Standard Operating Procedure

Magnetic Resonance Imaging
Safety Procedures at PERFORM

PC-SOP-IM-003-v02

Revision History

Version	Reason for Revision	Date
01	New SOP	17 -April -2013
02	2.5 Added Associate Director, Bio Imaging & responsibilities 3.1.4 Changes to safety screening forms and signature requirements 3.5, 3.6 Changes made to emergency response 3.11.6 Simplified response to incident Appendix II, III Changes to safety screening forms	22-January-2016

Summary

The content of this standard operating procedure (SOP) is to maintain safe practice, during procedures in the Magnetic Resonance Imaging (MRI) suite of PERFORM, as magnetic fields present known safety hazards.

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1. Definition of Terms

CGS	Unit of measure based on centimeters, grams, and seconds
Cryogen	A liquid, such as liquid nitrogen or helium, that boils at a temperature above about 110 K (-160°C) and is used to obtain very low temperatures; a refrigerant
dB	Decibel is a logarithmic unit that indicates the ratio of a physical quantity (usually power or intensity) relative to a specified or implied reference level
EHS	Concordia University Environmental Health & Safety
EMR	Electromagnetic Radiation A form of energy travelling through space at the speed of light with wave-like behavior, with both electric and magnetic field components oscillating in phase, perpendicular to each other and with the same direction of propagation. EMR energy is a function of frequency and wavelength
EPR	Electron Paramagnetic Resonance Spectroscopy Also known as Electron Spin Resonance (ESR); a technique for studying chemical species with unpaired electrons, which are excited by radiofrequency EMR applied in conjunction with a static magnetic field
ESR	Electron Spin Resonance Spectroscopy See EPR
fMRI	Functional Magnetic Resonance Imaging A type of specialized MRI scan which measures changes in blood flow related to neuronal activity of the brain or spinal cord of humans
G	Gauss is the CGS-derived unit of magnetic field strength (intensity), also known as magnetic flux density or magnetic induction. One G equals 0.0001 Tesla
Magnetic Field	A force field created by a magnet or as a consequence of movement of electric charges
Medical Device	Includes internal/external electronic devices, metallic implants, surgical clips, prostheses, and hearing aids
MRI	Magnetic Resonance Imaging A technique using intense magnetic fields in combination with radiofrequency EMR to generate images of internal anatomical structures

MRS	Magnetic Resonance Spectroscopy Also known as Nuclear Magnetic Resonance (NMR) spectroscopy; an *in vivo* technique using NMR properties of nuclei in molecules to identify chemicals in body organs
NMR	Nuclear Magnetic Resonance (NMR) is a technique that exploits the fact that magnetic nuclei of atoms in large static fields resonate with specific radiofrequency EMR to generate characteristic signals
Principal Investigator (PI)	Head researcher that is responsible for all aspects of a given research project or program at PERFORM.
Quenching	Refers to the loss of liquid nitrogen or helium cooling of superconducting coils in magnets present in NMR or MRI equipment and reverting to a resistive state, with total loss of magnetic field
RF	Radiofrequency Field An electromagnetic field oscillating in the range of 30 KHz and 300 GHz
RSO-NM	PERFORM's Radiation Safety Officer – Nuclear Medicine
Specific Absorption Rate	A measure of the rate at which energy is absorbed by the body when exposed to a RF electromagnetic field in W/kg tissue
T	Tesla is the SI-derived unit of magnetic field strength, also known as, magnetic flux density and magnetic induction. One T equals 10,000 G
Technologist	An authorized and qualified user with specialized training on a given equipment; normally carrying a certification.
User	Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training.

2. Introduction

2.1 Background

Work involving magnetic resonance at high magnetic field strengths presents unique hazards to both research participants and individuals working within and around the MRI equipment. There is a potential for serious personal injury.

2.2 Purpose

This SOP outlines the requirements for the safe access and operation of the MRI scanner in order to minimize the risk of an adverse incident. It also describes the procedures to respond to emergency situations.

2.3 Scope

This SOP applies to all PERFORM users working with or around the MRI, including but not limited to PERFORM researchers, staff, University auxiliary staff, students, research participants and authorized visitors.

2.4 Responsibility

All users are responsible for:

- Following all applicable safety rules and practices.
- Reporting all potential hazards, unsafe conditions or safety issues to the Associate Director, Bio Imaging or delegate.
- Using and wearing personal protective equipment.
- Attending all applicable training courses.

2.4.1 Associate Director, Bio Imaging (or delegate)

The Associate Director, Bio Imaging or delegate, has overall responsibility for safety and general training of all users.

2.4.2 Principal investigator/Project lead

The principal investigator/project lead is responsible for ensuring their team members and all users in their team have completed the proper training to be able to conduct activities in a safe manner.

2.5 Relevant documents

- VPS-54 Magnetic Field Safety Policy
- VPS-40 Environmental Health and Safety Policy
- VPS-42 Policy on Injury/Incident Reporting and Investigation
- VPS-45 Policy on First Aid and Medical Emergencies
- PC-SOP-GA-009 Emergency Response Procedures at the PERFORM Center

Note: This SOP defers to Concordia policies at all times

3. Procedure

The following procedures must be adhered to when around the magnetic resonance equipment:

3.1 Procedures

3.1.1 All users entering the MRI facility must be aware that the static magnetic fields of the superconducting magnets are always present and are not detected by human senses.

3.1.2 Access to magnets must be restricted to authorized, knowledgeable staff. Authorization is provided by the Supervisor, Nuclear Medicine once all SOP's have been signed off and orientation of the Bio Imaging suite has been done.

3.1.3 Those authorized to work within and around high field magnetic resonance equipment must have completed appropriate safety training and must comply with all approved SOPs.

3.1.4 Any individual entering the MRI scanner area will need to have completed the MRI Safety Screening form (see Appendix II, III) and be authorized by the MRI technologist or delegate before accessing the scanner room. The signature for regular users is required on an annual basis.

3.2 MRI Technologist

3.2.1 All MRI technologists will be trained as evidenced by signed documentation and will be accredited by federal/provincial associations for MR technologist.

3.2.2 All participants to be scanned in the MRI have to complete the MRI Safety Screening form and have to be approved to be scanned by the PERFORM MRI technologist for each imaging session

3.2.3 The MRI technologist must be present at all times and will verbally monitor the participant throughout the procedure.

3.2.4 The MRI technologist has the authority to stop procedures when they are deemed to be unsafe.

3.2.5 MRI technologist scanning human research participants must have current CPR training.

3.3 Participant Safety

3.3.1 Researchers using the MRI system for human studies must have an ethics approved protocol prior to scanning human research participants.

3.3.2 Individuals who are or may be pregnant are not allowed to remain in the MRI scanning room while the RF system is operating.

3.3.3 Research participants in MRI studies must be screened for safety risks prior to entering the magnetic field.

3.3.4 Implant devices and other objects within or on research participants or other individuals intending on entering the magnetic environment must be investigated by manufacturer label and documented prior to the individual or research participant entering the scanner magnet room.

3.3.5 Individuals with Vagal Nerve Stimulation (VNS) implants cannot participate in a MRI study due to the rapid gradient switching required for echo planar imaging utilized in MRI.

3.3.6 Research participants with suspected metallic ocular injury must be investigated and if necessary, cleared by a physician before entering the magnetic environment or participating in an MRI study.

3.3.7 Research participants must be evaluated for medical status that would indicate a safety risk and or prevent a successful MRI study.

3.4 *Spill or Leakage*

Accidental spill or leakage into the magnet or control room of the MRI must be reported to the Associate Director, Bio Imaging or designate and followed by aborting any scan in progress. The decision to shut down the magnetic resonance equipment (Magnet Stop button) can only be made by the PERFORM Administration or MRI Technologist.

3.5 Fire, Smoke or Odor in the MRI suite

****** IMPORTANT: Fire extinguishers are not to enter the MRI suite ******

3.5.1 In the event of a suspected or real fire of the MRI scanner, fixed equipment or walls of the magnet room, follow these steps:

3.5.1.1 Stop scan. Turn off the electrical supply (Emergency stop button on the gantry or the wall). Activate the fire alarm. Ensure your safety and that of any participant in the magnet room. Evacuate the magnet room.

3.5.1.2 Move to a safe location and communicate with Security 514-848-3717 or go directly to their office at the main entrance of the PERFORM Centre.

3.5.1.3 Respond to any injury and notify security, EHS, and the department manager or designate.

3.5.2 In the event that a piece of equipment starts to smoke or smell of fire in the MRI suite and can be removed safely, follow these steps:

3.5.2.1 Ensure your safety and that of any participant and evacuate the magnet room and everyone towards the back end of the Bio Imaging suite.

3.5.2.2 Move the item from the MRI suite to the adjacent tiled bathroom or hallway and close the MRI door. Leave yourself an evacuation route.

3.5.2.3 Contain the fire using a fire extinguisher (Bio Imaging Hallway or fire blanket (Hot lab 1.140).

3.5.2.4 If the fire can't be contained close the door, evacuate and activate the fire alarm.

3.6 Victim Pinned to MRI

The following steps must be taken **only if** an individual is pinned to the magnet, trapped or in a potentially life-threatening or injury-inducing situation by a non-removable ferromagnetic object or if fire fighters need to access the room. The decision to shut down the magnetic resonance equipment (Magnet Stop button) can only be made by the PERFORM Administration or MRI Technologist.

3.6.1 Alert Security 3717.

3.6.2 If the victim is otherwise unharmed and the situation is stable contact GE to assist in a controlled shutdown of the magnet.

3.6.3 If the victim's wellbeing is at stake or the situation is not under control: Be prepared to evacuate the victim from the MRI room. Depress the red Magnet Stop 'kill switch' button in the magnet room (GE system). An audio alarm will sound with warning lights. The result is a rapid reduction of the magnetic field, a "quench", within 2 minutes. There is a boil-off of helium accompanied by loud crackling and hissing sounds. Evacuate everyone from the magnet room as there is potential for it to fill with helium, replacing oxygen and causing asphyxiation.

3.6.4 Treat any injuries in a well ventilated area away from the MRI room.

3.7 Medical Emergency

3.7.1 An individual or research participant who becomes ill or injured must be removed from the magnetic environment immediately by the researcher or technologist.

3.7.2 Extract the person from magnet room on the magnetic resonance imaging bed, the MRI safe stretcher or the MRI safe wheelchair.

3.7.3 Close the magnet room door.

3.7.4 If emergency response is required, call Security 3717 and follow procedures.

The security department shall:

3.7.4.1 Answer emergency phone calls and other calls for assistance.

3.7.4.2 Arrive on the site of emergency with appropriate first aid equipment to assess the situation and, if necessary, administer first aid.

3.7.4.3 The Security department shall contact the appropriate health and safety, Facility or municipal emergency response personnel.

3.7.4.4 The Security department: shall arrange for appropriate transportation to a medical facility as required.

3.7.5 The incident report form must be completed (see Appendix VI).

3.7.6 Notify EHS within 24 hours or, in case of a serious medical situation, as soon as possible.

3.8 Radiofrequency (RF) Field

3.8.1 Only properly trained individuals should operate devices and monitoring equipment in the magnetic environment.

3.8.2 Only electrically conductive equipment, accessories and materials that have been thoroughly tested and determined to be safe for MRI procedures are allowed.

3.8.3 Manufacturer recommendation for safe use of all devices must be followed.

3.8.4 All non-essential electrically conductive materials must be removed from MRI bore, including unsafe RF coils, cables and wires prior to scanning.

3.9 Acoustic Noise

3.9.1 All research personnel must have completed all required safety training.

3.9.2 Any researcher or individual who remains in the scanning room during data acquisition must wear hearing protection.

3.9.3 Research participants must be supplied with hearing protection, either foam ear plugs or an MRI-compatible headset system.

3.9.4 The intercom and auditory stimulus equipment must be adjusted to not exceed safe dB level for the research participant.

3.10 Infection Control

3.10.1 The scanning room table and any other surfaces that have come in contact with research participants must be cleaned and the linens changed before placing another research participant on the scanning table.

3.10.2 Gloves must be removed and disposed of properly before touching common areas such as scanner key board, log books, light switches, counter surface and other objects.

3.10.3 Surfaces touched with gloves must be cleaned properly before leaving the area.

3.10.4 All biohazard material must be disposed of according to PC- SOP-GA-002 Handling of Biological Materials at PERFORM.

3.11 Safety Screening

3.11.1 All equipment used for research MRI studies, including projectors and stimulus producing apparatus, must be tested for MRI safety before entering magnetic field. MRI safe equipment is developed for specific magnetic field strengths and MRI system configurations. Equipment that may operate safely within a magnet room is not necessarily safe to operate in another even if the magnets are of the same static field strength. Routine inspection and maintenance of equipment must be performed and any problem must be reported to the MR technologist.

3.11.2 Anyone with any of the following medical devices (internal or external), should identify these before entering the facility and may not proceed into the magnet room, beyond the 0.3 mT (3 G) line, unless the medical device or item can be removed or safety deactivated:

- Aneurysm clips
- Implanted Cardioverter defibrillator
- Electronic implant or device
- Magnetically activated implant or device
- Neuro stimulation system
- Spinal cord stimulator
- Brachytherapy needles (seeds)
- Any type of prosthesis
- Any type of implant containing metallic component
- Artificial or prostatic limb
- Any metallic fragment or foreign body
- Any internal or external metallic object
- Hearing aid
- Eyeglasses
- Stents
- Metallic dental fillings

3.11.3 All metallic objects have the potential to become projectiles in the magnetic resonance environment if they contain ferromagnetic elements.

3.11.4 The MR Technologist or User is responsible for screening all objects brought into the magnet room for ferromagnetic properties.

3.11.5 It is mandatory to remove all personal metallic objects before entering the magnet room, crossing the 0.3 mT (3 G) line.

These include but are not limited to:

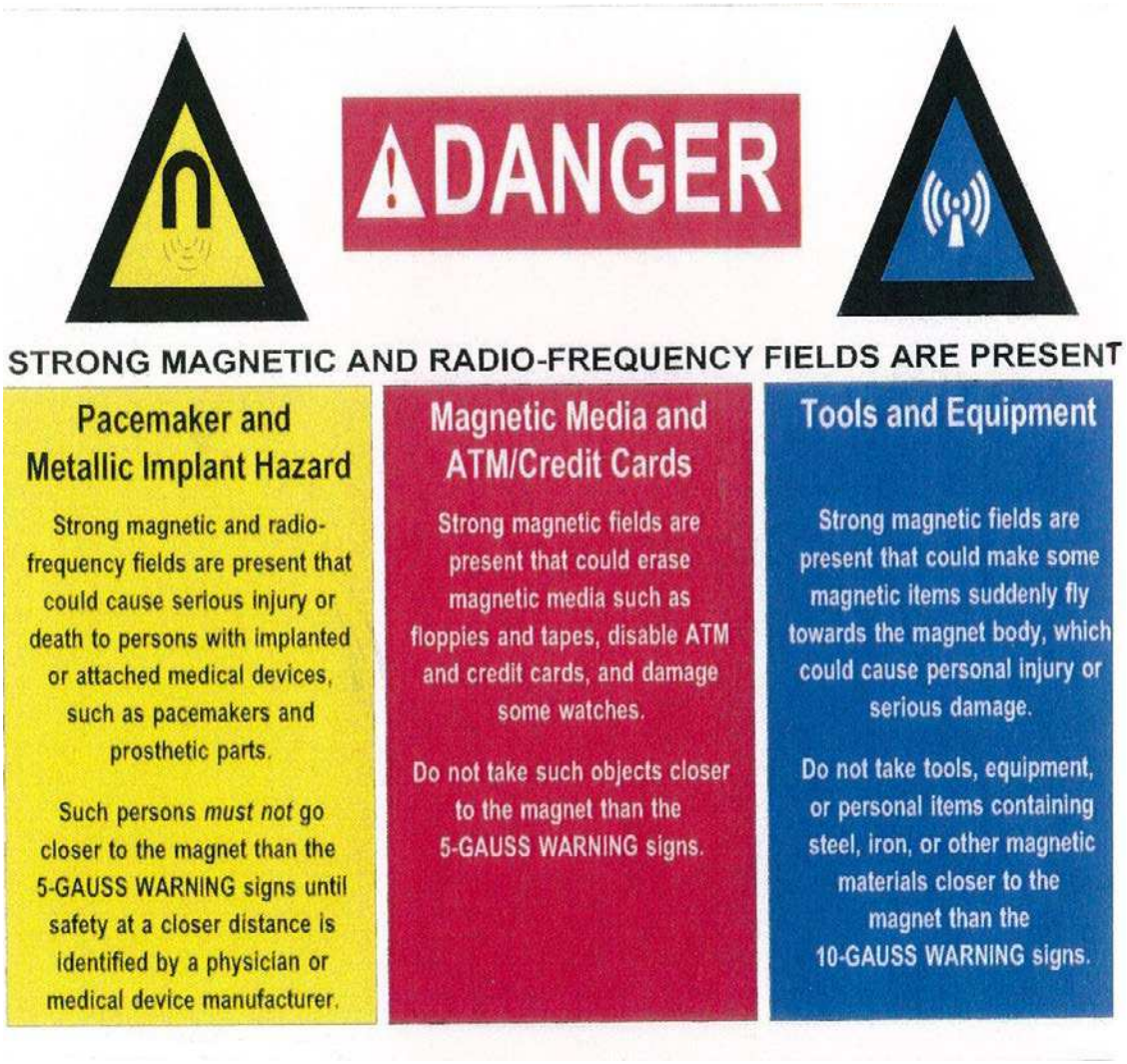
- Hearing aides
- Pagers, cell phones or any communication device
- Keys
- Hairpins, barrettes, clips
- Jewelry
- Watches
- Safety pins, paperclips
- Credit/debit cards, magnetic chip cards
- Pens
- Pocket knives, nail clippers
- Steel toed safety footwear
- Tools
- Eyeglasses
- Cosmetics

3.11.6 Any incident causing injury to an individual or research participant must be reported to the Associate Director, Bio Imaging or delegate as well as Environmental Health and Safety. In case of an accident or injury when the PI is not present, the technologist or user must report to PI. Follow the link below for the EHS incident report:

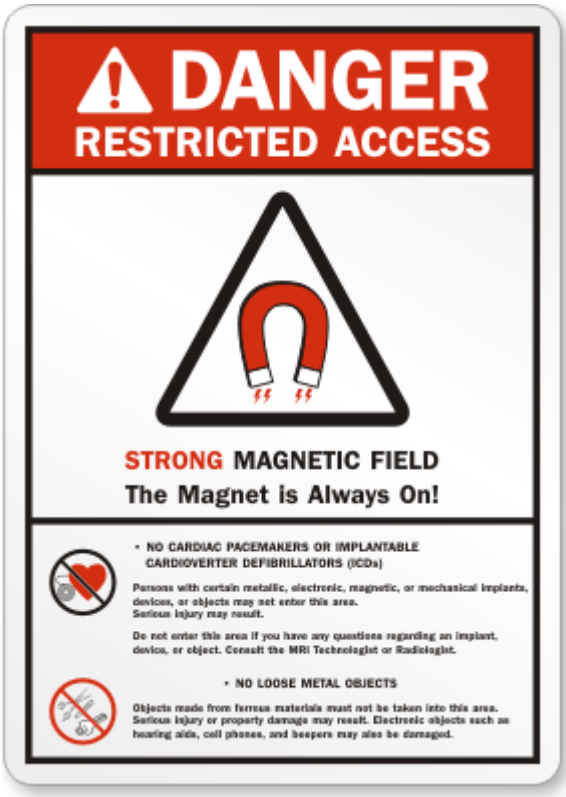
EHS Incident Report

Appendix I

Danger Warning Signs


DANGER
STRONG MAGNETIC AND RADIO-FREQUENCY FIELDS ARE PRESENT
Pacemaker and Metallic Implant Hazard
Strong magnetic and radio-frequency fields are present that could cause serious injury or death to persons with implanted or attached medical devices, such as pacemakers and prosthetic parts.
Such persons must not go closer to the magnet than the 5-GAUSS WARNING signs until safety at a closer distance is identified by a physician or medical device manufacturer.
Magnetic Media and ATM/Credit Cards
Strong magnetic fields are present that could erase magnetic media such as floppies and tapes, disable ATM and credit cards, and damage some watches.
Do not take such objects closer to the magnet than the 5-GAUSS WARNING signs.
Tools and Equipment
Strong magnetic fields are present that could make some magnetic items suddenly fly towards the magnet body, which could cause personal injury or serious damage.
Do not take tools, equipment, or personal items containing steel, iron, or other magnetic materials closer to the magnet than the 10-GAUSS WARNING signs.

PERFORM Centre



Appendix II

MRI SAFETY SCREENING FORM FOR USERS

PERFORM Centre

MRI SAFETY SCREENING FORM FOR USERS

Name: _____

Sex: _____

Date of Birth: _____

To ensure your safety, this form MUST BE completed in the presence of a qualified MRI

Yes	No		Specify
		Have you had a previous MRI?	
		Have you ever been a metal worker, grinder, or welder?	
		Have you ever had a metal foreign body in or around your eye?	
		Are you pregnant or breast feeding?	
		Are you claustrophobic?	
		Are you connected to any supportive medical devise? (pumps, catheters)	
		Have you ever had any surgery?	

Do you have any of the following in place?

		Cardiac pacemaker, implantable cardioverter defibrillators, or leads	
		Heart valve prosthesis	
		Aneurysm clip(s)	
		Orbital implants	
		Intraventricular shunt	
		Neurostimulator, bone growth stimulator, biostimulator	
		Implanted drug infusion device/insulin pump	
		Inner ear implants-cochlear, stapes, aids	
		Joint replacement/prosthesis/ artificial limb	
		Coil, filter or stent (intravascular)	
		Genital prosthesis/devices (penile, diaphragm, intra uterine device, pessary)	
		Surgical rods/wires/plates/shrapnel/bullets	
		Vascular access port (peripherally inserted central catheter, port-a-cath, etc.)	
		Dentures, Braces	
		Tattoos, permanent cosmetics	
		Body piercing, body jewelry	
		Medication patches	
		Colored contact lenses	

If you have answered yes to any of the above, please speak to the MRI technologist

I acknowledge that I have been informed about the requirements to work safely in and around the MRI. I understand the MRI magnet is always on and will not bring any unauthorized object or equipment into the suite. I have completed the above questionnaire and have spoken to the MRI technologist or principal investigator regarding any possible contraindications to entering the MRI suite.

Users Signature: _____ Date: _____

Physician/Technologist: _____

Signature: _____ Date: _____

APPENDIX III

MRI Screening Form for Participants

PERFORM Centre

MRI PARTICIPANT SAFETY SCREENING FORM

Project: _____ Participant: _____
Sex: _____ Height: _____
DOB: _____ Weight: _____
_____ Allergies: _____

To ensure your safety, this form MUST BE completed in the presence of a qualified MRI Technologist.

Yes	No		Specify
		Have you had a previous MRI?	
		Have you ever been a metal technologist, grinder, or welder?	
		Have you ever had a metal foreign body in or around your eye?	
		Are you pregnant or breast feeding?	
		Are you claustrophobic?	
		Are you connected to any supportive medical devise? (pumps, catheters)	
		Have you ever had any surgery?	

Do you have any of the following in place?

		Cardiac pacemaker, implantable cardioverter/defibrillator, or leads	
		Heart valve prosthesis, Stent	
		Aneurysm clip(s)	
		Orbital implants	
		Intraventricular shunt	
		Neurostimulator, bone growth stimulator, biostimulator	
		Implanted drug infusion device/insulin pump	
		Inner ear implants-cochlear, stapes, aids	
		Joint replacement/prosthesis/ artificial limb	
		Coil, filter or stent (intravascular)	
		Genital prosthesis/devices (penile, diaphragm, intra uterine device, pessary)	
		Surgical rods/wires/plates/shrapnel/bullets	
		Vascular access port (peripherally inserted central catheter, port-a-cath, etc.)	
		Dentures, Braces	
		Tattoos, permanent cosmetics	
		Body piercing, body jewelry	
		Medication patches	
		Colored contact lenses	

If you have answered yes to any of the above, please speak to the MRI technologist or the principal investigator.

I have informed the participant about the MRI exam and how it will be performed. I have completed the above questionnaire with the participant and reviewed any possible contraindications to the MRI exam. All of the participant's questions have been answered.

Physician/Technologist: _____ Date: _____

Participant Initials: _____

APPENDIX IV

SOP Training Record

PERFORM Centre

SOP Title

Magnetic Resonance Imaging Safety Procedures at PERFORM

SOP Code

Ownership	Document type	Area	SOP Number	Version
PC	SOP	IM	003	02

Training Record

Full Name	
Institution	
Contact (email or phone number)	

Signature

Sign here and return to SOP custodian	Date