the study will either be treated in their home by staff of the **institution name**, or they will attend a Parent Group at the local **insert name** Community Mental Health Center. This will be decided by random choice (much like flipping a coin). The home-based treatment group (MST) will receive visits in their home several times a week for about four (4) months. The visiting therapist will work with the family on better ways to handle problems in the family. The Parent Group will meet seven (7) times, each for about 1 to 12 hours, at the mental health center and receive help on handling family problems. All meetings of both the home-based (MST) and the Parent Group will be audio taped.

All families, the MST and the Parent Group, will be asked some questions by our trained workers and be given some written questions to answer. The questions will be about your child's behavior, your behavior, and how you and your child get along with each other and with other people. The assessments will be done at the beginning of the study and again 2, 4, 10, and 16 months later. Each of these assessments will take about 22 hours.

Your records at **insert name** County DSS office and other agencies will be reviewed to gain information on problems with child abuse, the services you have received, and how much these services have cost.

- C. **Duration:** The study will last about 16 months.
- D. **Possible Discomforts and/or Risks:** the physical, social, legal, and economic risks to you and your family are very small. The major risk of participation in the study is the release of personal information and the researchers have taken steps to make that risk very small. There is some loss of privacy with any treatment; however, your therapists are trained to keep all information private and to ask about only information that is needed.

Initial _____

- E. **Possible Benefits:** Both home-based MST and Parent Group treatments are expected to reduce family problems and help children and parents. The information from this study may help other families in which a child has been physically abused.
- F. **Other Ways to Gain Treatment:** If you and your child decide not to participate in this study, your child will still receive services that he/she would otherwise have received.
- G. **Cost of Participation:** There will be no charges to you for participating in this study.
- H. **Compensation:** You and your child will receive \$50.00 for each assessment you complete, \$250.00 for completing all five assessments.
- I. **Student Participation:** If you or your child is a student of **insert name** no record of your participation, or decision not to participate, will be part of your, his, or her academic record at **institution name**. Neither will your participation, or your decision not to participate, be part of any decisions in your, his, or her academic performance.
- J. **Employee Participation:** No record of participation, or decision not to participate, will be part of your or your child's personnel record if you, he, or she is an employee of **institution name**. Neither will participation, nor decision not to participate, be part of any decisions in job performance or evaluation.
- K. **New Information:** Any new information which is developed during the course of this study which might influence your or your child's willingness to continue participation in this study will be given to you and/or your child.
- L. **Confidentiality:** Every effort will be made to keep private all information that you give. All cases have been investigated by DSS and this information is already known to legal authorities. If any information about new or unreported abuse is learned during the course of this study, a new report will be filed with child protection authorities. Also, if you or your child report suicidal or homicidal information, services will be sought to protect you, your child, or others.

Dr. Jane Doe (**insert phone number**) has agreed to answer any questions that you may have about this study. You may also contact the **institution name** Institutional Review Board for Human Research (**insert phone number**) about the study and your rights.

In the event of any injury directly resulting from participation in the study reasonable medical treatment, not otherwise covered by third party payment or study sponsors, will be available free through the **institution name** (contingent upon approval of the Budget and Control Board of your state). Financial compensation is not available for medical treatment elsewhere, loss of work, or other expenses. The **institution name** Medical Director may be contacted at **insert number** concerning medical treatment.

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Records of participation in this study are not available to the public and every effort will be made to keep them private. However, all records in South Carolina may be obtained if ordered by a judge in a court of law. Information gained from this study will be used only for research and educational purposes. Information may be published in medical journals, but the participants' identity will not be revealed. However, identifying information is available to the **institution name** IRB for Human Research, the sponsor of the study (if applicable), and the US Food and Drug Administration.

Participation is totally voluntary and you or your child may choose not to participate. You are free to withdraw your consent and discontinue your child's participation at any time and at no risk to your ability to receive treatment for your child at **institution name**, now or in the future.

Your child's participation in this study may also be stopped by the researcher, with or without your consent, if in the researcher's best judgment and experience he thinks that your child's participation may not be in his/her best interest, if your child violates the study requirements, or for administrative reasons.

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

Signature of Research Assistant

Name of Participant

Witness

Signature of Parent/Legal Guardian
(if Applicable)

Date of Consent: _____

11-17 Years of Age: My participation has been explained to me, and all of my questions have been answered. I am willing to participate.

Signature: _____

Age: _____ Date of Birth: _____

(Reviewed/approved by MUSC IRB for Human Research: _____)

Initial _____