MossRehab
EINSTEIN HEALTHCARE NETWORK

RESEARCH SUBJECT INFORMATION
CONSENT and AUTHORIZATION
FORM

TITLE OF PROJECT:	Video and Temporal Spatial Parameters Assessment of Gait after Dysport Treatment: A Pilot Study
NAME OF PRINCIPAL INVESTIGATOR:	Alberto Esquenazi, MD
PRINCIPAL INVESTIGATOR'S PHONE:	(215) 663-6667
AFTER HOURS PHONE:	(215) 663-6000

Support/Funding Statement:
Funding to support the conduct of this study is being provided by Ipsen Biopharmaceuticals Inc., a pharmaceutical company.

WHAT IS A CONSENT FORM?
You are being asked to take part in a medical research study. Before you can make a knowledgeable decision about whether to participate, you should understand the possible risks and benefits related to this study. This process of learning and thinking about a study before you make a decision is known as *informed consent* and includes:

- Receiving detailed information about this research study;
- Being asked to read, sign, and date this consent form, once you understand the study and have decided to participate. If you don't understand something about the study or if you have questions, you should ask for an explanation before you sign this form;
- Being given a copy of your signed and dated consent form to keep for your own records.

The relationship that you have with the study doctor is different than the relationship you have with your family doctor. Your family doctor treats your specific health problem with the goal of making you better. The study doctor treats all subjects according to a research plan to obtain information about the experimental drug, device, or procedure being studied and with the understanding that you may or may not benefit from your participation in the study. You should ask questions of the study doctor if you want to know more about this.

PURPOSE OF THE STUDY:
There are techniques available to identify targeted muscles for spasticity treatment with medication injection, but they are not always available or effective. The purpose of this study is to evaluate the usefulness of video observation in lower limb spasticity as another technique to guide clinicians in identifying targeted muscles for spasticity treatment with medication injection.

You are being asked to participate in this study because you have ankle/foot spasticity; may use a leg brace and your treating physician identified you as a candidate to receive spasticity medication injections.

We plan to have up to 15 patients enrolled at MossRehab.

DESCRIPTION OF PROCEDURES:

Taking part in this study will involve two to three visits to the clinic. The follow-up final visit will be scheduled 4-6 weeks after the first visit. Each visit will last about an hour. To take part, you must agree to:

- Allow collection of information from you and your medical record about your medical history;
- Agree to be videotaped when you walk on at mat;
    - If you do not want to be videotaped, you will not be able to take part in this study
- Agree to receive a spasticity treatment injection medication called Dysport
    - Dysport is a medication currently used in clinical care that is FDA approved for the treatment of spasticity. Dysport for injection is indicated for the treatment of lower limb spasticity in adult patients. It is a botulinum toxin that blocks nerve activity in the muscles, causing a temporary reduction in muscle activity

Screening/Baseline Visit

A member of the study will:

- Review demographics (gender, date of birth/age, ethnicity, race, height and weight)
- Review your medical/surgical history, including ongoing medical history
- Review your spasticity injection treatment history
- Review your current medications and allergies
- Measure your ankle and knee passive range of motion (PROM), tone with the Modified Ashworth Scale (MAS) and spasticity with the Tardieu Scale (TS). This entails the examiner moving your ankle quickly from toe pointing down to toe pointing up and documenting the findings
- Ask you to walk and be videotaped walking with and without your shoes at your most comfortable walking speed and at your fast walking speed

After the above is completed, the study doctor will review the videotape of you walking and decide which muscles will be injected with the study medication Dysport.

- The study doctor will inject the study medication in the targeted location(s) in your ankle/foot muscles.
- You will receive a minimum of 1000 units, but no more than 1500 units of the study medication.

Once the study medication is injected, an appointment for your follow-up visit will be made in 4-6 weeks. Should you have any problems related to the study visit or the injection, you may call the study team immediately.

You may need to return for a second visit to complete the baseline procedures if the study doctor determines that is appropriate.

Follow-up Final Visit

A member of the study team will:

- Talk to you about your experience after your injection such as how you feel generally; how you feel walking, how your brace feels; how your foot feels.
- Review your medications

- Measure your ankle and knee PROM, MAS and TS
- Record video of your walking with and without shoes at your most comfortable walking speed and fast walking speed (MV) for observation and review

Withdrawal Visit

If for some reason, your participation ends before you return for the follow-up visit, we will contact you to collect the following information to include with your research record:

- Your general health; how you feel walking, how your brace feels; how your foot feels.

RISKS/DISCOMFORTS

Once you receive the injection, you may experience tenderness, soreness and bruising at the injection site.

After the injection, you may experience temporary adverse reactions such as: muscle weakness, nasopharyngitis (runny nose or sore throat), joint or muscle pain, dizziness and falls.

During video observation of your walking, there is a risk of loss of balance, tripping, and/or falling. The walkway mat has parallel bars to minimize this from occurring.

The risks to an unborn child or fetus are not known at this time. If you are sexually active, you and your partner should be using oral contraceptives, a barrier method of contraception, an intrauterine device (IUD), or Norplant. Also, you should not participate in this study if you are nursing an infant.

COSTS FOR STUDY PROCEDURES:

The cost for your routine medical care will be your or your insurance's responsibility. While you are participating in the study, you will receive the study medication Dysport at no cost to you.

Once your participation in the study has ended, you can still receive treatment with Dysport as part of your medical care for spasticity treatment. However, the cost of Dysport will be your or your insurance's responsibility.

BENEFITS:

There may be no personal benefit to you, but the knowledge received may be of value to humanity. The knowledge we gain may aid clinicians in improving treatment choices and outcomes for patients in spasticity.

ALTERNATIVES:

Alternative procedures or treatments for your condition are to continue with current standard of care, which may include Dysport or other botulinum toxins such as Botox and using other methods to aid in identifying targeted injection sites such as electrical stimulation, ultrasound and EMG.

RIGHTS:

Your participation is voluntary. You can choose to take part or not to take part in the study. If you choose to take part, you can change your mind at any time and stop taking part in the study. Whatever decision you make, it will not affect your care or the relationship you have with your doctors or the Albert Einstein Healthcare Network.

You will be told of any new information learned during the course of the study which might affect your

understanding of the information in this consent and your willingness to continue to participate.

Your participation in this study may be ended by the principal investigator or the sponsor if they feel it is in your best interests.

No guarantees have been made as to the results of your participation in the study.

COMPENSATION FOR INJURY:

In the event of an injury resulting from your participation in this project, you will be provided with clinically appropriate medical care for that injury within the capabilities of the Network. However, Albert Einstein Healthcare Network cannot assure that the medical care and treatment will be provided without charge, and the costs incurred may, ultimately, be your responsibility.

CONFIDENTIALITY / AUTHORIZATION:

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we create, collect, or use as part of the research. This permission is called an Authorization.

By signing this form, you authorize the use and sharing of the following information for this research:

- Information from your medical records that is necessary for this study (initials, date of birth, age, weight, height and race)
- Information we collect from you about your medical history
- Clinical and research observations made during your participation in the research

Your personal information will be removed and will be replaced by a unique number (coded) assigned by your study doctor.

Any health information that is used or shared under this Authorization will **NOT** include any special health information related to genetic testing, treatment for AIDS/HIV, psychiatric care and treatment, or treatment for drug and alcohol abuse unless specified above.

By signing this form, you authorize the following persons and organizations to receive your protected health information for purposes related to this research: members of the research team and the funding source (Ipsen Biopharmaceuticals Inc.).

In addition, regulatory agencies that provide research oversight such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP) or the appropriate offices of Albert Einstein Healthcare Network and its Institutional Review Board (IRB), which is the committee responsible for ensuring your welfare and rights as a research participant, may review and/or photocopy study records which may, if they feel it necessary, identify you as a subject.

If information obtained in the study is published, it will not be identifiable as your results unless you give specific permission.

The Albert Einstein Healthcare Network complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected. Our Notice of Privacy Practices (a separate document) provides more information on how we protect your information. A copy of the Notice will be provided to you.

The information collected during your participation in this study will be kept indefinitely. Your Authorization for this study will not expire unless you cancel it. You can cancel this Authorization at any time by writing to the study investigator at:

Alberto Esquenazi, MD
MossRehab
60 Township Line Rd.
Elkins Park, PA 19027

If you cancel your Authorization, you will not be able to continue to participate in this research. The principal investigator and the research team may continue to use information about you that was collected before you cancelled the Authorization. However, no new information will be collected about you after you cancel the Authorization.

You have a right to refuse to sign this form. If you do not sign the form, you may not be in the research study, but refusing to sign will not affect your health care outside the study.

WITHDRAWAL FROM STUDY:

In the event that you withdraw from the study, the study physician will ask your permission to continue study follow-up, and all clinical data, as it relates to the study, will continue to be collected from your medical records.

CONTACT INFORMATION:

If you feel that you have not been adequately informed of your rights with respect to the privacy of your health information or if you feel the privacy of your health information has not been adequately protected, you can contact the Network's Privacy Office at: Gratz Building, 1000 West Tabor Rd, Philadelphia, PA 19141, (215) 456-3517 or privacy@einstein.edu.

All questions regarding your participation in this study, or in the event of injury, all questions pertaining to that injury will be answered by Alberto Esquenazi, MD or his/her designate who can be reached at (215) 663-6667.

For any questions pertaining to your rights as a research subject, you may contact Robert Wimmer, MD, chair of the Institutional Review Board, Albert Einstein Healthcare Network, Paley Bldg., First Floor, (215) 456-6243.

UNDERSTANDING OF PARTICIPATION:

The information in this consent form has been explained to me and all of my current questions have been answered. I have been encouraged to ask questions about any aspect of this research study at any time. Whenever I ask questions, the questions will be answered by a qualified member of the research staff or by the investigator(s) listed on the first page of this consent form.

By signing this form, I agree to participate in this research study and give authorization to use the information collected for this research as explained in this consent form. A copy of this consent form will be given to me.

_____
Printed Name of Subject

_____ _____
Subject Signature **(relationship, if kin or guardian signs for subject)** Date:

_____
Printed Name of Person Holding Consent Discussion

_____ _____
Signature of Person Holding Consent Discussion Date:

Witness to consent when applicable:

Witness Statement: Your signature indicates that you were present during the informed consent discussion of this research for the above named participant, that the information in the consent form and any other written information was verbally discussed with the participant (or legally authorized representative) in a language that he/she could understand, that he/she was given the chance to ask and receive answers to his/her questions, that the decision to take part in the research was freely made by the participant (or legally authorized representative) who indicated his/her consent and authorization to take part in this research by:

- □ Signing his/her name
- □ By making his/her mark
- □ Other means: _____
  explain

Printed Name of Witness: _____

WITNESS SIGNATURE: _____ DATE: _____TIME:_____

INVESTIGATOR'S STATEMENT

I, the undersigned, certify that to the best of my knowledge, the subject signing this consent form has had the study fully and carefully explained by me or a member of the study staff and has been given an opportunity to ask any questions regarding the nature, risks, and benefits of participation in this research study.

INVESTIGATOR OR DESIGNEE*:_____ Date: _____
SIGNATURE

***DESIGNEE REFERS TO CO-INVESTIGATOR OR SUB-INVESTIGATOR ONLY.**