Study Title

Principal Investigator

|  |  |
| --- | --- |
| Name | |
| Address: | |
| Phone: | Fax: |
| Email |  |

UBC Ethics Certificate:

|  |  |
| --- | --- |
| UBC Ethical Review # |  |
| Approval Date (dd-mm-yy) |  |
| Expiry Date (dd-mm-yy) |  |

**Please email the completed Proposal Form and all attachments to**

[**pet.imaging@ubc.ca**](mailto:pet.imaging@ubc.ca)

If assistance is required in filling this form or with the PET components of your ethics application, please contact the PET-MRI Lab Manager

Elham Shahinfard

[elham.shahinfard@ubc.ca](mailto:elham.shahinfard@ubc.ca)

604-822-7605

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| **Form Completion Checklist** |

Please ensure that you have completed all parts of this form and attached the required documents as listed below.

Please specify if you are applying for “**MRI only**” or “**PET and MRI**” scans by checking the tick box beside “**MRI-only Studies**” or “**PET/MRI Studies**” in the check list below.

Items with an \* in front of them may be submitted later than this form but before the first scan is scheduled:

List of collaborators

Brief study abstract with sufficient information to detail how the scientific questions can be addresses by the requested MRI sequences and PET tracers

A Copy of full CREB (UBC Clinical Research Board) application. Alternatively you can add [UBC PET/MRI lab manager](https://med-fom-pet.sites.olt.ubc.ca/team/elham-shahinfard/) (Elham Shahinfard) to your [ethics application](https://www.rise.ubc.ca/).

Copy of ethics certificate \*

All informed consent/assent forms \*

Table of participant characteristics

Study timeline information

Funding information \*

Additional documents to support the study abstract

3 sentence project summary for the <https://pet.ubc.ca/> website

Checklist of requested MRI sequences

**MRI-only Studies:**

Detailed list of MRI sequences with estimated scan time calculation

**PET/MRI Studies** (please skip this section if your study is an MRI-only study.)**:**

Checklist of requested tracers

Detailed list of required scans per subject

Detailed list of MRI sequences with estimated scan time calculation

Detailed timing of the PET scan and timing synchronization with the MRI sequences

TRIUMF confirmation of tracer supply\*

Health Canada approval certificate \*

Hospital approval certificate \*

List of Study Personnel \*

**Additional support**

Unexpected/Incidental findings follow up procedure

Radiologist Report on MRI Images

Data Analysis and Transfer Blood Metabolite Analysis

Drug Intervention

Blood Glucose Measurement

Hematocrit Measurement

*Thank you for ensuring all sections are complete, this will help to expedite your study’s approval!*

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| **Collaborators** |

Please list all collaborators and affiliations

|  |  |
| --- | --- |
| **INTERNAL** collaborators: | **EXTERNAL** Collaborators: |
| 1. | 1. |
| 2. | 2. |
| 3. | 3. |
| 4. | 4. |

**Study Abstract**

Please provide a summary of up to two pages in length of the proposed research including the background, specific aims, significance of the project, as well as the Research Plan including a justification for how the requested scans would address the hypotheses. This abstract should provide enough detail to help us evaluate study feasibility at our facility, and potential safety issues.

If necessary, please attach additional materials to support this proposal.

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| **Participant Characteristics** |

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| --- | --- | --- | --- |
|  | **Pilot Subjects** | **Controls** | **Patients** |
| **Number of Subjects for PET/MRI scans** |  |  |  |
| **Number of subjects for MRI-only scans** |  |  |  |
| **Number of Scan Time points** (for longitudinal studies) |  |  |  |
| **Number of Scans** per Subject (at each time point, if applicable) |  |  |  |
| **Age Range** |  |  |  |
| **Cognitive Deficits**  (Please describe) |  |  |  |
| **Anticipated Mobility**  (indicate all that apply) | Mobile  Mild Assistance  Walking Support  Wheelchair | Mobile  Mild Assistance  Walking Support  Wheelchair | Mobile  Mild Assistance  Walking Support  Wheelchair |

Please note that due to scanner bore size there will be a physical limitation on BMI and shoulder length. To fit in the scanner comfortably, we suggest to not book participants if their elbow to elbow length exceeds 22” or if their BMI is higher than 35.

If your study has fmri task with PET-tracer, please talk to us about a simple reading test to make sure they will be able to see the screen without glasses.

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| **Anticipated Study Timeline** |

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| --- | --- |
| Requested Start Date (dd/mm/yy) |  |
| Estimated End Date (dd/mm/yy) |  |
| Requested scanner time per session\* |  |
| Estimated Number of Subjects per Year\*\* |  |

\* Please allow minimum 15min for bed positioning and patient preparation/positioning on the bed

\*\* Please put your best estimate to help with our centre resource planning

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| **Funding** |

Funding Sources:

Invoices paid via:  UBC account OR  external account

Is pilot scanner time required and why? For instance, do you require a dry run to test timing, time to develop an fMRI paradigm, or seed data for a grant application?

Number of PILOT hours requested (maximum 3 hours at no charge):

Is technical development time requested?For instance, will you require MR sequences which are currently not in use at the Centre?

**Study Summary for PET/MRI Imaging Centre’s Website**

Please summarize your study in no more than three sentences, including a link to your website (if you wish), for inclusion in our “Research Projects” page on the [PET/MRI Imaging Centre’s website](https://pet.ubc.ca/):

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| **Types of MRI Sequences Requested:** *(please mark all applicable categories)* |

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| --- | --- | --- | --- | --- | --- |
| **Qualitative Anatomical Images:** | | | | | |
| T1W | T2W | | PDW | | FLAIR |
| Contrast Enhanced |  | |  | |  |
| **Functional Imaging:** | | | | | |
| Task based, # per session \_\_\_\_\_\_ | | | Resting state, # per session \_\_\_\_ | | |
| Task Description: | | | | | |
| Additional Devices: | | | | | |
| **Angiography:** | | | | | |
| IV Contrast Enhanced | | | Non-IV Contrast Enhanced | | |
| **Spectroscopy:** | | | | | |
| Single Voxel, # per session \_\_ , location(s) | | | MRSI | | |
| **Perfusion:** | | | | | |
| Arterial Spin Labeling | | | IV Contrast Enhanced | | |
| **Diffusion:** | | | | | |
| DWI | | DTI | | DTI Multi-shell (i.e. NODDI analysis) | |
| **Quantitative Relaxation Measurements:** | | | | | |
| Inversion or Saturation Recovery T1 | | Multi-spin-echo T2 (Myelin Water Imaging) | | Multi-gradient-echo T2\* Imaging | |
|  | | | | | |
| **Magnetization Transfer** | | | | | |
| **Susceptibility Weighted Imaging** | | | | | |
| **Other sequences, please specify:** | | | | | |
| **Additional equipment; for example, RespirAct or physiological monitoring? Please specify:** | | | | | |

**MRI Protocol Details for MRI-only Scans**

Please prepare a detailed description of the MRI protocol including sequence parameters estimated time for each MR sequence and total scan time per session. Please include details if any additional equipment is required, such as response boxes or physiological triggering units. If assistance is needed with this please contact [ecat.pet@ubc.ca](mailto:ecat.pet@ubc.ca)

A list of available/recommended sequences in V-Brain [available here](https://pet.ubc.ca/research/)(to be updated when finalized).

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| **MRI Sequence Specifics** | | |
| **MRI sequence Name** | **Parameters** | **Time (mins)** |
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| Total time | |  |

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| **Types of PET Tracers Requested:** *(please mark all the tracers you are planning to use)* |

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| **TRIUMF Supplied Tracers** | |
| (+)TBZ ((+)-α-[11C]-dihydrotetrabenazine) | DASB ([11C]3-amino-4-(2-dimethylaminomethylphenylsulfanyl)-benzonitrile) |
| RAC ([11C]-raclopride) | FD or DOPA ([18F]-6-fluoro-L-dopa) |
| MP ([11C]-d-threo-methylphenidate) | PBB3 (2-[(1E,3E)-4-[6-(methyl-[11C]-amino)-3-pyridinyl]-1,3-butadien-1-yl]-benzothiazol-6-ol) |
| PBR ([11C] peripheral benzodiazepine receptor-28) | PIB ([11C]Pittsburgh Compound-B) |
| PMP ([11C]methylpiperidin-4-yl propionate) | YOH ([11C]Yohimbine) |
| **Tracers Supplied by Other Sources** | |
| ☐FDG (2-[18F]-fluoro-2-deoxy-D-glucose) (delivered from BCCA) | Other Tracers? If the tracer you intend to use is not listed, please provide the tracer information and supplier. |

Will blood sampling be required with any of these tracers?  Yes  No

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| **Detailed List of Requested PET Scans Per Subject:** (For each tracer please indicate the dose and number of scans required ***per subject)*** |

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| **Tracer Type** | **Dose in mCi** | **Number of subjects for PET scan** | **Number of PET scans per subject** | **Estimated Number of PET scans per year** |
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**Notes:**

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| **PET scan timing and MRI protocol** |

Please prepare a detailed description of the PET and MRI protocol, you may adjust the tables below to reflect your specific study needs.

**For MRI** please prepare a detailed description of the MRI protocol including MRI sequence parameters, estimated time for each MR sequence and total scan time per session and include them in the **“MRI Sequences Specifics” table**. Please include details if any additional equipment is required, such as response boxes or physiological triggering units.

**For PET** scan please specify the total PET scan duration and the time between injection and the start of the scanning. Consider the injection time as time 0 and specify the scanning time based on that.

In addition, if blood sampling is required, indicate appropriate timing (note that a blood sample cannot easily be taken if an MRI sequence is running).

**IMPORTANT**: Please notify if a particular MRI sequence MUST occur at a particular time with regard to the tracer injection or if the order of the MRI sequences must be followed as presented. If not, MRI technologists may alter the acquisition order to optimize the overall acquisition protocol.

If assistance is needed with this please contact [elham.shahinfard@ubc.ca](mailto:pet.imagin@ubc.ca) or [ecat.pet@ubc.ca](mailto:laura.barlow@ubc.ca)

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| --- | --- | --- |
| **MRI Sequence Specifics** | | |
| **MRI sequence Name** | **Parameters** | **Time (mins)** |
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|  |  |  |
| Total time | |  |

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| **PET and MRI Synchronization** | | | | |
| **PET scan** | **MRI sequence name** | **Duration** | **Start time** | **End Time** |
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| **Health Canada and UBC Hospital Approval Certificate** |

* We will need your health Canada approval certificate to be able to start scanning human participants. However please fill your form and send it to us before submitting to health Canada so we can confirm the dosage and related information. If your tracer is supplied by TRIUMF, they will issue a letter of confirmation for tracer supply at this stage. You can submit your application to health Canada after that.
  + The Health Canada guidance document and application form for Authorization of Positron-emitting Radiopharmaceuticals for Use in Basic Clinical Research Studies can be found at <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/guidance-document-guide-preparation-applications-authorization-radiopharmaceuticals.html>
  + Please note that for studies with more than 30 subject additional justifications is required during the submission process. Health Canada may request a full CTA application for studies with more than 30 subjects if the justification is deemed insufficient/inappropriate. Information available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/applications.html>
* Information for the UBC hospital approval certificate is available at section 11 of UBC RISE ethics application form and <https://www.vchri.ca/operational-approval>

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| **Study Personnel** |

Carefully read the document entitled [“Responsibilities of Principal Investigators (PI) performing PET scans with the UBC PET group”](https://pet.ubc.ca/responsibilities-of-principal-investigatorsp-i-performing-pet-scans-with-the-ubc-pet-group/). The document clearly defines the role of the study coordinator and the requirement for a medical doctor.

Indicate that you have read and understood this document:

Indicate who will fill the role of study coordinator.

Study Coordinator: Phone: ( ) - -Email:

Indicate the medical doctor who will be on call during imaging. This person must have approval to practice at UBC hospital.

Medical Doctor: Phone: ( ) - -Email:

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| **Additional Supports** |

**Unexpected/Incidental Findings Procedure:**

The Centre does not have a routine screening process in place for unexpected or incidental findings - although it does have a procedure for reporting such findings when identified during standard image quality assessments.  The P.I. is expected to have a procedure in place for the identification and reporting of such findings when:

* The brain pathology or population under investigation is likely to have unexpected or incidental findings (for example populations likely to have findings not previously imaged)
* The brain pathology under investigation may impact the ability to differentiate unexpected or incidental findings from known pathology (for example brain injury or unknown manifestation of pathology).

Please describe the procedure to be followed by the P.I. to address incidental/unexpected findings or justify why such procedure is not needed (This entry is necessary for the study to be approved):

**Does your study require a radiologist report?**

**Does your study require data transfer to central reader/uploader? Please state company/analysis site or centre:**

**Does your study require data analysis provided by the PET-MRI Imaging Centre? Please detail data analysis needs below:**

**Does your study require blood metabolite analysis? Please detail data analysis needs below:**

**Does your study require drug intervention?**

**Does your study require blood glucose measurement?**

**Does your study require hematocrit measurement?**