**CRIF APPROVAL GROUP**

**DEVELOPMENT WORK APPLICATION FORM**

* CRIF Approval Group approval will constitute R&D sign off for your development study. An R&D number will be provided on approval.
* In order to aid the discussion of the proposed development work, this form **MUST** be fully completed and checked to enable triage by the CRIF project assistant.
* A study specific PIS must be included with all applications with the appropriate text added.
* Incomplete applications will be returned which could impact on the submission deadline.
* Email the application **2 WEEKS PRIOR** to meeting date: CRIFdevelopmentapplications@ggc.scot.nhs.uk
* Meetings are scheduled for the last Tuesday of each month.
* Once submitted the application will be assigned a ‘DA’ number for AG review.
* A 10 min slot will be allocated for the day of the meeting where a member of the project team must be available to give a 5 minute presentation to the AG with a further 5 minutes be allocated to questions by the AG. Applications where researchers cannot be available for to present will be carried over to the next date.

For further advice please contact Abbey.rea2@ggc.scot.nhs.uk or tracey.hopkins@ggc.scot.nhs.uk

# 1: Which Ethical Approval Does This Application Fall Under?

Please specify:

1. Generic REC Approval for ‘Protocol Optimisation for Advanced MRI Research Studies’
**REC Name:** WoS REC3

**REC Reference:** 22/WS/0080

**Or**

1. B. Project specific REC approval

**REC Name:**

**REC Reference:**

# 2: Project Specification

## Study Title:

### APPLICANT

Name:

Institution:

Position:

E-mail address:

Telephone number:

### ADDITIONAL INVESTIGATOR(S)/SUPERVISOR

Researcher 1 - Name:

Institution:

Position:

E-mail address:

Telephone number:

Researcher 2 - Name:

Institution:

Position:

Email address:

Telephone number:

## 2.1. Previous development application? If yes please provide details

## 2.2. What is the purpose of your development application?

|  |  |
| --- | --- |
|  | **Check if applicable** |
| To improve quality of current imaging | [ ]  |
| To optimise novel imaging associated with a funded study | [ ]  |
| To develop imaging to support a grant application  | [ ]  |

## 2.3. What work will the development application support? Include references

Provide the detail of which project(s) the development work will support. If relevant, please specify which funder/grant scheme will be targeted.

Check boxes to confirm this information is included:

What project(s) [ ]  How it will support the project [ ]

## 2.4. Study Summary

The summary should state clearly what analyses or criteria will define the success of the development work to be undertaken. Include references.

Check boxes to confirm this information is included:

Study background [ ]  Development need/aims [ ]  Indicative numbers [ ]

Methodology [ ]  What analyses/criteria defines the success of the development work [ ]

# 3: Recruitment Information

## 3.1 Patient Group

Which patient group will be involved in this project? **Please tick all that apply**.

[ ]  Healthy Subjects from Volunteer Bank

[ ]  Healthy Subjects recruited by other means (must have own REC approval)

[ ]  Clinical Patients (No Contrast/Stress)

[ ]  Clinical Patients (Contrast/Stress)

## 3.2 Recruitment Strategy

Check boxes to confirm this information is included:

How recruitment will be performed [ ]  Expected number of patient’s [ ]

## 3.3 Inclusion Criteria

Check boxes to confirm this information is included:

Cover any specific inclusion criteria e.g. pathology of interest [ ]

## 3.4 Exclusion Criteria

Check boxes to confirm this information is included:

Any exclusion criteria e.g. use of certain medicine [ ]

The generic exclusion criteria stated in the study protocol will also apply.

## 3.5 Further Information for PIS

A project specific PIS is required for all applications. Add the further information here

Check boxes to confirm this information is included:

Project-specific text included in the “Further Information” section of the PIS, PIS attached to application [ ]

# 4: Resources Required

## 4.1 Imaging systems

|  |  |
| --- | --- |
| **Research systems** | **Clinical systems** Subject to additional approval from the service |
| [ ]  Siemens 3T Prisma  | [ ]  1.5T MRI  |
|  |  |
| [ ]  Siemens 7T Terra |  |

**4.2 NHS Staff Resources needed or in place -**CRIF Approval Group will agree access to NHS Scotland R&D resource.

|  |  |  |  |
| --- | --- | --- | --- |
| **Staff resource** | **Required** | **In research team** | **Approval required** |
| NHS Radiographer | [ ]  | [ ]  | Y N |
| NHS MRI Physicist  | [ ]  | [ ]  | Y N |
| UoG Physics | [ ]  | [ ]  | Y N |
| Research fellow/associate | [ ]  | [ ]  | Y N |
| Radiologist | [ ]  | [ ]  | Y N |
| Medical cover | [ ]  | [ ]  | Y N |
| Research Nurse | [ ]  | [ ]  | Y N |
| UoG Authorised operator | [ ]  | [ ]  | Y N |

* *Please ensure there is appropriate staff cover for your project - MRI Local Rules do not permit lone working within the MR Environment - minimum requirement is an Authorised MR Operator (Radiographer/Physicist/ Trained Research Fellow) and an Authorised Non-Operator.*

**4.3 Specific imaging requirements**

Any **new equipment** to be installed must have been approved/ authorised by MRSE/MRRP and/or ICE safety committee.

|  |  |
| --- | --- |
|  | **Check if required** |
| ***Audio-visual equipment for fMRI:*** |  |
| * Auditory
 | [ ]  |
| * Visual
 | [ ]  |
| * Eye tracking
 | [ ]  |
| * Response box
 | [ ]  |
| * Tactile
 | [ ]  |
| * Real-time fMRI
 | [ ]  |
| * Other-please specify:
 | [ ]  |
| ***MRI coils – please provide details**** Product coil:
* Non-standard:
	+ If the intended use of the coil is not compliant with approved please provide give details of intended use:
 | [ ] [ ]  |
| ***Full applications packages for complex imaging in MRI:*** * Cardiac
 | [ ]  |
| * Neuro
 | [ ]  |
| * Vascular
 | [ ]  |
| * Flow
 | [ ]  |
| * Spectroscopy
 | [ ]  |
| * ASL
 | [ ]  |
| * MSK
 | [ ]  |
| * Tumour detection and volumetric analysis
 | [ ]  |
| * Other-please specify:
 | [ ]  |
| ***Novel Sequences*** – please provide all appropriate information e.g. WIP/ agreement number, version number, sequence title, contact details: |  |
| * Work in Progress (WIP) sequences with full applications and technical support from Siemens MRI:
 | [ ]  |
| * Sequences requiring CP2/IPA agreement:
 | [ ]  |
| * In house sequence development:
 | [ ]  |
| * **Phantom** – please provide details if you have require a specific phantom
 | [ ]  |

## 4.4 Other Resources requested (include details)

|  |  |
| --- | --- |
| **Facility** | **Check if required** |
| Clinical Research Facility | [ ]  |
| Biorepository sample storage | [ ]  |

# 5: Project Planning

## 5.1 Details of total scanning and testing requirements for this study

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Total number of participants** | **Testing Start/End Dates** | **Number of sessions per participant** | **Scan Duration** | **Total hours required** | **Estimated hours per month** |
| **MRI** |  |  |  |  |  |  |
| **fMRI** |  |  |  |  |  |  |

**5.2 Data storage plan**

# 5.3 Additional scan anonymisation and data upload requirements

**5.4 Does the study have any specific timing requirements? For example, out of hours / weekend scanning?**

### 5.5 Training

Please describe any training that you, or the team likely to be working on the project will need in order to be able to carry out the work. **This should include the need for MRI entitlement.**

**CRIF CHECK:**

* All sections marked completed with required information? [ ]
* Relevant documentation included:
	+ Study specific PIS [ ]
	+ If linked to a separate ethics approval, include copy of documents [ ]
	+ C2P/ WIP sequence to be used (section 4.3) [ ]