How to process the Annex A and B´s

For each project at the national 7T, the research agreement between Philips and Lund University has to be undersigned by the project participants.
These papers have to be signed before you are allowed to start your project.

The research agreement has three parts:

- **IIS** (investigator initiated study): The main agreement, negotiated by lawyers at Philips and Lund University, with input given from representatives for the national user group. Signed on May 1st, 2015, by representatives for LU and Philips.
- **Annex A:** Describes the project and gives contact information to the principal investigator (PI). To be signed by:
    - PI
    - Representative for LBIC (currently co-director Pia Maly Sundgren)
    - Representative for Philips (currently Paul Folkers)
- **Annex B:** Each project participant ("investigator") agrees to follow the IIS agreement. To be signed by:
    - Investigator
    - Representative of investigators employer
    - Co-director of LBIC
    - Representative for Philips

The process:

1. The PI gets the templates for Annex A and B from the 7T staff after the project is accepted in the 7T research board.
2. The PI fills out the fields marked with yellow in Annex A.
3. The PI distributes the Annex B to the project co-workers. Either the PI or the investigator fills out all yellow fields in the Annex B.
4. The PI collects all the annexes and makes a digital copy.
5. Email the digital copies to

    ***To**: Pia.Sundgren@med.lu.se*
    ***cc**: karin.markenroth@med.lu.se*
    ***subject**: signatures required 7T Annexes*
    ***message text contains**: PI, project number (7T_XXX), project name, names of people who signed the Annex B.*

    This email is your receipt that you have fulfilled your part of the agreement, and you can start the project!

    You can also ask Pia Sundgren to sign the hard copies, and then hand the hard copies to Mads Andersen. You should still make digital copies for your own records.

6. Pia Sundgren will sign the Annexes, and hand them to Mads, alternatively email the signed copies to Mads Andersen.

7. Mads Andersen will as clinical scientist request the signature from the Philips representatives in Holland. This step can take several months.
8. When Mads gets the signed copy back, he will send those to the PI, either in digital form or in hardcopy.

Frequently asked questions:

- **Who should sign Annex B?**
  Everyone who is at the scanner and/or is using the data. In doubt, contact 7T staff.
- **Can I read the IIS agreement?**
  Of course! Contact anyone in the 7T staff for a copy. A brief summary is attached to this memo.
- **The contract only talks about "clinical research", and I do physics research?**
  The term "clinical research" is a legal term that refers it to the correct sets of laws, and it was required by the lawyers. Just read it as "research".

Following pages:

In the following, you will find the user guides' summary of the IIS, as well as examples of filled out Annex A and B.

The following is an unofficial summary of some contract items relevant for investigators. For the legally binding text, the reader is referred to the full IIS, which can be obtained by from the 7T facility staff.

- **Obligations of the PI**: The PI is responsible for the scientific conduct of the research, for the Clinical Research plan, and for ensuring that informed consent is obtained from all humans subjects. PI shall obtain ethics approval prior to start of project and before enrolling subjects. If the PI can't pursue the Clinical Research, Philips and LBIC can consent to a substitute PI. The PI is responsible for all investigators in the project.
- **Obligations of the institution:** As the institution. LBIC is responsible for the technical conduct of the research. LBIC is responsible towards Philips to ensure that the PI and all investigators have signed all documents needed, including Annex A and Annex B, ethical permissions, and so forth. LBIC must ensure that only qualified personnel operate the 7T MR and other equipment. LBIC must report any incidents (adverse events or situation that could have resulted in such an event) to Philips within two days.
- **Standard clinical research:** Using the system as delivered by Philips without additional support from Philips. Support from the Clinical Scientist on site is considered a part of the delivery.
- **Expanded clinical research:** Projects where hardware, software or other support not included in the system delivery is supplied by Philips. (Example: a patch provided by Philips). For such projects, more extensive reporting to Philips is required (i.e. PIs CV, periodic progress reports).
- **Publications:** The IIS requires all publications to be made available to Philips before submission; for conference abstracts 5 days before submissions and for papers 30 days before.

- **Confidentiality:** Items and information that Philips provides are presumed to be confidential until Philips in writing advises to the contrary. Confidential information must be kept confidential and may only be used for the research carried out under this agreement. It is not allowed to copy or transfer any part of the Philips software.
- **Intellectual property rights:** All rights to an invention made solely by LBIC, PI or investigators resides with the inventor, who must have signed Annex B. Philips and its affiliates are granted a worldwide license to Inventions made by Philips personnel resides with Philips. Any joint invention, meaning that both Institution and Philips personnel are involved, will be jointly owned and each party will have equal and unrestricted ownership.

EXAMPLE

ANNEX A

Clinical Research for: Optimization of time resolved, volumetric, three-directional velocity measurements in intracranial applications at 7T

Ref number: 7T_020

The Clinical Research shall be conducted according to the Clinical Research Plan identified below, having the reference number and dated as indicated below.

Clinical Research Plan	
Title:	Optimization of time resolved, volumetric, three-directional velocity measurements in intracranial applications at 7T
Reference number: (assigned by Institution)	7T_020
Date of final version:	2016-05-31
Type of Clinical Research : (indicate with "X")	**Standard Clinical Research** ☒ **Expanded Clinical Research** ☐

1. Institution Information & Notice Address	
Institution's Name:	Lund University Bioimaging Centre
Institution's site address where Equipment shall be installed and Clinical Research conducted:	National 7T Facility, Klinikgatan 13B, 221 85 LUND
Notices to Institution shall be sent to:	Professor Freddy Ståhlberg
2. Sponsor Information	
The Sponsor of the Clinical Research described herein is:	Principal investigator (see below)
3. Principal Investigator & Notice Address	
This Clinical Research will be conducted by Principal Investigator:	Karin Markenroth Bloch
Notices to Principal Investigator shall be sent to:	Karin Markenroth Bloch, National 7T Facility, Klinikgatan 13B, 221 85 LUND, Sweden
Telephone:	+46 78 32 25 04
Email:	Karin.markenroth@med.lu.se
4. Philips Information & Notice Address	
Notices to Philips shall be sent to:	Ruud de Boer, Clinical Science Director Veenpluis 6 5684PC Best The Netherlands
With a copy to:	Julius Cohen, IP&S Europe Cluster Healthcare High Tech Campus Eindhoven P.O. Box 80036

EXAMPLE

	5600 JW Eindhoven The Netherlands Philips Medical Systems Nederland B.V., having its registered office in Best, The Netherlands
5. Equipment involved in this Clinical Research (only applicable for Expanded Clinical Research)	
Released Equipment:	Not applicable as Standard Clinical Research
Unreleased Equipment:	Not applicable as Standard Clinical Research
6. Deliverables to be delivered by Institution (only applicable for Expanded Clinical Research)	
Item For example papers, conference contributions, IP, clinical or technical feedback.	**Deadline** For each item, set a corresponding deadline date
As the project is considered Standard Research, no deliverables are set.	Progress meetings to be held annually.
7. Summary of the study	
List of investigators: List the investigator signing Annex B	Karin Markenroth Bloch Freddy Ståhlberg Boel Hansson Johanna Arborelius
Objective of the study: Describe in a few sentences the objectives and hypothesis of the study	The main goal of the project is to optimize time resolved, volumetric, three-directional velocity measurements (4D flow, for short) for intracranial applications at 7T. Of specific interest is to push the spatial resolution in order to quantify the velocity field in small vessels, and to increase the velocity to noise ratio for slow flow.
General methods description: (Only required for Expanded Clinical Research) Include the number of subjects and examinations planned and the general techniques that will be used (examples: 31P MRS, resting state fMRI, DTI...). Specifically mention the methods/technique that makes the study type Expanded Clinical Research.	
Project duration: Note anticipated start date of the project and expected duration	Anticipated start date: 2016-09-01 Anticipated project duration: 2 years

AGREED AND ACCEPTED:

Principal Investigator
Karin Markeroth Bloch, Lund BioImaging Center as "Principal Investigator", acknowledged to have read the Agreement and accept the terms of it as applicable to his activities under this Annex A.
Signature: Karin Bloch

EXAMPLE

Signature Date: 2016-05-31	
Name: Karin Markenroth Bloch	
Title: Researcher	
Principal Investigator acknowledged by Institution	**Principal Investigator acknowledged by Philips**
Lund University, Lund University Bioimaging Center (hereinafter referred to as "Institution")	**Philips Medical Systems Nederland B.V.,** acting through its business unit MR, (hereinafter referred to as "Philips")
Address: SE-22100 Lund, Sweden	**Address:** Veenpluis 4-6 in Best, The Netherlands
Signature:	**Signature:**
Signature Date: JUNE 13 2016	**Signature Date:** 13/7/16
Name: Prof. Freddy Ståhlberg	**Name:** Dr. Paul Folkers
Title: Director Lund University Bioimaging Center	**Title:** Senior Director MR Clinical Excellence

EXAMPLE

Ref. project number: 7T_020
Clinical research plan project title: Optimization of time resolved, volumetric, three-directional velocity measurements in intracranial applications at 7T

Annex B
Acknowledgment for Investigator

Background
The core activities of Lund University (hereinafter "LU") are education and research. LU provides infrastructure and conducts research in bioimaging. LU cooperates with Philips Medical Systems Nederland B.V. through the Agreement dated May 1, 2015 as attached hereto, in order to jointly conduct clinical research in the above indicated field.

The publication of the research results that are generated in such research cooperation is of great importance to the researchers participating from the university.

Acknowledgment

Johannes Töger, identified as Investigator in the Clinical Research Plan "Optimization of time resolved, volumetric, three-directional velocity measurements in intracranial applications at 7T" under the Agreement between Philips Medical Systems Nederland B.V. and LU dated May 1, 2015, as attached hereto ("Agreement"), hereby acknowledges to have read the Agreement and agrees to be bound, as Investigator, to the terms and conditions of the Agreement including the above identified Clinical Research Plan.

Investigator hereby represents and warrants to be fully entitled to and without any encumbrances comply with the terms and conditions of this Agreement. In particular, Investigator hereby represents and warrants that he/she is fully entitled to assign any and all rights to Subject Inventions made by the Investigator (whether or not together with other inventors) to Philips or Philips' Affiliates as the case may be.

Investigator shall notify Philips forthwith of any prior commitments that could be relevant for the Clinical Research prior to commencing the Clinical Research.

Investigator hereby agrees that Clause 12.4 of the Agreement regarding governing law and dispute resolution shall apply also to this Adherence undertaking.

The department of Diagnostic Radiology, being Investigator's employer, hereby acknowledges to have read the Agreement and agrees to be bound to the terms and conditions of the Agreement and the above identified Clinical Research Plan as if were Institution.

AGREED AND ACCEPTED:

Investigator

Signature: _____
Printed Name: Johannes Töger
Title: Post Doctoral researcher
Date: 2016-11-14

Investigator acknowledged by Institution

Signature: _____
Printed Name: Prof. Freddy Ståhlberg
Title: Director Lund University Bioimaging Center
Date: NOV-16 2016

Investigator acknowledged by Investigator's employer

Signature: _____
Printed Name: Pia Maly Sundgren
Title: Head of dept. of Diagnostic Radiology
Date: _____

Investigator acknowledged by Philips Medical Systems Nederland B.V.

Signature: _____
Printed Name: Dr. Paul Folkers
Title: Senior Director MR Clinical Excellence
Date: 8 March 2017