**INSTRUCTIONS for use of the NOTE TO FILE TEMPLATE**

*This form is able to be adapted as needed, refer to* [*CC BY-NC 4.0*](https://creativecommons.org/licenses/by-nc/4.0/)*. Remove ‘Instructions for Use’ and all guidance text, in purple, prior to finalising of Note to File.*

*Note that purple text enclosed with <> is a placeholder for a specific detail (e.g., <protocol number>) to be filled.*

*Background*

*A Note to File (NTF), also known as a File Note, is written to document a discrepancy or other issue in the conduct of a research study. The NTF also provides a forum for you to document the action taken to correct this.*

*The NTF can apply to a single participant, multiple participants or to the study/trial as a whole. Reasons for using an NTF could include:*

* *documenting a missing data item*
* *clarifying/adding information regarding source documentation*
* *clarifying/adding information regarding site-specific regulatory file requirements*
* *documenting/addressing issues that are protocol and/or site specific.*

*A Note to File should be printed on institution letterhead and should be initiated and authored by the individual or organisation responsible for its content, as follows****:***

* *If the issue relates to site, the author (e.g. trial coordinator) should sign and date the NTF. To ensure oversight, the PI should countersign and date the NTF in a timely manner.*
* *If the issue relates to PI responsibilities the PI should write and sign the NTF.*
* *If the issue relates to actions taken by the sponsor or monitor (e.g., clarification of a protocol section), an appropriate credentialed individual from the sponsor should write and sign the note to file.*

*For \*externally sponsored or MCRI-led research being conducted at RCH as a site, the NTF should be on an RCH letterhead. If research is \*externally sponsored or MCRI-led and being conducted at MCRI as site or the research is MCRI-led and the NTF is used to document MCRI Sponsor activities, the MCRI letterhead should be used. In the case of a trial being sponsored by the MCRI but being run at a site that is neither MCRI nor RCH, the Note to File should be on the local site institutional letter head. In most cases the letterhead used on patient facing documents such as the Informed Consent Forms will be the same as used for the Note to File.*

*Filing of the NTF*

*Where the NTF refers to a study/trial participant, the complete, signed NTF should be filed with the participant’s study records.*

*Where the NTF refers to a study/trial-level issue, the NTF should be filed in the Study/Trial Master File and the Investigator Site File (both previously known as the Study Binder) in the section it is relevant to.*

*All NTF should be kept on file, and made available to the monitors, auditors and inspectors reviewing the site’s trial documentation.*

*Where an issue is considered to be a medium to high risk\*\* (taking into account the likelihood of recurrence and the severity of the impact), you should also prepare a MCTC061* [*Corrective and Preventive Action (CAPA) plan*](https://metis.melbournechildrens.com/media/runjc4k3/mctc061_sop_capa-plan.pdf)*. A CAPA plan lists the actions taken to collect information and identify a problem, determine its root cause, and identify and implement a corrective action (the action taken to remedy the issue) and/or a preventive action (the action taken to prevent a recurrence of the issue).*

*\* Includes commercial, academic or collaborative research group*

*\*\* Refer to the CRDO guidance “MCTC035* [*Trial risk assessment*](https://metis.melbournechildrens.com/media/vlbfptel/mctc035_template_trial_risk_assess_and_mx.docx)*”*

**NOTE TO FILE TEMPLATE**

|  |
| --- |
| **STUDY PROTOCOL #/NAME:** |
| **SITE NAME/NUMBER:** |
| **PARTICIPANT ID** *(Provide if this Note to File pertains to a participant, if not, write “Not Applicable”)***:** |
| **ISSUE:** *<brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list or bulleted items>* |

|  |
| --- |
| **DETAILED DESCRIPTION OF THE ISSUE AND ACTIONS TAKEN TO ADDRESS:***<If needed, provide more information here>* |

**REPORTED BY:** *<insert name, title, site or institutional affiliation of person reporting content of NTF>*

**ROLE IN STUDY:** *<enter role>*

**AUTHOR’s NAME:** *<insert name, title, site or institutional affiliation of person authoring the NTF>*

**AUTHOR SIGNATURE:** *<sign here>* **DATE:** *<record date of signing>*

**PI SIGNATURE:** *<sign here>* **DATE:** *<record date of signing>*