ASSENT TO PARTICIPATE AS A RESEARCH SUBJECT
FOR ADOLESCENTS 16-17 YEARS OLD

TITLE:	A Phase 2a, Multicenter, Randomized, Patient and Evaluator Blinded, Controlled Study Evaluating the Safety and Efficacy of NTX-001 Compared to Standard of Care in the Treatment of Acute Single Transected Peripheral Nerve Injury Occurring below the Distal Border of the Brachial Plexus Requiring Surgical Repair.
PROTOCOL NO.:	NTx20201 WIRB® Protocol #20200955
STUDY-RELATED PHONE NUMBER(S):	Phone Number Phone Number (24 hours) [24 hour number is required]

WHO ARE YOU AND WHY ARE YOU MEETING WITH ME?

I am [Name] and I work at [Site]. I would like to tell you about a research study that involves people like yourself and see if you would like to take part in it. Please ask me, other study staff, or your parent(s) to explain any words you do not understand about the study.

WHAT IS THIS RESEARCH STUDY ABOUT?

This study involves the use of an experimental study medicine called NTX-001. It is used in the repair of nerve injuries and is used in the operating room. Neuraptive Therapeutics, Inc. (Neuraptive) is sponsoring this study. Taking part in this study is entirely up to you and your parent(s). Your medical care will not be changed if you do not want to participate.

WHY HAVE I BEEN ASKED TO TAKE PART IN THIS STUDY?

You have been asked because you have a nerve that has been cut in your arm or hand that needs surgery and the doctors are asking if you want to be in this study.

WHO CAN BE IN THIS STUDY? AND WHO MAY NOT?

Anyone that is between the ages of 16 and 65 year old, that has had a nerve completely cut in their upper arm or hand that needs surgery can be in the study except if they have other diseases that might affect the way the injury heals.

HOW LONG WILL THE STUDY TAKE?

It will last about 12 months.

WHAT WILL HAPPEN TO ME IF I TAKE PART IN THIS STUDY?

First, your parents will be asked if they give their permission for you to be in this study. They will also be asked if they agree to participate themselves, by doing some things like answering questions about you. If your parents don't agree, you cannot be in the study. Site staff conducting the following tests will not know if you are in the NTX-001 group or the standard of care group. The tests may be done in your home during the study visits and will require certain equipment in order to measure how you are doing. The research nurse will have all the equipment required to conduct these tests.

If your parents do agree, and you agree too, here's what will happen next:

Before you begin the study -

- The study doctor will ask your parents some questions about you.
- The study doctor will ask you questions about your health.

During the study – the various tests will include and be done at several times:

- Measuring heart rate, blood pressure, temperature, and respiratory rate.
- **Blood Samples** will be taken from a vein for safety testing, and to check for pregnancy in girls who can become pregnant. These blood samples will be drawn two (2) times during the study, unless collecting more samples is needed.
- During your nerve repair a **Nerve Stimulation Test** will be done in the operating room and you will not feel this test.
- Another nerve function test called an EMG (electromyography) will be done at the weeks 12 and 48 and must be done in at the clinic. This is to see if your nerve is beginning to function normally, you may feel pain and/or tingling in your arm or hand during these tests.
- **MRCC Scale – Sensory**: This assessment is done by your study staff. There is a test included in this assessment to measure if you can feel pressure (touch) below the nerve injury site in your hand or fingers. You will be required to be blind-folded or in some way, unable to see this procedure during this test.
- **MRCC Scale – Muscle**: This assessment is done by your study staff. This assessment is done to measure if you can move your arm after your nerve repair. It is done on the affected arm and on your other arm to compare your movement between the two.
- **Semmes Weinstein Monofilament Test**: This assessment is done by your study staff. This test measures light touch to deep pressure, including protective sensation in your finger(s) and is done to detect minor differences in sensory feeling. This assessment uses a tool that consists of a set of monofilaments (small, colored, and hair-like) that vary in stiffness and diameter. You will be required to be blind-folded or in some way, unable to see the test procedure being done.
- **Grip and Pinch Strength Test**: This assessment is done by your study staff. This test measures the strength of your hand grip and your ability to pinch with your fingers using tools that can measure your strength. If you have a splint on after your surgery, you will not have this assessment done until the splint is off and your study doctor agrees you can test your strength.
- **Michigan Hand Questionnaire (MHQ):** The MHQ is a questionnaire with a total of 37 questions specifically related to the hand injuries. The MHQ can measure your general hand function and changes or improvements in your hand function after your nerve repair. It takes about 15 minutes to answer these questions.
- **Cold Intolerance Symptom Severity (CISS):** The CISS is a 6 question test that asks about the impact of cold on your hand or arm. It takes about 5 minutes to answer these questions.
- **Patient Global Impression of Change (PGIC):** This scale asks about your health and if there things have improved or gotten worse since your nerve repair. It consists of one question and will take about 1 minute to answer this question.
- **Numeric Pain Rating Scale (NPRS):** You will be asked to select a number between 0 (no pain) and 10 (worst possible pain) to rate current pain at rest or with activity. It takes approximately 1 to 2 minutes to answer these questions.
- **Physical and Occupational Therapy**: The study will track how many times you attend

your scheduled physical and/or occupational therapy sessions after your nerve repair.

CAN SOMETHING BAD HAPPEN TO ME OR WILL I FEEL UNCOMFORTABLE IF I TAKE PART IN THIS STUDY?

Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks. Blood drawing may hurt when the needle is put into and taken out of your hand or arm. There may be a black or blue spot on your hand or arm called a bruise, or bleeding, or infection, at the place where your blood is drawn, but the chances of getting an infection are rare. You may have side effects from the study medicine. You may have an allergy to the study medicine as well that is not known. If you feel any side effects, you should tell your parents or the study doctor about this right away.

Telemedicine Risks: "Telemedicine" or "Telehealth" are the words used when talking about clinical diagnosis and monitoring that is delivered by technology. In-home or remote research visits may be done during this study. Qualified registered nurses will visit you in your home to do the same assessments or tests that were going to be done in the clinic. Telemedicine doctors may visit with you during some of these visits to check on you. These visits will be done over the internet using secure connections. Telemedicine must also meet all privacy requirements. "The rules are no different for telemedicine than for in-person visits." The technology used is compliant with HIPAA privacy rules. This physician will conduct the visit in a location where no one can overhear the discussions. The technology is fully encrypted for data transmission.

FOR ADOLESCENT GIRLS IN THE STUDY

If you have had your first menstrual period, a pregnancy test will be done at your first visit to make sure that you are not pregnant. The study doctor will take blood from your hand or arm with a needle placed in a vein. At three, six, nine and twelve months into the study, you will be asked to "pee" in a cup and the pregnancy test will be done. If this pregnancy test is positive we will share the information with you and assist you in sharing this information with your parents should you chose to do so. It is important that you tell your parents or the study doctor if you think you are pregnant while you are in this study. You should also tell the study doctor about all medicines that other doctors may have given you to take.

CAN SOMETHING GOOD HAPPEN TO ME IF I TAKE PART IN THE STUDY?

We do not know if this study will make you feel better. You may get a little better by being in this study, or you may stay the same, or you may get worse.

WILL OTHERS KNOW WHAT I SAY AND DO IN THE STUDY?

Your health information may need to be shared for this research and other reasons. Therefore, complete privacy of your health information cannot be promised. However, sharing your information will be guided by professional standards and the law. Information from this study may be presented at meetings or published in medical journals. The information included at meetings or in journals will not include your name or information that can easily be traced back to you. There may be other information that may be used and given to others that have not been stated above. You should discuss this with the study doctor or a member of the study staff and ask any questions that you may have about the sharing of your health information. This permission to use and disclose your personal health information does not expire.

WILL I BE GIVEN ANYTHING TO TAKE PART IN THIS STUDY?

You will be paid for your time related to participation in the study. The research site will collect your social security number and address to meet federal requirements for reporting tax information.

You will be paid up to $1400.00 if you complete all study visits. The following amounts will be paid for each completed visit:

Screening	$0.00
Surgery	$0.00
Week 1	$100.00
Week 4	$125.00
Week 8	$150.00
Week 12	$275.00
Month 6 (Week 24)	$225.00
Month 9 (Week 36)	$225.00
Month 12 (Week 48)	$300.00
Total	$1400.00

[enter site specific subject compensation language regarding method of compensation and timing of payments]

WHAT IF I DO NOT WANT TO TAKE PART IN THIS STUDY?

You do not have to take part in this study if you do not want to. No one will get angry or upset if you do not want to be in the study. Just tell us. And remember, you can change your mind later if you decide you do not want to be in the study anymore once you start.

When receiving telemedicine visits, you have the right to stop or refuse care at any time.

WHAT IF I HAVE QUESTIONS?

You can ask questions at any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else at any time during the study. You can contact the IRB about concerns or complaints due to the use of telemedicine (visits over the internet). Here is the telephone number to reach us:

Contact the Institutional Review Board (IRB) at
Telephone: 800-562-4789

Contact the study doctor at
[Name]
[Address]
[Telephone]
[E-mail]

WHAT ARE MY RIGHTS IF I DECIDE TO TAKE PART IN THIS RESEARCH STUDY?

You may ask questions about any part of the study at any time. Do not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions and

agree to take part in the study. If you say yes, your parent(s) or guardian will also be asked if they permit you to take part in this study.

IF YOU DON'T WANT TO BE IN THIS STUDY, JUST SAY SO, AND DON'T SIGN THIS FORM.

If you want to be in this study, please sign your name below. If you sign here, it means you agree to participate in this study. The doctor will give you a copy of this form to keep.

- All children are required to assent.
- If assent is obtained, have the child sign an assent form, unless the investigator determines that the child is physically not capable of signing.

Adolescent's Signature	Date	Age

Adolescent's Name (*print*)

☐ The subject is not able to physically sign but agrees to be in the study.

Signature of person obtaining assent	Date

Signature of Person Conducting Assent Discussion	Date

Name of Person Conducting Assent Discussion (*print*)

OPTIONAL CONSENT

Authorization to Take images of Surgical Procedure

The Sponsor would like to take pictures of the nerve repair before stitching the wound closed or to video the procedure itself, from suture of the nerve until wound closure. These images will not be identifiable and will be used to improve training on the procedure during the study.

☐ I agree to allow pictures or video taken during my nerve repair;

☐ I do not want pictures or video taken during my nerve repair.

Initials: _____

For Sites in California

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.

Who may use and give out information about you?
The study doctor and the study staff. [They may also share the research information with [enter SMO company name], an agent for the study doctor. delete if the site does not have an SMO]

Who might get this information?
The sponsor of this research. "Sponsor" means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?
This permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
There is a risk that your information will be given to others without your permission.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

AUTHORIZATION SIGNATURE:

Signature of Subject	**Date**