SOP Number **OCMR_007**

SOP Title **Technical Development Scans**

	NAME	TITLE	SIGNATURE	DATE
Author	Dr Hanan Lamlum	Head of clinical research co-ordination	H. Lamlum	16/09/2016
Reviewers	Jane Francis	Head of Imaging Applications	J. Francis	18/09/2016
	Prof. Chris Rodgers	Head of Cardiac Spectroscopy Group	C. Rodgers	23/09/2016
Authoriser	Prof. Stefan Neubauer	Clinical Director	S. Neubauer	29/09/2016
	Prof. Matthew Robson	Chief Cardiac MR Physicist	M. Robson	16/09/2016

Effective Date:	September 2016
Review Date:	September 2018

1. PURPOSE

To describe the precise circumstances in which MR scanning of human volunteers is permissible for technical development purposes, without the need for explicit ethics committee or HRA approval, and to describe the procedures that should be followed in these cases.

2. INTRODUCTION

Following discussions with the Research Ethics Service and the University of Oxford Insurance Office, we have identified certain circumstances under which ethical approval is not required in the performance of technical development scans.

Situations in which technical development scans can be undertaken are essentially only those where there are a limited number of scans that are performed "in house", i.e. those scanned are members of OCMR/ RDM Division of Cardiovascular Medicine or close collaborators. **Any large scale studies involving multiple volunteers, interventions, external volunteers or patients CANNOT be performed without ethics approval.**

3. SCOPE

This Standard Operating Procedure (SOP) relates to all technical development scanning performed on OCMR MR scanners.

4. DEFINITIONS

4.1 Technical Development Scans

A technical development scan is one in which the purpose of the scan is to develop, test or validate an MR sequence, often prior to application in a research study. **In all cases the volunteer will be a researcher involved in the project or a member of other groups within OCMR/ RDM Division of Cardiovascular Medicine.** There are no specific exclusion or inclusion criteria, other than the existing safety requirements for someone to ensure that they are safe to be scanned (e.g. no pacemakers, metal implants etc.)

Studies may only be performed when volunteers can be treated as anonymous and healthy (i.e. when the investigation is of a general nature unrelated to the volunteer's health or background). Any technical development scan that requires additional personal data about the volunteer (other than date of birth, weight and gender) is assumed to require separate ethics approval.

Examples of technical developments, where it has been advised that ethics committee approval is not required include:

- Evaluating, testing or fixing a sequence whose use will be for other studies running under their own ethics approval - data collected will not be published.
- Acquiring a few data sets for demonstration of an image analysis methodology or optimising sequence parameters – data may be published as proof of method.
- Developing and validating a new imaging sequence – validation data may be published. Typically only 6 – 12 datasets are required to demonstrate such a

sequence. If external volunteers are to be used then it is presumed that Ethics Committee permission is required.

- Testing a device for use in the MRI scanner, including radiofrequency coils and stimulus delivery equipment – data may be published. Tests must comply with relevant Health and Safety regulations and must be preceded by appropriate preliminary tests on inanimate (phantom) objects. The volunteer must be an investigator on the project who is fully aware of the relevant safety issues.

4.2 Procedures associated with technical development scans

Measurements and assessments which are not required for validation purposes and/ or require invasive procedures are not permitted without specific ethical approval.

Volunteers may also be subject to basic stimuli while being scanned, to detect brain activity or changes in cardiac output. However, there should be no particular discomfort to volunteers above that usually experienced lying in the scanner. Examples of permitted stimuli include:

- Light exercise
- Simple sensory stimuli, such as visual or auditory presentation or basic cognitive tasks (e.g. word reading or finger tapping).

Examples of procedures NOT permitted without specific ethical approval include:

- Strenuous exercise
- Painful or strong emotive stimuli
- Taking/ storage/ analysis of blood or other tissue
- Insertion of cannulae
- The use of any drugs/ infusions (e.g. contrast, stimulants, adenosine, breathing gases).

4.3 Training Scans

A training scan is one performed for the purposes of training other researchers or scanner operators in imaging techniques, and should be logged accordingly. Individual volunteer log sheets (see appendix 1) should still include these scans, which count towards the total – Data will not be published.

5. RESPONSIBILITIES

5.1 Researchers

For their own studies: To identify if their scanning can be classified as Technical Development Scanning. To scan their volunteer in accordance with the principles laid out in this document.

As a volunteer: To have read this SOP and to keep a record of the number of technical development scans that they have participated in.

6. SPECIFIC PROCEDURES

6.1 Exclusion of volunteers

Prior to scanning all volunteers will be screened using the standard safety screening procedure. In general a volunteer will be excluded if they:

- Have retained ferromagnetic substances/ implants in their body (e.g. pacemakers). Such materials pose a risk for the participants and produce artefacts in the imaging data.
- Are pregnant. While there is no evidence to suggest that MRI is harmful during pregnancy, volunteers who believe that they may be pregnant should not be asked to participate in technical development scans.
- Are claustrophobic. The procedure would be uncomfortable for the volunteer.
- Express a preference not to participate in the requested scan.

6.2 Informing Volunteers

Volunteers should be informed of the purpose and nature of the scan and should be reminded that participation is optional. Volunteers must also be given an estimate of the duration of the scan, and be allowed to terminate the scan at any time for any reason.

6.3 Consent

Volunteers who participate in technical development scans for the first time should be made aware of this SOP document and should update their OCMR SOP sign off sheet to indicate that they are aware of the issues. The updated sign off sheet should be returned to the OCMR operations manager.

6.4 Scan Database

The OCMR Calpendo system holds specific project codes for technical development and training scans, these should be used for logging scans in the scan database. Only project owners can designate individuals to book development scans on the Calpendo system.

6.5 Number of scans a volunteer can undertake

MRI is a non-invasive technique with no known risks from prolonged or repeated exposure, provided the volunteer has been screened for contra-indications as described in the safety screening questionnaire. However, in order to ensure volunteers are not over-used and do not feel compelled to assist, the number of hours spent as a volunteer in the scanner should be limited to:

- No more than 2 hours in the scanner in any 48 hour period.
- No more than 104 hours in the scanner per year.

It is the responsibility of the volunteer to keep records of their participation in technical development scans. A record sheet is provided at appendix 1 below to assist with this process.

6.6 Data storage and protection

Technical development scans may only be performed when volunteers can be treated anonymously, therefore no identifying personal information should be recorded in the technical development records. Any data that is shared outside the University of Oxford must be completely anonymised and no information about the volunteer disclosed.

6.7 Unexpected findings on the scan images

In the case of an unexpected incidental finding cardiac researchers should consult OCMR SOP_005 Cardiac Incidental Scan Findings. Non cardiac researchers should consult OCMR SOP_006 Non Cardiac Incidental Scan Findings.

6.8 Scanning at 7 Tesla

Please refer to the relevant FMRIB SOP

7. FORMS/ TEMPLATES TO BE USED

Technical development scanning record (appendix 1)

8. INTERNAL AND EXTERNAL REFERENCES

OCMR SOP_003 Screening Subjects for Safety to Scan

OCMR SOP_005 Cardiac Incidental Scan Findings

OCMR SOP_006 Non Cardiac Incidental Scan Findings

Copies of all documents are available via http://www.ocmr.ox.ac.uk/documents

9. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.
OCMR_007	**September 2016**	**New version**	**CVM_015_V3**

Appendix 1 – Technical Development Scanning Record

Name:

TECHNICAL DEVELOPMENT SCANNING RECORD

Staff and students, or their academic collaborators who participate in technical development scans as described in OCMR SOP_007 are obliged to keep a record of their time spent in the scanners. These forms should be kept for one calendar year.

Note: the following limits should be adhered to:

No more than 2 hours in the scanner in any 48 hour period.

No more than 104 hours in the scanner per year.

Date of Scan	Pulse sequence(s)	Field Strength	Scan duration