UTS IMPACCT Trials Coordination Centre

Standard Operating Procedure

4.5.3 File Notes

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Introduction / Background

File notes, or notes to file, are sometimes used within the practice of clinical trials. File notes are additional to all essential documents (Case Report Forms, etc.) and source documents (investigation results, etc.). File notes can be used to explain an issue which is not (and cannot) be explained elsewhere in the documentation.

The International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines do not specifically or directly address the use of file notes in clinical trials. It is important to understand the purpose of file notes and to use them appropriately.

Objective

There are some circumstances where a well written file note may be appropriate. This SOP describes the use of file notes for the IMPACCT Trials Coordination Centre (ITCC) studies to achieve consistency in the use, writing and application of appropriate file notes within ITCC studies.

Scope

This SOP applies to all staff involved in clinical studies conducted by the ITCC irrespective of individual organisational employment, role, or position.

Ownership and Responsibility

Responsibilities of the Principal Investigator and/or other designee(s) as documented in the Staff Signatures and Delegation Log (refer SOP 4.2.4 Delegation of Duties)

- To oversee the overall conduct of the study at their site, including those activities that may vary from the study protocol, or where documents or source documents indicate a discrepancy with the study data via the Case Report Forms (CRFs) and other study documents
- To identify discrepancies in the research processes and correct them appropriately
- To initiate a file note if an identified discrepancy cannot be corrected

Responsibilities of the IMPACCT Trials Coordination Centre

- To review file notes for appropriateness and content. This can be done during central monitoring, on-site visit monitoring or when file notes are generated spontaneously (or on request)

Procedure

1. Determining if a File Note is appropriate

- First, identify if other study documentation exists where the issue can be addressed. Acceptable documentation includes:
  - within the data collection worksheet using an accepted method of correction, or within a comment section at the appropriate data point;
  - as part of a response to monitoring through the Corrective Action Sheet (*refer* SOP 5.18 Monitoring) and confirmation that the action has been completed;
  - within the participant's clinical record;
  - in the electronic CRF using the notes and discrepancy items within the study database;
  - within other forms of correspondence where the issue was discussed and a solution reached, such as Human Research Ethics Committee (HREC) correspondence to clarify or amend erroneous approvals or email correspondence of decisions reached between the investigator and sponsor regarding recruitment.
- If a File Note is determined to be the appropriate form of documentation and correction of the identified issue, the File Note Template is used (Template 9).

2. Generating a File Note

The following general principles of generating a file note for ITCC studies apply:

- File notes are generated on a case-by-case basis
- File notes include the participant and study protocol referred to
- File notes are signed and dated by the individual who writes them and who can confirm the accuracy of the events detailed in the file note
- File notes are legible, if handwritten
- File notes clearly and specifically explain the reason for the error/omission/discrepancy or process/policy it aims to address
- File notes include any corrective action or follow-up when applicable
- File notes are filed with the document, participant file or study folder tab to which it applies
- A file note is not a solution to an issue; it is a vehicle to explain the problem and the solution
- All file notes include a plan to correct the problem and a plan to prevent future problems.

It is **not appropriate** to generate file notes for the sole purpose of documenting the following:

- Incorrect (or incorrectly signed) consent form
- Incorrectly administered (or omitted) study drug
- Missed scheduled visit
- Routine trial conduct
- A statement that a file note has been written (as a request of monitoring for example).

3. Completing a File Note

- A file note is to be completed by following the File Note Guidance (Guidance 1).

Related SOPs

4.2.4 Delegation of Duties
5.18 Monitoring
5.23.3 Data Collection Worksheet Completion

Related documents

Template 9: File Notes
Guidance 1: File Note Completion

References

Aditi Hazra. Use and misuse of notes to file. Perspectives in Clinical Research. 2(1): 38-40. 2011

Carl Anderson – Note to self – no more file notes. Applied Clinical Trials. March 2008

Tatjana Markovic. Writing notes to file at the study site. Journal of Clinical Research Best Practices. 7(1): Jan 2011

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). November 2016 (accessed 23/10/2017) https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4.pdf

History			
Version	Date	Author	Reason
1.1	8/10/2013	B Fazekas	New procedure
1.2	13/07/2015	C Hope	Periodic review
1.3	28/02/2018	B Fazekas, S Kochovska	Periodic review Publication of the ICH GCP E6 (R2)
1.4	16/03/2020	C Strauss	Periodic review
1.5	04/01/2022	C Strauss	Periodic review

Approval		
Version	Approval Name	Approval Signature
1.5	Meera Agar