

Duty of Care Significant Incidental Findings Reporting Procedure

Purpose:

The purpose of this document is to outline the procedures that users need to adhere to if there is a significant incidental pathological finding identified on a participant's 3T Magnetic Resonance Imaging (MRI) research scan.

Rationale:

It is acknowledged by SESLHD and UNSW that there is a duty of care (DoC) to any participant if a significant incidental finding is identified during a 3T MRI scan. Additionally, for research purposes, a procedure for how the Chief Investigator (CI) will ensure a duty of care process to deal with any significant incidental finding of pathology must be included in the application to use the facility's equipment and the approved Human Research Ethics Committee (HREC) application prior to scanning. This process will be consistent with what is outlined in this document, but may however require more altered or more stringent mechanisms in incidental findings reporting.

Procedure:

- 1) Every Participant must understand that there is a possibility that a significant incidental finding may be identified as part of their 3T MRI scan.
- 2) Every Participant consents to:
 - nominating a preferred medical practitioner who will be contacted if an incidental finding is identified,
 - being contacted directly by the DoC radiologist if their preferred medical practitioner is not contactable or not able to deal with the incidental finding (e.g. a finding needing urgent action). In this case the radiologist and participant will discuss a plan of action which may include referral to another medical practitioner,
 - the CI being notified if an incidental finding is deemed to be relevant to the research study.
- 3) Participants' Consent Forms are identifiable (as evidence that voluntary consent was provided to partake in the scan). These are kept in the highly secure UNSW recordkeeping system separate from the scan image data.
- 4) Each Participant will agree to complete a clinical data form which will include the name and contact details of their nominated medical practitioner, as well as their own contact details. This will include a section where the Participant may elect to provide any relevant medical history that could be important in the DoC reporting. This form will be: used by the DoC radiologist to assist in interpreting the research scan images; kept confidential; and scanned into the Prince of Wales Hospital Radiology Information System (RIS).
- 5) Participants' research images will be reviewed by an accredited SESLHD Radiologist and a DoC report entered into the Prince of Wales Hospital RIS.
- 6) If a significant incidental finding is seen on the radiological image data, then the reporting DoC SESLHD Radiologist will contact the nominated medical practitioner to discuss the significant incidental finding. The nominated medical practitioner will be responsible for contacting the Participant to discuss the incidental finding.

- 7) If the nominated medical practitioner is not contactable or not able to deal with the incidental finding (e.g. a finding needing urgent action), the radiologist will contact the participant directly and discuss a plan of action which may include referral to another medical practitioner.
- 8) If the radiologist identifies an incidental finding that may be relevant to the research study, then they will contact the CI and inform them of the finding.
- 9) The facility will keep a record of the significant incident findings and its communication including:
 - a) the RIS accession number of the study,
 - b) the date, time and nature of any correspondenceThis will likely take the form of a spreadsheet and will be audited regularly to ensure the DoC process has been achieved in each relevant case. This record will contain no confidential patient information.
- 10) No scan report or image data will routinely be provided to the participant or nominated medical practitioner. Scan report or image data may be provided to nominated medical practitioners if there is a significant incidental finding. At no point will the SESLHD Radiologist transmit the report or image data of the study directly to the Participant