Document Title: Clinical Trial Participants and Pregnancy

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Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
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Summary of Amendments

Version Number	Modification:
1.0	New SOP to be reviewed
2.0	Minor administrative changes. Patient changed to participant. Reviewed for changes in regards to the new clinical trial R3 regs.

Key related documents:	Trust Policy DN001 Document Control Procedures SOP012 Adverse Event Reporting FRM079 Notification of Pregnancy in a CTIMP FRM080 Pregnancy on a Clinical Trial – Follow up form

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff for the procedure for identifying and recording and reporting pregnancy events whilst patients are participating in a clinical trial.
- The SOP is applicable to Clinical Trial of Investigational Medicinal Product (CTIMP) research recruiting female trial participants or female partners of male trial participants who may become pregnant. This SOP applies to all researchers and Research & Development (R&D) personnel working on such a CTIMP.

1 Purpose and Contents

a. This document defines the Trust's research procedures for the receiving of informed consent to follow up pregnant female study participants or the pregnant partner of a male study participant.

b. The document details the process for reporting, duration of follow up and documents required for the reporting of pregnancy.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust.

b. It is the responsibility of all personnel involved in research at the Trust to ensure that they are familiar with and adhere to all current SOPs and have signed on IQM to confirm that the relevant SOP's have been read.

c. The Principal Investigator of a research study is responsible for ensuring that every effort is made to gain informed consent for the follow up of a pregnancy. The actual procedure may be delegated to a responsible member of the research team deemed appropriately qualified by knowledge and training.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with it may result in disciplinary procedures.

4 Procedure

4.1 Duty and Responsibility of Staff

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

b. All trials staff and clinicians in contact with study participants are responsible for documenting adverse events to include pregnancy.

c. Participants entered into clinical trials must be encouraged from the outset of any study to contact their Research Nurse/Team at the time of a pregnancy event occurring.

d. Trials staff will record and ensure follow up of all pregnancies that occur during a CTIMP study.

e. The Sponsor retains overall responsibility for the trial and the accurate identification, recording and follow-up of pregnancies on a CTIMP study.

4.2 Procedures for recording a Pregnancy

Although pregnancy itself is not considered an adverse event or a serious adverse event, the pregnant participant or the female partner of a male participant must be followed up until 6 months postpartum to ensure absence of congenital anomaly or birth defect that may have resulted from maternal exposure or transmission of the study drug via semen following paternal exposure. The following procedures should be completed:

a. All pregnancies must be reported to the Sponsor.

b. Should a participant or their female partner become pregnant while taking part in a clinical trial of an investigational medicinal product (IMP), the protocol should be followed as to their continued participation.

c. The participant or female partner of a male participant must be followed up until 6 months postpartum to verify whether there are any congenital anomalies or birth defects.

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

e. Pregnancy occurring in a participant or in a female partner of a male participant in a CTIMP, whilst not considered a Serious Adverse Event, does require monitoring and follow up by the investigator.

f. The Chief Investigator (CI) or Principal investigator (PI) 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.

g. In Trust-sponsored CTIMPs, any pregnancy should be reported by the Research Team to R&D (on behalf of the sponsor) using FRM079 (Notification of Pregnancy in a CTIMP) and followed up using the follow up form FRM080 (Pregnancy on a Clinical Trial – Follow up form). This should be submitted to the safety reporting inbox: papworth.safety-reporting@nhs.net. 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.

h. Any occurrences due to pregnancy that result in an SAE should also be reported as per SOP012 Adverse Event Reporting.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken.

SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current approved version date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research version 3.3 (07/11/17) and authorised amendments thereafter.

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Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

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