

# Study Initiation Form

Study Title: \_\_\_\_\_

Short Name (1 or 2 words): \_\_\_\_\_

<b>Principal Investigator Information</b>	
Name: _____	
Email: _____	
Address: _____ _____	
Phone: _____	Fax: _____
<b>Study Contact Person, if different from PI</b>	
Name: _____	
Email: _____	
Phone Number: _____	
Date: _____	

REB Review #	
Ethics application submitted to:	
Approval Date (dd-mm-yy)	
Expiry Date (dd-mm-yy)	

**Attach to this application:**

- **participant consent form**
- **study details**
- **other supporting documents**
- **(if feasible) a copy of the ethics application**

**Please return this Form with all attachments to:**

Junaid Lalani, Operations Director  
 SFU ImageTech Lab at Surrey Memorial Hospital  
 Building A (North), Level 1  
 13750 96<sup>th</sup> Avenue Surrey, BC V3V 1Z2  
 Email: [jlalani@sfu.ca](mailto:jlalani@sfu.ca)  
 Phone: 604-581-2211, ext 77-4986

**A. Investigators, Collaborators, Study Team Info**

Please list the study's collaborators. Attach additional page if needed.

Name	Affiliated Institution/Organization

If your project involves an enrolled patient group, please provide the contact information for the **Physician Investigator** named in the Ethics Application:

Name: \_\_\_\_\_  
 Address: \_\_\_\_\_  
 Email: \_\_\_\_\_  
 Phone: \_\_\_\_\_

**There must be at least one study team member that will serve as the "Research Coordinator"** for: pre-screening participants for MRI/MEG, making the appointment bookings, and attending the appointment at ImageTech with the participant. There may be multiple study team members trained to support and contribute to these tasks, but one primary or lead person.

Name	Role? Student? Affiliation?	Email <u>and</u> Phone Number

**B. Study Timeline**

This is a:     Cross-Sectional Study         Longitudinal Study

Requested Start Date (dd/mm/yy)        \_\_\_\_\_

Estimated End Date (dd/mm/yy)        \_\_\_\_\_

**C. Type of Study** (mark all applicable categories)

- MEG:**
- Resting state, # per session \_\_\_\_\_
  - Task-based, # per session \_\_\_\_\_
  - Simultaneous EEG, specify channel layout:
- Stimuli:
- SEF (electrical)                       AEF
  - SEF (tactile)                               VEF
  - Buttons                                       Stimulus computer
  - Other: \_\_\_\_\_

**MRI:**

**Anatomy**

- T1W     T2W     PDW
- Flair     Contrast Enhanced

**Angiography**

- IV Contrast Enhanced
- Non-IV Contrast Enhanced

**Perfusion**

- ASL     IV Contrast Enhanced

**Relaxation**

- T1     T2

- Simultaneous MRI-EEG,**  
specify channel layout:

**Functional Imaging**

- Resting state, # per session \_\_\_\_\_
- Task-based, # per session \_\_\_\_\_

\*If you have your own equipment to attach to ours, please detail in Section H

**Spectroscopy**

- Single Voxel, # per session \_\_\_\_\_
- MRSI

**Diffusion**

- DWI     DTI

- Magnetization Transfer**

- SWI**

- Other, please specify:** \_\_\_\_\_

**D. Participants**

	<b>Pilot Subjects</b>	<b>Controls</b>	<b>Cohort/Patient</b>
Number of:			
Test intervals –MRI (week#, etc)			
Test intervals –MEG (week#, etc)			
Age Range			
Anticipated Mobility (indicate all that apply)	<input type="checkbox"/> Mobile <input type="checkbox"/> Mild Assistance <input type="checkbox"/> Walking Support <input type="checkbox"/> Wheelchair	<input type="checkbox"/> Mobile <input type="checkbox"/> Mild Assistance <input type="checkbox"/> Walking Support <input type="checkbox"/> Wheelchair	<input type="checkbox"/> Mobile <input type="checkbox"/> Mild Assistance <input type="checkbox"/> Walking Support <input type="checkbox"/> Wheelchair
Describe any special considerations needed for serving this group or cohort			

**E. Data Transfer and Analysis Plans**

Does your study require **data transfer** to a central reader/uploader?  Yes  No

**If Yes**, please state name and location of company/analysis centre:

\_\_\_\_\_

**If No**, indicate how you plan to receive the data (CD/DVD, will supply flash drive, etc):

Is a **radiologist report** required (clinical trials only)?  Yes  No

**Who on your study team will process and analyze the MRI/MEG data?**

(And if you plan to request analysis support or services from ImageTech, describe in detail)

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## **F. Funding**

Please describe the funding sources for this study:

Invoices will be paid via:  SFU Account (JV)  External Account

\*Once this application has been reviewed and approved, a rate agreement will be issued, which must be signed by the P.I., with complete billing information confirmed prior to booking any research time at ImageTech.

If requesting **Pilot Scanner Time**, please provide details and reason (a dry run to test protocol timing, or developing an fMRI paradigm, or seed data for a grant application, etc):

Number of Pilot hours requested:

\*The maximum allowed Pilot Time is: 3 hours of MRI at \$100/hr, 6 hours MEG at \$0/hr

## **G. STUDY ABSTRACT**

Please provide an abstract of the proposed research below, or attach separately to this form. You may choose to submit as separate attachments the Study Details as submitted to REB. The information should cover the background, specific aims and the significance of the project.

## H. Appointment planning: MRI Protocol Details

*If your study includes MRI, provide a detailed description of the MRI protocol, including estimated time for each MR sequence and total scan time per session. We recommend that you consult with ImageTech's Head of MRI, the ImageTech Philips Clinical Scientist, and/or MR Technologist before completing this section.*

Protocol Details:

Total scan time per appointment:

- Note that MRI appointments are booked as half-hour increments for the first hour, then in 15-minute increments beyond 1 hour,
- Every MRI appointment requires a minimum 15 minutes of time for the MR Technologist to conduct confidential participant screening, explain the protocol and safety mechanisms, position participant in the scanner, etc.
- The typical MRI appointment is 1hour, with a maximum protocol length of 45 minutes.
- The shortest MRI appointment is a 30-minute booking, with a maximum protocol length of 15 minutes.
- If you are collecting ONLY the standardized anatomical scan to support MEG data, a special discount price may apply.

## I. Appointment planning: MEG Protocol Details

*If your study includes MEG, provide a detailed description of the MEG protocol, including estimated total scan time per session and any use of stimulus software (Presentation, Eprime, MATLAB, or indicate other).*

We recommend that you consult with ImageTech's Head of MEG Program and/or MEG Technologist before completing this section.

Protocol Details:

Total scan time per appointment:

- Note that MEG appointments are booked as half-hour increments for the first hour, then in 15-minute increments beyond 1 hour,
- Generally, it is the participant's time in the MEG Lab space that is billable time for MEG appointments and this will typically be 5-10 minutes more than the protocol or scan time, which allows for introducing the participant to the space and safety features, positioning in the scanner, explaining protocol steps, etc
- When associated with paid MEG appointments for participant scans, the time spent in the MEG Lab space for pre-appointment lab set-up and post-appointment clean-up is not considered billable time.
- Studies not running a set protocol with human participants are subject to a different and negotiable arrangement regarding billable time for use of the MEG system and Lab space.

## J. Appointment Planning: Other Activities

If you are planning to conduct other research activities at ImageTech in conjunction with your MRI or MEG appointment, please provide details below. For example, if you plan to review participant consent before the appointment, or if you plan to conduct questionnaires or other testing before/after the MRI/MEG scan.

There is a multi-purpose "Patient Prep" room that can be booked for these types of activities, upon approval. (This is not considered billable time.)

Please describe the activity, amount of time needed, whether before/after the scan, and whether any materials or equipment will be brought to ImageTech.

## K. Connecting, Sharing

We would like to include your study on the ImageTech website's "Projects" page. Please summarize your study in 2-3 sentences here, using lay terms:

*\*\*If your study's ethics explicitly allows it, we can share your recruitment poster on our website and in our lab, and/or some details and contact info on the lab's website for potential participants to connect with you. Check here to discuss further:*

## L. Acknowledging SFU ImageTech Lab

*SFU ImageTech was built through generous funding from federal, provincial and other agencies. ImageTech Lab and these funding agencies must be acknowledged in any publications and presentations of work that results from using our facilities by using the following text:*

**"This work made use of the SFU ImageTech Lab facility supported by the Canada Foundation for Innovation (CFI), British Columbia Knowledge Development Fund (BCKDF), Western Economic Diversification Canada (WD) and Simon Fraser University (SFU)."**



**ImageTech Study Initiation Form: FAQ**

page 1

1. Ethics: If there is no current ethics certificate, please leave the approval date on Page 1 blank.
2. MRI: Billable Time
  - a. Please note that the time booked for MRI begins when the MR Technologist comes into Zone 2 to greet the Participant, and ends when the Participant and study team member exit the MRI Suite (Zone 3) following the scan. The booking time must be adequate to include:
    - MC Technologist conducts confidential MR Screening with Participant in MRI Zone 2 before entering the MRI Suite.
    - Participant preparation inside Zone 4 by the MR Technologist including physical positioning on the scanner bed and description of events that will occur during scanning.
    - Participant preparation inside Zone 4 by other study personnel including fMRI screen placement and MRI response device explanation to participant.
    - Verbal communication with the participant by the MR Technologist throughout the scanning procedure.
    - Removal of the participant from Zone 4 at the end of scanning.
  - b. The activities described above require a 15 minute time period *for participants who are reasonably mobile, and without impairments of cognition, hearing, etc.* Participant physical or cognitive limitations may extend this process and more time should be factored for this.
    - **For a one hour booking, there should be a maximum protocol scan time of 45 minutes for a subject who is reasonably mobile.**
  - c. If the protocol includes fMRI task description between scans then there needs to be additional time considered for this.
    - An fMRI protocol with multiple tasks and a scan time of approximately 65 minutes can be booked in a 90 minute period.
  - d. Scanning participants back-to-back "to save time":
    - Please note that the activities described above (a-b-c) must be repeated for each participant, with the exception of hanging the fMRI screen, which takes only a few minutes. Thus there is no real time savings when booking participants back-to-back.
    - The exception to this is set-up of a considerable piece of MR Conditional equipment (eg. MRE or tDCS).
  - e. Participant movement during a scan can result in poor images. The MR Technologist may recommend repeating a sequence. This can only be completed if there is sufficient time, and requires that the PI has provided standing guidelines on how to prioritize sequences to truncate the protocol to within the available/billable time and/or authorized the attending study assistant to approve extending the appointment to extra billable time. This will be discussed during finalization of the protocol and appointment plan.

### 3. MEG: Billable Time

- a. Billable time for MEG is greater than just the minutes of scanning as it includes, in principle, use of the MEG Lab space that otherwise precludes other studies or personnel from using the space.

Beyond the number of minutes of actual scanning, the billable time for each MEG appointment is the time that the participant spends in the MEG Lab, which may include time spent introducing the participant to the MEG/MSR environment, positioning the participant comfortably in the MEG, explaining and demonstrating the safety and communication devices, and explaining the protocol or sequences as they occur.

- b. Time that the participant spends outside of the MEG Lab space is not billable - for example preparations that occur in the Patient Prep room, including head tracing or Polhemus or EEG-related set-up. If the study opts to complete any of these or similar activities in the MEG Lab space, then the associated time is billable.
- c. Use of the MEG Lab for preparation and set-up prior to the scan appointment, conducted partly by trained study team members, is not considered billable time on the MEG; this is a complimentary aspect of the billable time. Likewise, cleaning up or putting away of equipment after the scan appointment is not considered billable time on the MEG, so long as the time doesn't unreasonably impede other users or potential users from beginning their work.
- d. Some use of the MEG system for research or development is paid time even if it doesn't involve running a scan protocol or substantial data collection. For example, developing or testing a new device or software element may require considerable use of the MEG Lab or MEG System with only small amounts of actual scanning time or data collection. Referring to (a) above, any use of the MEG Lab space that otherwise precludes others studies or personnel from using the space is considered billable MEG time, and the complimentary time referred to in (b) above is associated with billable time. The billing principle here is use of the MEG Lab space if primarily always billable, but set-up and clean-up time is complimentary when associated with a reasonable amount of billable time.
- e. Any device or equipment that will be brought into the MEG Lab must be inspected and approved by the Head of MEG.

### 4. Time Overages:

- a. Appointments that run over the booked time slot will be billed for additional time in 0.25-hour increments at the hourly rate.
- b. The MRI/MEG Technologist and the study personnel attending the appointment should be mindful of the time, which starts based on requested booked time or the time the appointment commences, whichever is earliest.

5. Late Arrivals, and Missed or Canceled Appointments (also shown on Rate Agreement)
  - a. ImageTech advises all studies to budget and plan for the likelihood of charges for missed appointments and canceled appointments.
  - b. If the study personnel or research participant are late, the MRI/MEG Technologist will advise whether there is sufficient time remaining on the MRI calendar to complete the appointment, and the attending study personnel shall be authorized to approve proceeding either with a truncated protocol or a potential billable time overage.
  - c. Appointments that are missed, or canceled with fewer than 5 business days notice, are charged for the appointment time. The PI has the option to substitute a participant, or use the time for a different study (if approved), but the lab is not liable if the substitute participant cannot be pre-screened in time.
  - d. If a canceled appointment time becomes booked by another study, there will be no charge for the unused time to the study that canceled the appointment.

## DOCUMENT CHANGE LOG

### Changes to Version 3.4

Page 1, added sentence about submitting copy of ethics application and consent form.

Page 4, in chart at D, re-worded "other medical conditions"

Page 4, in chart at D, re-worded test intervals for clarity

Page 4, added more blank lines to Data Analysis support details.

Page 5, removed reference to max pilot time and added referral to FAQ

Page 10, added to 3.d) regarding requests for +6 MEG Pilot hrs

Page 10, added "ImageTech" to 3.e)

### Changes to Version 3.42

Adjusted form field parameters like font size and long-scroll throughout

### Changes to Version 3.43, June 2018

Added option for simultaneous EEG.

### Changes to Version 3.44, July 2018

Section E: changed the wording of question about radiologist report

### Changes to 3.5, May 2020

Extensive: sections added, deleted, rearranged.