

SAMPLE FORMAT FOR INFORMED CONSENT DOCUMENT (For Adults and children)

CROUSE HOSPITAL

Title of Study: *A Phase 3 randomized study comparing Behavioral Therapy to Clumisol for the Treatment of Clumsiness.*

Consent Form

Background/Purpose:

1. State why this particular person is being asked to participate. *You are (your child is) being asked to participate in a research study because you have (your child has) been diagnosed with clumsiness (add diagnosis).... or because you have (your child has) already decided to undergo behavioral therapy for clumsiness.*

2. Add a paragraph of pertinent background information. This paragraph should make it clear why the study is being done. *Currently, we have no drugs, which can treat clumsiness (add specific diagnosis). It is felt that clumisol (add specific drug) may be helpful because.... OR The current treatment for clumsiness is behavioral therapy; however behavioral therapy is only successful in a small number of people (about 1 in 100). In early studies, subjects responded well to clumisol.*

3. Include study objectives. *The purpose of this research study is to see if the investigational drug, clumisol, is safe and effective in treating people with clumsiness. An investigational drug is a drug which has not been approved by the Food and Drug Administration (FDA) for general use.*

4. Add how many total subjects will be participating in the study. *Twenty people are expected to participate in this research study.*

Procedures:

Explain all study procedures in easy to understand language. Use short paragraphs to explain procedures in the order in which they will occur. *If you (your child) choose(s) to participate, you (your child) will be randomly assigned by chance (similar to flipping a coin) to one of two study groups. Your (your child's) chance of being assigned to either group is equal.*

If you are (your child is) assigned to Study Group A (control group), you (your child) will receive 1-hour of behavioral therapy a week for 6 weeks. A research assistant will conduct the behavioral therapy sessions. The sessions will be private and will be held at the Syracuse building. The same research assistant will conduct each of the 6 sessions. At the first and last session, you (your child) will be asked to complete a questionnaire about your (your child's) condition. This should take about 15 minutes.

Add current date, should be changed any time revisions are made. *Version 11/5/02*

If you are (your child is) assigned to Study Group B (investigational group), you (your child) will receive 60 mg of clumisol each day. You (your child) will take one pill, by mouth, each day for six weeks. At the end of the first week, you (your child) will be asked to come to the clinic to have blood (about 1 teaspoon) drawn to check your (your child's) blood count. A research assistant will call you (your child) each week and ask you (your child) questions about your (your child's) condition and any side effects you (your child) may be having from the medication. These calls will take about 15 minutes.

Risks:

Explain all risks/discomforts of study participation (use lay terms).

The risks involved with participating in this study are:

***Behavioral Therapy** may cause you (your child) to become emotionally upset.*

***Clumisol** may cause fatigue, gait disturbances and dry mouth.*

***Blood drawing** may cause pain and/or bruising at the location on your (your child's) arm where the blood was taken. On rare occasions, it may cause lightheadedness or fainting and an infection.*

***Answering Questionnaires** should not pose any risk to you (your child).*

Benefits:

State the potential or known benefits of participation. If there are none, you may state, There is no direct benefit to you (your child) for participating in this research study; however, the information learned may help others in the future. **Discussion of free medical care or payments should not be included in this section.** *In any medical research study certain benefits may be derived. Such benefits include the possibility that your (your child's) clumsiness will be better controlled, and that information learned during this study may help others in the future. It is possible that there will be no benefit to you (your child) for participating in this study.*

Voluntary Participation:

Tailor this standard statement to be specific for each study.

Your (your child's) participation in this study is entirely voluntary and you (your child) may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you (your child) would normally be entitled. Your (your child's) decision about whether or not to participate in the study will not affect *[the care you (your child receive(s) at] or [your (your child's) relationship with]* Crouse Hospital.

OR

There is no obligation for you (your child) to have these blood samples taken, which are being done for research purposes only. Your (your child's) participation in this study is entirely voluntary and you (your child) may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you (your child) would normally be entitled. Your (your child's) decision about whether or not to participate in the study will not affect the care you (your child) receive(s) at Crouse Hospital.

You do (your child does) not have to participate in this study to receive treatment for your (your child's) clumsiness. Your (your child's) participation in this study is entirely voluntary and you (your child) may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you (your child) would normally be entitled. Your (your child's)

decision about whether or not to participate in the study will not affect the care you (your child) receive(s) at Crouse Hospital.

Alternatives:

State specifically what the alternatives are to study participation. Examples are:

1. If you (your child) decide(s) not to participate in this research study, you (your child) will continue to receive your (your child's) usual care and will not have any of the above procedures done for research purposes.
2. If you (your child) decide(s) not to participate in this study, your (your child's) left over blood (tissue) will not be used.
3. If you (your child) decide(s) not to participate in this study, your (your child's) medical information will not be used for this study.
4. If you (your child) decide(s) not to participate in this sub-study, you (your child) may still participate in the main (treatment) study.
5. If you (your child) decide(s) not to participate in this study, you (your child) will have the surgery as planned and none of the above procedures will be done for research purposes.
6. If you (your child) decide(s) not to participate in this research study, you (your child) may still receive behavioral therapy or other investigational treatments, which may be available. You (your child) may also choose no treatment at this time.

Costs/Payments:

Specify what will be provided free of charge and/or what will be charged to the subject.

State what payments (if any) will be made to subjects. Some examples are:

1. There are no costs to you (your child) or your (your child's) insurance carrier for participating in this study. You (your child) will not be paid for participating in this study.
2. All costs associated with this study will be billed to you (your child) and/or your (your child's) insurance carrier. You (your child) will not be paid for your (your child's) participation.
3. There are no costs to you (your child) for participating in this study. All costs for the required study visits, examinations, laboratory procedures, and study drugs will be paid by, (add the sponsor's name), the sponsor of this study. You (your child) will be paid \$25.00 at each visit to cover your (your child's) travel expenses. In the event that your (your child's) participation in the study is discontinued early, you (your child) will only be paid for the visits completed.
4. All costs associated with your (your child's) participation in this study will be free of charge. You (your child) will not be paid for your (your child's) participation.

If there will be payment to subjects; the following statement should be added:

In addition, by accepting payment for participating in this study, certain identifying information about you (your child) may be made available to professional auditors to satisfy audit and Federal reporting requirements, but confidentiality will be preserved. Please note that if you (your child) earn(s) \$600 or over in a calendar year as a research subject, you (your child) may have to pay taxes on these earnings.

Questions:

Use these standard statements, add appropriate names and phone numbers.

1. *(If there is a potential for research injury):* If you have (your child has) any questions about the research, or in the event of a research-related injury, please contact Dr. at (315) XXX-XXXX. If you have (your child has) any questions about your (your child's) rights as a research subject, please contact the Crouse Hospital Institutional Review Board Office at (315) 470-8836.
2. *(If there is no potential for research injury):* If you have (your child has) any questions about the research, please contact Dr. at (315) XXX-XXXX. If you have (your child has) any questions about your (your child's) rights as a research subject, please contact the Crouse Hospital Institutional Review Board Office at (315) 470-8836.

In Case Of Injury:

The following standard statement must be included, exactly as written below, in all treatment studies. Studies which carry no physical or emotional risk do not need to include this section paragraph (e.g., some surveys, chart review studies).

“In the event of illness or physical injury resulting from taking part in this research study, medical treatment will be provided at Crouse Hospital. You (your child) will be responsible for any costs not paid by your (your child's) insurance company. No other compensation is offered. We have no plans to give you (your child) money if you are (your child is) injured. You have not waived any of your (your child's) legal rights by signing this form”.

Compensation For Research Related Injury:

“The above paragraph states the policy of (pharmaceutical). (Pharmaceutical) will make the final determination as to whether any injury suffered during this study is a “direct result” of the study procedures. Your physician will provide supporting information to (pharmaceutical), but cannot guarantee reimbursement.”

“Neither the researchers nor Crouse Hospital make any representation, warranties or guarantees with respect to the above policy, including either its continued existence or its applicability to yourself should any adverse side effects occur.”

Confidentiality of Records and Authorization to Use and Share Health Information

If you agree to participate in this research, identifiable health information about you will be used and shared with others involved in this study. You agree to permit Crouse Hospital, your doctors and other health care providers to disclose health information in your medical records to the researchers and (study sponsor).

Individually identifiable health information that may be used and shared includes all information collected during this research study. This includes any information from your medical record, and information obtained from this study that can be associated with you.

The researchers may use and share your health information to conduct the research, share your health information with (study sponsor), or share your health information as required by law with

representatives of government organizations, Crouse Hospital Institutional Review Board, and other persons who are required to watch over the safety and the process of research.

Once information that could be used to identify you has been removed, the information that remains is no longer subject to this Authorization and may be used and shared by the researchers and (sponsor) as permitted by law.

Once your health information has been shared with a third party, federal privacy laws may no longer protect it. However, the researchers and (sponsor) agree to protect your health information by using and disclosing it only as permitted by you in this Informed Consent. Also, no publication about the research will reveal your identity without your specific written permission. These limitations continue even if you revoke (take back) this authorization.

You may change your mind and take back this authorization at any time by writing to (Principal Investigator) at (address). If you do this, you will no longer be allowed to participate in the research. However, even if you take back this Authorization, the information already obtained may be used and shared as permitted by this Informed Consent.

At the end of the study, you have the right to see and copy your health information according to Crouse Hospital policies; however, your access may be limited while the study is in progress.

There is no scheduled date at which your information will be destroyed or no longer used. This is because information that is collected for research purposes continues to be used and analyzed for many years and it is not possible to determine when this will be complete.

Consent To Participate In Research & Authorization To Use And Share Personal Health Information:

For Subjects 18 Years Of Age And Older

I hereby give my consent to participate in this research study and agree that my personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form.

Signature of subject

Date

Signature of Legally Authorized Representative (*if appropriate**)

Date

Print name of Legally Authorized Representative (*if appropriate**)

Relationship to subject (*if appropriate**)

Signature of Person Obtaining Consent/Authorization

Date

Signature of Witness (*if appropriate***)

Date

**NOTE: The 2nd, 3rd and 4th lines should only be included in studies where a legally authorized representative may provide consent for the subject and this has been described in the IRB application.*

***NOTE: This may not be required for all studies. Follow guidance in sample consent from sponsor.*

Consent To Participate In Research & Authorization To Use And Share Personal Health Information:

For Subjects less than 18 Years of Age

The nature and the purpose of the above Research Study have been explained to my child and me; we have agreed to have my child participate in the research study. We also agree that my child's personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. We will receive a signed copy of this consent form.

Signature of Parent/Guardian

Date

Signature of Subject (when appropriate)

Date

Signature of Person Obtaining Consent/Authorization

Date

Signature of Witness

Date

The nature and the purpose of the above research study have been explained to me; I have agreed to have my child participate in the research study. I also agree that my child's personal health information can be collected, used and shared by the researchers and staff for the research study described in this form. I will receive a signed copy of this consent form. My child's consent has not been obtained for the following reasons:

Signature of Parent/Guardian

Date

Signature of Person Obtaining Consent/Authorization

Date

Signature of Witness

Date