PURPOSE: This procedure describes the process to be followed, including follow-up, confidentiality and documentation, in case a researcher discovers an anomalous region in the brain of a **healthy competent volunteer** (age ≥ 16) participating in a standard (f)MRI study at the Donders Centre of Cognitive Neuroimaging (DCCN).

SCOPE: This procedure applies to ***healthy competent volunteer*** (age ≥ 16) participants at the Donders Centre for Cognitive Neuroimaging (DCCN) as part of all standard (f)MRI studies conducted within the scope of CMO 2014/288, entitled "Imaging Human Cognition")

PERSONNEL RESPONSIBLE: This procedure includes responsibilities for the designated staff member(s), investigators, MR lab manager, research assistants and all designated personnel who conducts MR research at the DCCN.

DEFINITIONS:

- **Standard DCCN studies-** Standard studies are defined as cognitive neuroscientific studies that do not apply any invasive intervention (e.g. medication, TMS etc.) and include only healthy, legally competent volunteers (≥ 16) as participants.
- **Incidental Finding (IF) -** An incidental finding (IF): a finding concerning an individual research participant that has potential health impact and is discovered in the course of conducting research but is beyond the scope of the study. IFs range from those that have clear clinical significance and reveal conditions that can be treated.
- **Incidental Finding Report (IFR) – The** investigator reports, as part of the screenings procedure, the suspicion of an incidental finding in writing on the screening form.

- **Standard Operating Procedure--SOP**: is a set of written instructions that document a routine or repetitive activity carried out in an organization indicating: *who* will perform the task, *what* materials are necessary, *where* the task will take place, *when* the task shall be performed, and *how* the person will execute the task.

PROCEDURES:

Before inclusion, each volunteer serving as study participant is informed that all scanning protocols at the DCCN are designed to answer research questions and thus not designed for clinical diagnosis. They are also informed that scans will NOT be routinely reviewed by a radiologist. Nevertheless, each study participant provides name and address of his /her home physician. The participant may only participate if registered in the SONA volunteer database. In case the participant has no (local) home physician, the participant will be informed about the possibility to register as patient at the local site department Academic General Practitioner Center Heyendaal (UCGH). Finally, based upon his/her consent each study participant agrees that if a deviation within 1 year after acquisition in the MRI scans by the researcher is identified the following steps are undertaken. If the potential participant does not agree with the written procedure, he/she cannot participate in any imaging study at the DCCN.

1. If a researcher incidentally notices a deviation in the MRI scan, as soon as possible and/or within 1 year after actual data acquisition, he/she will follow the procedures as indicated on intranet: https://intranet.donders.ru.nl/index.php?id=sop : 2. Incidental finding standard studies + form.

2. The researcher will subsequently contact the MRI lab manager, who sends the images out for assessment by a radiologist. At this stage, the participant is not informed, but the incidence will be documented in the study specific data management system Castor.
3. If, according to a written report of the radiologist, no clinically relevant finding is observed the participant will not be informed, but the documentation updated.
4. In case the radiologist determines an incidental discovery that is not directly related to the research, but does concern the participant's health the radiologist will send report including advice for follow-up/ additional examination to the MRI-labmanager. The Clinical Research Coordinator (CRC) will be informed and additionally process according to the advice of the radiologist.
5. The CRC will arrange a telephone consult between the participant and the radiologist.
6. The CRC will prepare a letter for the home physician or the General Practitioner of the Academic Center which includes the radiologist's report. The letter consists of instructions for the GP to make an appointment for his/her patient at the Neurology outpatient department of the RadboudUMC. The participant will be seen with priority.
7. The participant will be contacted by the CRC to explain the procedure in place: the participant will be asked to pick up a package which consists of a CD/ DVD with his/her MRI-images including the report and advice of the radiologist. The participant is instructed to take to the package to the arranged appointment at Neurology or the specialist as indicated by the radiologist .
8. The CRC will ask the participant if he/she agrees with a follow-up telephone contact when the consult took place and results are available.

9. The CRC will document all followed steps and report the findings as well as follow up annually to the Medical Ethics Review Committee.

RESOURCES:

- General DCCN information brochure , new version 3.0
- Informed consent, new version 3.0
- MRI screening form, new version 3.0

  Donders Centre of Cognitive Neuro imaging internet website :

  https://www.ru.nl/donders/vm-site/proefpersonen/engelse-versies-centers/participants/donders-centre-cognitive-neuroimaging-en/
- **www.ugc-heyendael.nl /**
- **https://ugc-heyendael.praktijkinfo.nl/pagina/55/english/**

TOOLS

- DCCN intranet: Standard Operation Incidental Finding Procedure, new version 1.8
- Intranet DCCN : https://intranet.donders.ru.nl/index.php?id=sop : 2.Incidental Finding Staandard studies + request form.

Incidental Finding Report, (Investigator: MRI- screening form/ Castor)

- Praktijkfolder UGCH https://ugc-heyendael.praktijkinfo.nl/pagina/55/english/

Effective Date:	Revision Dates:	Reference:
May 2010	October 2011/ December 2012/ September 2013/March 2015/ February 2016/ April 2019/ August 2019/ November 2020	DCCN