Validation of a Computed Tomography (CT) based Fractional Flow Reserve (FFR) software using the 320 Detectors Aquilion ONE CT Scanner

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Research Team

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IRB Approval Period
HRPP Revision Date: Oct 12, 2015

Permission to Take Part in a Human Research Study

University at Buffalo
The State University of New York
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203
UB Federalwide Assurance ID#: FWA00008824

Title of research study:

Validation of a Computed Tomography (CT) based Fractional Flow Reserve (FFR) software using the 320 Detector Aquilion ONE CT Scanner. Only adults able to consent are included

Version Date: 1/7/19

Investigator(s):

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Ciprian N Ionita PhD

Michael Wilson MD

Vijay Iyer MD

Umesh Sharma MD

Why am I being invited to take part in a research study?

You are being invited to take part in a research study because we believe that the information acquired during your clinical evaluations could help with improvement and validation of a software measurement tool that would aid in the diagnosis of certain vascular disease.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.
- No clinical procedure will be changed as a result of your participation

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at:

Principal Investigator: Kenneth Snyder MD at 716-218-1000

OR

Co-Investigator: Ciprian Ionita, Toshiba Stroke and Vascular Research Center (716) 829-5413
cnionita@buffalo.edu

- You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.
- This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu
  - Your questions, concerns, or complaints are not being answered by the research team.
  - You cannot reach the research team.
  - You want to talk to someone besides the research team.
  - You have questions about your rights as a research subject.
  - You want to get information or provide input about this research.

Why is this research being done?

Dr. Ciprian N Ionita and colleagues from the Department of Neurosurgery and Cardiology are collecting data to validate and develop new software for vascular disease severity diagnosis. Such software could improve the efficacy of cardiologist diagnosis while reducing the need for additional procedures to acquire physiological information.

In the long term such software could help reduce the radiation dose due to reduced number of interventions.

How long will the research last?

We expect that you will be in this research study until 30 day follow-up done after the angio Fractional Flow Reserve evaluation .

How many people will be studied?

We expect 50 people to be in this research study.

What happens if I say yes, I want to be in this research?

The research team will acquire data from the CT scanning and angio-lab evaluation. No clinical procedures or protocols will be changed. CT data will be de-identified and used post-procedure in the University at Buffalo computer labs to estimate blood flow in the heart arteries. The computer results will be compared with the angiography lab results and 30 day follow-up, for software validation.

If CT scan procedure is not clinically driven the investigators will cover the expenses associated with the Coronary CT Angiography.

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

Is there any way being in this study could be bad for me?

During CT procedure patients will receive standard doses of Nitrates, Beta blockers and up to 70ml of iodine contrast. The radiation dose associated with the study is ~4.9mSv, which is within the nationally reported averages for coronary CT scanning. In very rare cases, the contrast agents used in CT can cause allergic recations. Some people experience mild itching or hives (small bumps on the skin). Symptoms of a more serious allergic reaction include shortness of breath and swelling of the throat or other parts of the body. Tell your study doctor if you experience any of these symptoms.

The risk of a breach in medical data confidentiality will be minimized by removing any personal information from the images and lab results. Only the Principal Investigator will be in the possession of the relation between the patient ID and the study identifier. We will destroy the identifiable data as soon as possible, but not greater than 3 years after the completion of the study.

Will being in this study help me in any way?

There is no direct benefit to you for your participation in this study. However, your willingness to take part may help doctors improve your medical care. The use of software to estimate blood flow based on CT data only could be beneficial for future patients by reducing the radiation dose associated with additional lab procedures.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

What else do I need to know?

You will be notified of any significant new developments that may cause you to change yourmind about participating in the research study.

It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call.

You will get medical treatment if you are injured as a result of taking part in this study. Your study doctor will explain the treatment options to you and tell you where you can get treatment.

Generally, this care would be billed to you, your insurance or other third party. University at Buffalo has no program to pay for medical care for research-related injury.

Permission to Take Part in a Human Research Study

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

__X___Information from your full medical records: CT imaging data and Fractional flow Reserve measurements from the catheterization labs

__X___New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

__X__ KALEIDA Health, Buffalo NY
__X__ Principal Investigator or designee
__X__ Buffalo General Medical Center/ Gates Vascular Institute

C. With whom may your protected health information be shared?

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

__X___Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment
__X___The organization(s) responsible for administering this research: UB Medical School

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your

information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Research Coordinator, Department of Neurosurgery, Kaleida Health 100 High Street, Suite B-4, Buffalo, NY 14203 (716)218-1000

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

IRB Approval Period