



## RESEARCH ASSENT FORM *Screening*

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

**Protocol Title: Hand Transplantation**

**Principal Investigator: Amir Taghinia, MD**

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about transplanting hands in children. This is an experiment - no one has ever transplanted hands in children. Hand transplantation is when hands are taken off a person who has died and given to a person who needs them. We want to see whether these hands will help children do normal things like picking up a cup or brushing teeth. We are asking you to be evaluated for this study because you lost your hand(s) or were born without them. We think that you would be able to do more things if you had two hands. We think that you might even be more independent and happier with your abilities if you joined this study, but because this has never been done before for children or adolescents, we cannot know ahead of time for sure.

If you think you may be interested in a hand transplant we first have to determine if you are able to receive a hand transplant. This means we need to do lots of tests to make sure it is okay to do the transplant. Some people have conditions that will make it difficult or impossible for the hand transplant to work and we need to do tests to make sure you can have a hand transplant. Since there are many tests to determine if a hand transplant may work and they take a long time we want to make sure that you first understand what it means to have a hand transplant. We also want to make sure you understand information about the many medications and physical therapy you will need after you have the hand transplant. It is important for you to understand this information and feel it is something you want to do before we begin to test you to see if you are able to have a hand transplant. The doctors will talk to you about the hand transplant and what it involves and we have also attached another form which you may read now. You may be asked to sign this other form at a later time if all the tests turn out ok and you are able to receive a hand transplant. This form contains important information for you to think about and talk with your parents and doctors about before you decide to be tested to see if you are able.

We are asking for your permission to see if you are able to have a hand transplant. To do this, you will come to the hospital with your parents and meet with the team. This will take a few days and many hours. We will ask you questions about your health, how you lost your hand(s) and how you are feeling. You will need to have some tests done like x-rays and a test that looks at the blood vessels in your arms to see how they would match up to the new transplant. You may also need to have an MRI or CT. For both of these tests you lie on a narrow table and slide into a scanner so we can take pictures of the inside structures of your arm(s). Sometimes these tests require that we put a special dye through an IV so that we can see things better. We will need to draw your blood to run special tests to see if you can be part of this study. Some risks for doing this screening include pain from blood draws, sometimes the dye that we put in the IV can leak into your skin and can hurt. You may also feel sad or upset answering all of our questions. After all of these tests are done and you have met with the whole team we will discuss if you want to be part of the study and if we think it is a good idea.

It is possible that after we do the tests, you will not be able to have a hand transplant. This may be very upsetting to you especially if you have decided that you want a hand transplant. It is important to realize that



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Pt Name: \_\_\_\_\_

we can do a hand transplant if we feel it may work for the person. If we feel it may not work, we do not want to put you at any risk. It is not your fault if you cannot receive a hand transplant, because everyone is different and has different conditions.

You do not have to join this study. It is up to you. You can say okay now and change your mind later before you have the new hand(s). All you have to do is tell us you want to stop. No one will be mad at you if you don't want to be in the study. Once you have the hand transplants, though, it will be very hard to stop because removing them from you will hurt and your arms may not function as well as they did before transplant. So you have to make sure that you really want to have the hand transplants – even though it means that bad things can happen.

Before you say **yes or no** to being in this study, we will answer any questions you have. If you join the study, you can ask questions at any time. Just tell the researcher that you have a question.

**To do some of the tests, it is important to see if you are pregnant, because some of the tests may hurt a developing baby. We will do a pregnancy test.**

### **For young women:**

The results of the pregnancy test are confidential and will be told to you by one of the study nurses or doctors in private. Every effort will be made to maintain confidentiality regarding positive pregnancy test results. Our policy is that we would not tell your parent(s) or guardian(s) without your permission. However, under certain circumstances, we might be compelled to reveal this information. For example, if your life or someone else's life was at risk or if abuse was suspected, it may be necessary to inform your parent(s) or guardian(s) of a positive pregnancy test. If we believe it's necessary to tell your parent or guardian of a positive pregnancy test without your permission, we would meet with you first in private to discuss our concerns prior to giving any information regarding pregnancy.

You have been informed about special concerns about pregnancy and unknown reproductive risks of the drug(s). You have informed the study personnel that you will abstain from sexual intercourse or practice effective birth control methods during the study.

Sign here: \_\_\_\_\_ Date: \_\_\_\_\_

If you have any questions about this study please feel free to contact Dr. Amir Taghinia at 617-355-3421

If you sign your name below, it means that you agree to take part in this research study.

I have read both the screening and transplant assent forms and I understand the risks and benefits associated with this experimental study:



\_\_\_\_\_  
Date (MM/DD/YEAR)

\_\_\_\_\_  
**Signature of Child/Adolescent Participant**