WESTERN HEALTH MEDICAL IMAGING

Clinical Trial Application Form

The application form is to be completed by the Principal Investigator or Research Coordinator and signed by the Director of Radiology prior to the commencement of any clinical trial involving Medical Imaging at Western Health.

This application form will be reviewed by the Director of Radiology and will be responded to within 10 business days of receiving all the relevant documentation.

Please attach the Clinical Trial Imaging protocols, Schedule of Investigations and the Medical Physicist report.

**Declaration from Principle Investigator:**

Section 1:

Sponsored Trial Name of Sponsor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Non-Sponsored Trial

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Details:** |  |  |  |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | Title of project/study |  | | | | | Summary title of project/study. Must be used in all email communications |  | | | | | Brief Summary of project/study  Include a brief summary here or attach as an appendix a one page executive summary of project |  | | | | | Protocol no: |  | Dept./Unit |  | | | Principal Investigator | | | Research Coordinator | | | Name: |  | |  | | | Address: |  | |  | | | Phone: |  | |  | | | Email: |  | |  | | | No. patients |  | |  |  | | Expected start date |  | | Expected End date |  | |  |  |  |

WESTERN HEALTH MEDICAL IMAGING

Services for Clinical Trials

Section 2

|  |  |
| --- | --- |
| Please complete all questions below: | Y/N |
| **Do you require a specific imaging protocol?**  *(See guidelines for explanation) If Yes then please submit copy of protocol.* |  |
| **Do you have a Medical Physicist report for this study?**  *If so please submit with this application* |  |
| **Do you require a print out of the patient report?** *If yes, (please complete below)*  ***Name of requesting Doctor:***  ***Copies to:*** |  |
| **Do any study specific forms need to be completed?** *If yes, please provide a copy of the forms*  *(NB: WHMI staff will not complete CRFs or organise shipment of digitised data to sponsor)* |  |
| **Will you require a CD of the imaging ?**  *If yes, do they need to be de-identified?* |  |
| **For CT imaging do you require 3D reconstruction of your images?** |  |
| **Will you require any other image measurements?**  If yes, please specify: |  |
|  |
|  |
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|  |
| **Do you require previous outside imaging from external organisation to be uplifted into PACS?** |  |
| **Will you require a QC imaging data to be sent to the sponsor?**  If yes, how frequently |  |
|  |
|  |

Section 3: Billing Details

|  |  |
| --- | --- |
| Company Name: |  |
| Contact Name: |  |
| Telephone: |  |
| Cost Centre: |  |
| Billing Address: |  |
| Email Address: |  |

Section 4: Medical Imaging Protocol Review, Costing and Capiticy

**Please attach a copy of the Schedule of Investigations – this must indicate which investigations are Standard Clinical Care and Above Standard Clinical Care**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Imaging required (with or without contrast)** | **WHMI to complete**  Imaging protocol review, Comment | **WHMI to complete**  **Fee Ex** GST | **WHMI to complete**  Capacity within Modality | **WHMI to complete**  Chief Radiographer  sign off |
|  |  |  |  |  |
|  |  |  |  |  |
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Medical Imaging Comments/Feedback regarding investigations requested **(include discussion if investigations are agreed to be standard clinical care or above standard clinical care)**

|  |
| --- |
|  |

Section 5: Approval

**Radiology**

Director of Radiology ............................................................. Date:............................

Signature:...................................................................

**Research:**

Principal Investigator:..................................................................Date:...........................

Signature...................................................................

Please email this form and the supporting documentation to:

WHMIResearch

Section 5 – Fees and Charges

**5.1 Medical Physicist Report**

**No charge**

**5.2 Imaging Fee**

Imaging will be charged according to the MBS schedule for sponsored and non-sponsored clinical trials.

Additional costs may be incurred should specific reporting be required as part of the clinical trial protocol. This will be discussed with the Principal Investigator or their delegate.