

SAMPLE FORMAT FOR INFORMED CONSENT DOCUMENT (For Adults)

Crouse Hospital (or print on department letterhead)

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 being asked to participate in a research study because you have been diagnosed with clumsiness (add diagnosis).... or because you have 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 choose to participate, you will be randomly assigned by chance (similar to flipping a coin) to one of two study groups. Your chance of being assigned to either group is equal.*

If you are assigned to Study Group A (control group), you 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 will be asked to complete a questionnaire about your 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 assigned to Study Group B (investigational group), you will receive 60 mg of clumisol each day. You will take one pill, by mouth, each day for six weeks. At the end of the first week, you will be asked to come to the clinic to have blood (about 1 teaspoon) drawn to check your blood count. A research assistant will call you each week and ask you questions about your condition and any side effects you 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 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 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.

Benefits:

State the potential or known benefits of participation. If there are none, you may state, There is no direct benefit to you 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 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 for participating in this study.*

Voluntary Participation:

Tailor this standard statement to be specific for each study.

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

You do not have to participate in this study to receive treatment for your clumsiness. Your participation in this study is entirely voluntary and you may refuse to participate or discontinue participation at any time without penalty or loss of benefits to which you would normally be entitled. Your decision about whether or not to participate in the study will not affect the care you receive at Crouse Hospital.

Alternatives:

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

1. If you decide not to participate in this research study, you will continue to receive your usual care and will not have any of the above procedures done for research purposes.
2. If you decide not to participate in this study, your left over blood (tissue) will not be used.
3. If you decide not to participate in this study, your medical information will not be used for this study.
4. If you decide not to participate in this sub-study, you may still participate in the main (treatment) study.

5. If you decide not to participate in this study, you will have your surgery as planned and none of the above procedures will be done for research purposes.
6. *If you decide not to participate in this research study, you may still receive behavioral therapy or other investigational treatments, which may be available. You 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 and/or your insurance carrier for participating in this study. You will not be paid for your participation.
2. All costs associated with this study will be billed to you and/or your insurance carrier. You will not be paid for your participation.
3. There are no costs to you 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 will be paid \$25.00 at each visit to cover your travel expenses. In the event that your participation in the study is discontinued early, you will only be paid for the visits completed.
4. *All costs associated with your participation in this study will be free of charge. You will not be paid for your 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 may be made available to professional auditors to satisfy audit and Federal reporting requirements, but confidentiality will be preserved. Please note that if you earn \$600 or over in a calendar year as a research subject, you 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 any questions about the research, or in the event of a research-related injury, please contact Dr. at (315) XXX-XXXX. If you have any questions about your 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 any questions about the research, please contact Dr. at (315) XXX-XXXX. If you have any questions about your 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 will be responsible for any costs not paid by your insurance company. No other compensation is offered. We have no plans to give

you money if you are injured. You have not waived any of your 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.

