

Accessing participant medical notes for potential MRI contraindications

Guidance for Clinical Studies

The guidance in this document is new and we are keen to keep track of how many people are using it within the WIN community. Therefore, if you are using this guidance for your study, please could you contact Jess (jessica.walsh@ndcn.ox.ac.uk). Any feedback on how we could improve this guidance to make it more useful for you is appreciated.

Scope

This guidance is intended to apply to clinical studies only, defined as studies that require HRA approval. Clinical studies will include involvement of NHS Trusts, which may be listed as a participant identification centre (PIC) or as a full site within the study.

Background

Research scans bring no benefit to the participant. Therefore, unlike when scanning for clinical purposes, undue risk associated with scanning a research participant with a contraindication to MRI (e.g. surgical implants) is not justifiable (in terms of diagnostic benefit). When a participant has a potential contraindication to research MRI, we often require access to participant's medical records for more details on the device or implant, so that a suitable risk assessment can be carried out on the safety of the participant to undergo the scan. Medical records can either be accessed by a member of the patient's direct clinical care team or by a member of the research team who has access to medical records through a research contract (usually an honorary contract or research passport) with the Trust.

Although not all participants will have a potential contraindication to MRI, most research studies will find a significant proportion of participants do, which therefore requires access to medical records for further details. It is important to establish who will carry out any required checks of the participant's medical records during the study design phase, as the required procedures are different depending on whether this person is a member of the direct clinical care team or a researcher.

Procedure

Direct clinical care team member: If a member of the patient's direct clinical care team is taking responsibility for accessing medical records for further details on potential MRI contraindications, then no consent is required to be in place for this. The direct clinical care team member can carry out these checks as part of their general eligibility checks for study suitability. It should be clearly detailed in the study

protocol that this is the process for obtaining further details on potential MRI contraindications:

- PIS: the PIS must detail that a member of their direct clinical care team may use their medical records to check details of any potential contraindications to MRI and that they will not be recruited to the study if MRI safety cannot be confirmed
- Protocol: The protocol must list 'Contraindication to MRI' as an exclusion criteria and detail that the direct clinical care team member will use participant's medical records to check for further details of any potential MRI contraindications

Research team member: If a research team member (e.g., any individual who is outside of the patient's direct clinical care team, including radiographers) is taking responsibility for accessing medical notes for further details on potential MRI contraindications, then consent must be in place from the patient to allow this to happen. The following must be in place:

- Consent form: must contain a clause that confirms participants give permission for their medical notes to be accessed and the participants must have consented to this BEFORE their medical notes are accessed
- PIS: the PIS must detail that you may use their medical records to check for further details of potential contraindications to MRI and that they will be withdrawn from the study if MRI safety cannot be confirmed
- Protocol: the protocol must list 'Contraindication to MRI' as an exclusion criteria and detail that the research team member will use participant's medical records to check for further details of any potential MRI contraindications

Suggested wording: Protocol

Direct clinical care team member accessing medical records

In the 'Screening' section:

Participants will be screened for MRI suitability and safety using the MRI safety screening form before they are recruited to the study. If participants are found to have a potential MRI contraindication, a member of the direct clinical care team may check the participant's medical records for further details. If we cannot confirm the participant's safety for MRI, they will not be recruited to the study.

In the 'Exclusion criteria':

- *Contraindication to MRI*

Research team member accessing medical records

In the 'Recruitment' section:

Participants will be screened for MRI suitability and safety using the MRI safety screening form after they have been recruited to the study. If participants are found to have a potential contraindication, a member of the study team may check the participant's medical records for further details. If we cannot confirm the participant's safety for MRI, they will be withdrawn from the study.

In the 'Exclusion criteria':

- *Contraindication to MRI*

Suggested wording: PIS

Direct clinical care team member accessing medical records

In the 'What will happen to me if I decide to take part?' section:

You will be screened for MRI suitability and safety using the standard research MRI safety screening form to ask you some questions that check your suitability for research MRI. The MRI scanner uses strong magnetic fields to generate images and therefore it is important that we ensure you do not have any incompatible metallic devices in your body e.g. a pacemaker or metal implant. If you have anything that may be unsafe to scan with the MRI scanner, then a member of your direct clinical care team may check your medical records for further details. If we cannot confirm your safety for MRI scanning, then we will not be able to recruit you to the study.

Research team member accessing medical records

In the 'What will happen to me if I decide to take part?' section:

After we have taken consent from you to participate in the study, we will use the standard research MRI safety screening form to ask you some questions that check your suitability for research MRI. The MRI scanner uses strong magnetic fields to generate images and therefore it is important that we ensure you do not have any incompatible metallic devices in your body e.g. a pacemaker or metal implant. If you have anything that may be unsafe to scan with the MRI scanner, then we may need to access your medical records for further details. A member of the study team will do this. If we cannot confirm your safety for MRI scanning, then we will withdraw you from the study at this point.

Suggested wording: Consent Form

Direct clinical care team member accessing medical records

No consent is required for the direct clinical care team to check a participant's medical records.

Research team member accessing medical records

Consent must be in place for a research team member to access a participant's medical records. These clauses are taken from the template in person and remote consent forms on the CTRG website

(<https://researchsupport.admin.ox.ac.uk/ctrq/resources>)

For in person consent:

I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities, and from NHS Trusts where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

For remote consent:

Do you understand that relevant sections of your medical notes and data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities, from NHS Trusts where it is relevant to my taking part in this research? Do you give permission for these individuals to have access to your records?

FAQs

Q: What if I am a researcher who usually screens for MRI safety in advance but only consents my participants immediately prior to their MRI scan?

A: If you require access to participant's medical records for more details of potential MRI contraindications prior to consenting the participant, then you will need to have a member of the participant's direct clinical care team engaged in the study and happy to carry out these checks as part of their eligibility screening for the study. As a researcher, you cannot access the participant's medical notes before you have taken consent. Another option would be to consent your participants remotely in advance of their MRI scan. The template remote consent form can be found on the CTRG website (<https://researchsupport.admin.ox.ac.uk/ctrg/resources>). Each question must be asked in full by the researcher, and the box ticked when the participant replies in the affirmative. Once you have taken remote consent to access their medical records for research, you can then access them to check details of potential MRI contraindications.

Q: If I have already consented my participant and then a contraindication arises – can I withdraw them from the study?

A: Yes, this is absolutely fine. You just need to make sure that you have detailed this as an exclusion criteria in your protocol and that you have informed the participants in the PIS that this is the procedure.

Q: What about participants who have had a potential contraindication (e.g. an operation) at a Trust that we are not collaborating with for this study?

A: As long as the patient has consented to medical records being accessed for research purposes, then their medical records can technically be accessed at any Trust. The only difficulty here is that it is unlikely that you will have a researcher on the team who has access to the medical records directly. Therefore, the best course of action would be to find the direct clinical care team who were involved in the potential contraindication (e.g. the surgical team if the contraindication is due to surgery) and ask them to check further details for you. The consent form can be provided to the relevant Trust as 'proof' of access.

Q: Who does the 'regulatory authority' sentence refer to in the suggested wording for the consent form?

A: The consent form suggested wording comes from the CTRG template (<https://researchsupport.admin.ox.ac.uk/ctrg/resources>). The reference to 'regulatory authorities' applies primarily to Trials, where the MHRA may also review, but can include HTA inspectors (for studies with samples) or the Information Commissioner's Office, should they wish to audit any data processing. Any individuals who review the study are subject to the same requirements of confidentiality as the study and clinical teams.

We hope you've found this document helpful. If you have any further questions, please don't hesitate to contact Jess by emailing jessica.walsh@ndcn.ox.ac.uk.