This Informed Consent Form is for women who attend Chungbuk National University Hospital, and who we are inviting to participate in research on neurofibromatosis I (NF1). The title of our research project is "Life-threatening brachial artery hemorrhage and the lethal outcome in patients with neurofibromatosis type I: two case reports and review of literature".

PART I: Information Sheet

Introduction
I am Yook Kim, working for Chungbuk National University Hospital. We are doing research on NF1, which is uncommon in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.
Purpose of the research
NF1 is an autosomal dominant multisystem neurocutaneous disorder that usually presents with café au lait spots, neurofibromas, and iris hamartomas.
In NF1, the brachial artery was mostly affected by stenosis, not aneurysm. Brachial artery aneurysms are usually asymptomatic but rupture of brachial artery aneurysms sometimes prove to be fatal. A few brachial artery aneurysms have been reported to spontaneously rupture in NF1 patients, and endovascular treatment has been reported as effective and safe in managing these aneurysms in NF1. There has been no report of post-traumatic brachial arterial injury in NF1 patients and the direction of treatment and prognosis are rarely investigated. We report our experience with a case of extensive and progressive bleeding from a ruptured brachial artery pseudoaneurysm caused by a traumatic injury in an NF1 patient with a lethal outcome and discuss optimal treatment strategies.

Type of Research Intervention
This research is retrospective chart review. A retrospective chart review is an evaluation or analysis of a patient’s medical record that already exists in the subject’s medical record.

Participant selection
We are inviting a patient with NF1 with brachial artery hemorrhage caused by a traumatic injury to discuss optimal treatment strategies.

Voluntary Participation
Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change.

Side Effects
There are not any known or anticipated side effects associated with retrospective chart review.

Risks
There are not any possible or anticipated risks associated with retrospective chart review.

Benefits
There may be no direct or indirect benefits to the study subjects, but it is likely to provide useful information to patients with the same disease.

Reimbursements
You will not be given any money or gifts to take part in this research.

Confidentiality
The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key.

Sharing the Results
The knowledge that we get from doing this research will be shared with you. Confidential information will not be shared. We will publish the results in order that other interested people may learn from our research.
Right to Refuse or Withdraw
You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Who to Contact
This proposal has been reviewed and approved by CBNUH IRB, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact Bora Son, Chunbuk National University Hospital, +82-43-269-6771. It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

PART II: Certificate of Consent
This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have “I understand...” phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant  S0ng Yoo  ng Lee
Signature of Participant  Z21 [mother of patient]
Date  10/Oct/2020
Day/month/year

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent  YooK Kim
Signature of Researcher/person taking the consent  Z21
Date  10/Oct/2020
Day/month/year