



**Sheffield Health  
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## **Information and guidance for primary care sites on the purpose of a note to file (NTF)**

The purpose of this guide is to provide primary care sites with guidance on the purpose of a study 'Note to File' (NTF), what it is, when it is used during a study and how to complete it.

### **1. What is a Note to File?**

A NTF, sometimes known as 'File Note' is used to provide additional information or clarification when other study documentation is unavailable or inappropriate.

### **2. When might I need an NTF?**

NTFs can be used to explain specific issues that may arise at a study site during a study such as a deviation from the protocol, missing information, errors or alterations made to data.

NTFs are also used as a placeholder in the Investigator Site File (ISF) for a missing study document or study documents that are filed elsewhere e.g. signed informed consent forms.

### **3. Who can write an NTF?**

The NTF may be written by any member of the study team, but usually by the person who identified the error or omission. NTFs that explain protocol deviations should be reviewed/discussed with the Principal Investigator (PI).

#### **4. What needs to be documented?**

The information on the NTF needs to be clear and concise so that current and future study staff can identify what happened, why it happened and any corrective action taken.

The NTF should include the protocol title, a clear summary of the issue leading to the error/omission/discrepancy and any corrective action or follow-up where applicable. The NTF should be signed and dated by the person writing it.

If the NTF refers to specific study participant the identification number should also be included. See example NTF Appendix 1.

The study sponsor should provide a template NTF, if not, please see website for the template that can be used.

#### **5. Where should NTFs be stored?**

NTFs are seen as source documentation and need to be filed either in:

The Investigator Site File – if the NTF refers to missing documentation or any issues with any of the essential documents.

Or

Participant research folder next to the study document that is addressed/explained by the note.

#### **6. Where can I find out more?**

An example NTF is shown at the bottom of this guide.

#### **7. Who do I contact if I have further questions?**

For any questions, please email: [rdu@shsc.nhs.uk](mailto:rdu@shsc.nhs.uk)

## Note to File

Project reference	12345 EXAMPLE Study	
Date	Comments	Initials
10/10/2022	<p>Incorrect Patient ID allocated to 2 participants in error and entered on to online screening tool.</p> <p>Patient ID 111 should be 112 Patient ID 120 should be 121</p> <p>Trial Coordinator informed 10/10/2022, a note has been added to the electronic forms by the study team. The patient IDs have been amended on the paper CRFs at XXXXX Health Centre and Principal Investigator informed.</p>	MC