STANDARD OPERATING PROCEDURE (SOP):

TITLE: DATA ENTRY AND QUERY RESOLUTION

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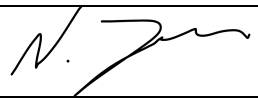
Signature:	
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TITLE: DATA ENTRY AND QUERY RESOLUTION

1. PURPOSE:

The purpose of this SOP is to outline the procedure for managing trial data entry into Case Report Forms (CRFs), both paper and electronic CRFs, and procedures for data query resolution for clinical trials at Epworth HealthCare (Epworth).

2. SCOPE:

All clinical trials conducted at Epworth.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in the research activity at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

The Principal Investigator (PI) is responsible for ensuring data entry and management of query resolution in a clinical trial is conducted in accordance with this SOP. The PI can delegate at his/her discretion certain trial duties to suitably qualified individuals. Delegation of trial activities must be recorded on the delegation log. The PI remains responsible for any delegated activity.

5.1 Data Entry

- Most of the clinical trials at Epworth use remote data capture (RDC) or electronic data capture (EDC). The Sponsor may provide commercially developed EDC systems for a specific trial. It is the responsibility of the Sponsor to ensure that these systems comply with Good Clinical Practice (GCP)[1] and applicable regulatory requirements.

- The data entered by Epworth clinical research staff in the CRFs is derived from source documents such as study specific worksheets, electronic medical records, laboratory reports and imaging/ scan reports. For more details on source document management please refer to SOP-TM-07 *Source Document Management*.

- Epworth clinical research staff assigned to data entry on the Delegation Log must ensure that they have adequate training on CRF data entry and all such training should be documented in the training log, or with a certificate of completion, for the respective trial. Data entry should be performed as per CRF Completion Guidelines provided by the Sponsor for respective trials.

- Data from source documents should be transcribed into the CRFs in a timely manner or as prescribed by the contract with the Sponsor.
- Data entered into the CRFs must be anonymised and the participant's identity must remain confidential. In order to ensure participant safety, the trial participant should only be identified in the CRF by means of the allocated participant number and/or initials (if applicable).
- Access to CRFs must be restricted only to designated users who have been identified to perform this activity in the Delegation Log. Users will access CRFs through their trial accounts which are password protected.

5.2 Query Resolution

- Data queries can be either automatic or generated by a Sponsor or study monitor after data verification. Pop-up queries or query icons should be checked frequently and a response provided within the required trial timelines.
- Queries in the CRF should reflect a full audit trail of queries raised and resolved, such that it can be retrieved and reported.
- If a query is unclear, or if more information is required, the study monitor should be contacted for further clarification.
- Once all data are verified and clean, the Sponsor will lock the participant data entered into the CRFs. The PI will review and approve the entered data by signing the specific field in the CRF.

5.3 Protection of Electronic Data / eCRFs

- A unique, confidential user ID and password will be issued by the Sponsor or system service provider to each designated EDC user. The EDC user must ensure he/she has received a user ID and password before the trial starts.
- For security reasons, the EDC users should not disclose their user ID/password to anyone else for any purpose.
- When a member of the trial team, leaves a trial, the Sponsor should be notified to ensure their access to the CRF is removed.

6. REFERENCES:

1. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

N/A

7.2 Related SOPs

- SOP-TM-07 Source Document Management
- SOP-Glossary-of-Terms

8. VERSION CONTROL

Document History	
Version	Summary of Changes
1.0	N/A First Issue

9. APPENDIX

N/A