STANDARD OPERATING PROCEDURE

CLINICAL TRIAL PARTICIPANTS & PREGNANCY S47

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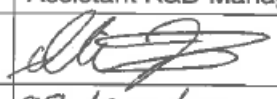
Signature	
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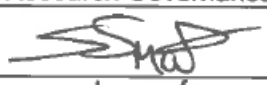
Signature	
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Controlled document

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It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

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Full History			
Version	**Date**	**Author**	**Reason**
V1.0	04 August 2011	Tracey Hill, PenCLRN Portfolio Coordinator	
V1.1	23 April 2014	Tracey Hill, PenCLRN Portfolio Coordinator	Link updated in section 6.
V2	9th August 2018	Assistant R&D Manager	Put on new template. Minor clarifications of process

Associated Trust Policies/ Procedural documents:	Research & Development Policy R&D SOP S22 Safety Reporting R&D SOP S04 Auditing Processes in R&D
Key Words:	Pregnancy CTIMP SAE

In consultation with:

- Local Research Meeting (April 2018)
- Quality Assurance Group (April 2018)

Contents

1 INTRODUCTION

In order to comply with the Medicines for Human Use (Clinical Trials) Regulations and Standards for Good Clinical Practice (GCP), it is important that all researchers are aware of the different definitions related to adverse events in research and how to record, report and review each of these specific occurrences.

Pregnancy occurring in participant in a Clinical Trial of Investigational Medicinal Product (CTIMP), while not considered an Adverse Event (AE) or Serious Adverse Event (SAE) requires monitoring and follow-up. The Investigator must collect pregnancy information for female trial subjects or female partners of male trial subjects. This includes subjects who become pregnant while participating in a CTIMP or during a stage where the foetus could have been exposed to the investigational medicinal product (e.g. if the active substance or one of its metabolites have a long half-life).

2. PURPOSE

This SOP describes the procedure for identifying and recording and reporting pregnancy events whilst patients are participating in a clinical trial.

3. SCOPE

This SOP is applicable to CTIMP research recruiting female trial subjects or female partners of male trial subjects who may become pregnant. This SOP applies to all researchers and Research & Development (R&D) personnel working on such a CTIMP.

4. DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HRA	Health Research Authority
ICH	International Conference on Harmonization
PI	Principal Investigator
R&D	Research and Development
RD&E	Royal Devon & Exeter (NHS Foundation Trust)
SOP	Standard Operating Procedure
Sponsor	An individual, company, institution or organisation which takes responsibility for the initiation, management and financing of a clinical trial. Sponsorship activities may be delegated to the Investigator, CTU and/ or other organisations as appropriate

5. DUTIES AND RESPONSIBILITIES OF STAFF

The **Investigator** has responsibility for ensuring that the rights, dignity, safety and wellbeing of the research subject are given priority at all times and to ensure the safety of all staff and other research subjects.

All **trials staff and clinicians** in contact with patients are responsible for noting adverse events, to include pregnancy, that are reported by the patient and making them known to appropriate medical staff. Patients entered into clinical trials must be encouraged from the outset of any study to contact their Research nurse/team at the time of an event occurring.

Trust R&D Office will record and ensure follow up of all pregnancies that occur during a CTIMP.

The **Sponsor** retains overall responsibility for the trial and the accurate identification,

recording and follow-up of pregnancies on a CTIMP.

6. PROCEDURES

Unexpected pregnancies must be reported to the Sponsor who will retain a separate record of the event on their pharmacovigilance database. Should a participant become pregnant while taking part in a clinical trial of an investigational medicinal product, the participant should be withdrawn from the trial where pregnancy is an exclusion criterion. The participant must be followed-up no less than 18 months after completion of the trial to verify whether there are any congenital anomalies or birth defects.

For further details, all trial protocols should describe in detail the process for monitoring and managing pregnancy occurrences in a trial.

Pregnancy occurring in a participant or in a female partner of a male participant in a Clinical Trial of Investigational Medicinal Product (CTIMP), whilst not considered a Serious Adverse Event, does require monitoring and follow up by the investigator. The Chief Investigator (CI) (Trust-sponsored) or Principal investigator (PI) (Trust-hosted trial) must collect all information to determine outcome, including spontaneous or voluntary termination, details of birth, and the presence or absence of birth defects, congenital abnormalities, or maternal and/or newborn complications.

In Trust-sponsored CTIMPs, any pregnancy should be reported by the CI to R&D (on behalf of the sponsor) using the R&D Pregnancy on a clinical trial form' and followed up using the follow up form.

In Trust-hosted CTIMPs, any pregnancy should be reported by the PI to their sponsor on the study specific forms or, if not available, using the R&D forms specified above. In addition to reporting to the sponsor, the PI should provide a copy to R&D.

Any occurrences that result in an SAE should also be reported as per SOP S22 Safety Reporting.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the Trust intranet and external website shortly after having been released.

7.2 All staff whose activities are subject to this SOP should ensure that they take time to read and understand the content of this SOP.

7.3 As applicable, the training log within the Investigator Site File/ Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.

8. MONITORING COMPLIANCE AND EFFECTIVESS OF THIS SOP

8.1 This SOP will be audited in line with S04 Auditing processes in R&D.

8.2 Outcomes from audit will be presented to the R&D Quality Assurance Group which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to the R&D Divisional Governance Group.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the Trust Intranet.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

UK policy framework for health and social care research https://rderesearch.co.uk/wp-content/uploads/2018/02/uk-policy-framework-health-social-care-research.pdf

Templates – FRM46 Pregnancy Whilst on a Clinical Trial – Notification Form
FRM47 Pregnancy Whilst on a Clinical Trial – Follow Up Form