WORK INSTRUCTION

WI22 – CLINICAL TRIAL PARTICIPANTS & PREGNANCY

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Controlled document

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It is the responsibility of all users of this Work Instruction 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 Work Instruction (WI) must be followed unless a study specific SOP/WI exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
1			New WI to link with S22. S47 has been archived and the content incorporated into S22.

Associated Trust Policies/ Procedural documents:	
Key Words:	R&D Work Instruction Pregnant Pregnancy
In consultation with: Quality Assurance Working Group – June 2022 Lead Research Nurses – June 2022	

Contents

1 INTRODUCTION

Pregnancy occurring in study participants taking part in an Interventional trial, while not considered an Adverse Event (AE) or Serious Adverse Event (SAE) may require monitoring and follow-up. The Investigator must collect pregnancy information for female trial participants or female partners of male trial participants. This includes participants who become pregnant while participating in a Clinical Trial of Investigational Medicinal Product (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). In other interventional research, pregnancy information may be needed to be collected where the intervention may have an impact on pregnancy.

2. PURPOSE

This WI describes the procedure for identifying, recording and reporting pregnancy events for trial participants or partners of trial participants.

3. SCOPE

This WI is applicable to CTIMP and interventional research recruiting female trial participants or female partners of male trial participants who may become pregnant. This WI applies to all researchers and Research & Development (R&D) personnel working on such a trial. Whilst this WI is written for Royal Devon sponsored trials, the WI may be followed in hosted trials where no pregnancy reporting procedures have been included in the Protocol or study paperwork.

4. DEFINITIONS & ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
GOG	R&D Governance Oversight Group
HRA	Health Research Authority
ICH	International Conference on Harmonization
PI	Principal Investigator
R&D	Research & Development
Royal Devon	Royal Devon University Healthcare 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 **Chief Investigator (CI)** (Trust sponsored trial) or **Principal Investigator (PI)** (hosted trial) has responsibility for ensuring that the rights, dignity, safety and wellbeing of the research participant are given priority at all times and to ensure the safety of all staff and other research participants.

The **Clinical Research Delivery Team** in contact with the research participants are responsible for noting safety events, to include pregnancy, that are reported by the participant and making them known to the appropriate medical staff. Research participants are encouraged from the outset of any study to contact their research delivery team at the time of an event occurring.

The **R&D Professional Services Team** is responsible for providing the pregnancy reporting forms and ensuring their accessibility. Furthermore, the recording and follow up of all pregnancies that occur during a relevant trial.

The **Sponsor** retains overall responsibility of study oversight and compliance, including the accurate identification, recording and follow-up of pregnancies on a trial.

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 trial with an intervention that may affect the pregnancy, 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.

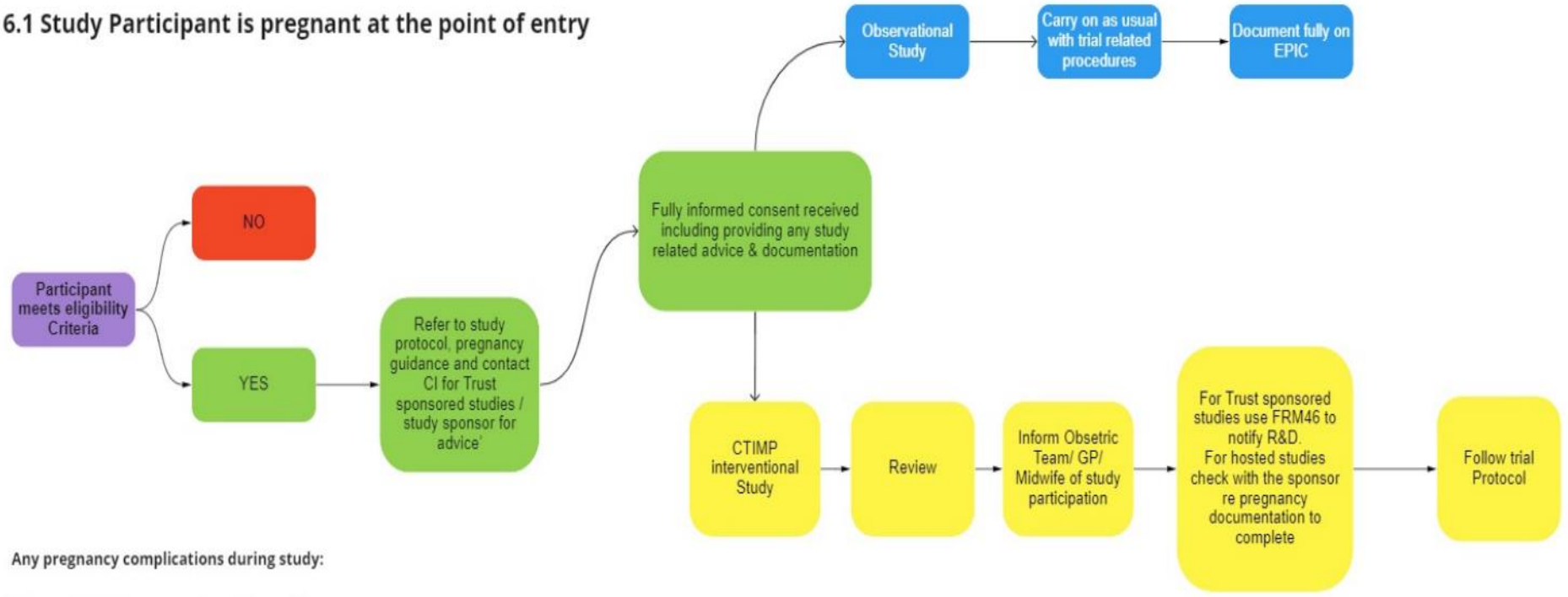
Pregnancy occurring in a participant or in a female partner of a male participant in a trial, whilst not considered a Serious Adverse Event, does require monitoring and follow up by the investigator. The Chief Investigator (CI) (Trust-sponsored) or Principal Investigator (PI) (Trust- hosted trial) must collect all information to determine the 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 interventional trials, any pregnancy should be reported by the CI to R&D (on behalf of the Sponsor) using the R&D FRM46 Pregnancy on a Clinical Trial Notification Form and followed up using R&D FRM47 Pregnancy on a Clinical Trial follow up form.

In Trust-hosted interventional trials, 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.

6.1 Study Participant is pregnant at the point of entry



Any pregnancy complications during study:

> Ensure PI/SUB-I aware and providing guidance
> Document **FULLY**
> Inform sponsor - complete AE/SAE or other sponsor pregnancy notification form (whichever is applicable)
> Use FRM 47 to notify R&D in Trust sponsored Studies
> Inform local obsetric team/ GP
> Follow trust SOP22 - Safety reporting & report to Royal Devon as required
> Carry out any relevant study related procedures.

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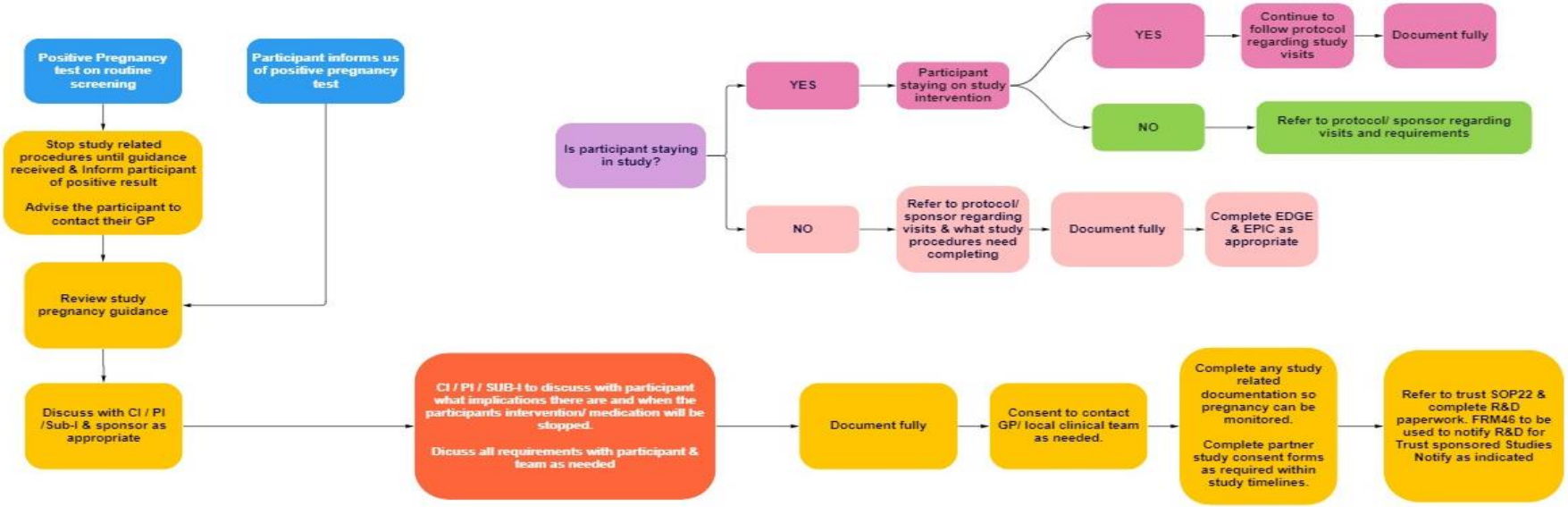
6.2 Participant becomes pregnant during the study



Any pregnancy complications during study:

> Ensure PI/SUB-I aware and providing guidance
> Document **FULLY**
> Inform sponsor - complete AE/SAE or other sponsor pregnancy notification form (whichever is applicable)
> Use FRM 47 to notify R&D in Trust sponsored Studies
> Inform local obsetric team/ GP
> Follow trust SOP22 - Safety reporting & report to Royal Devon as required
> Carry out any relevant study related procedures.

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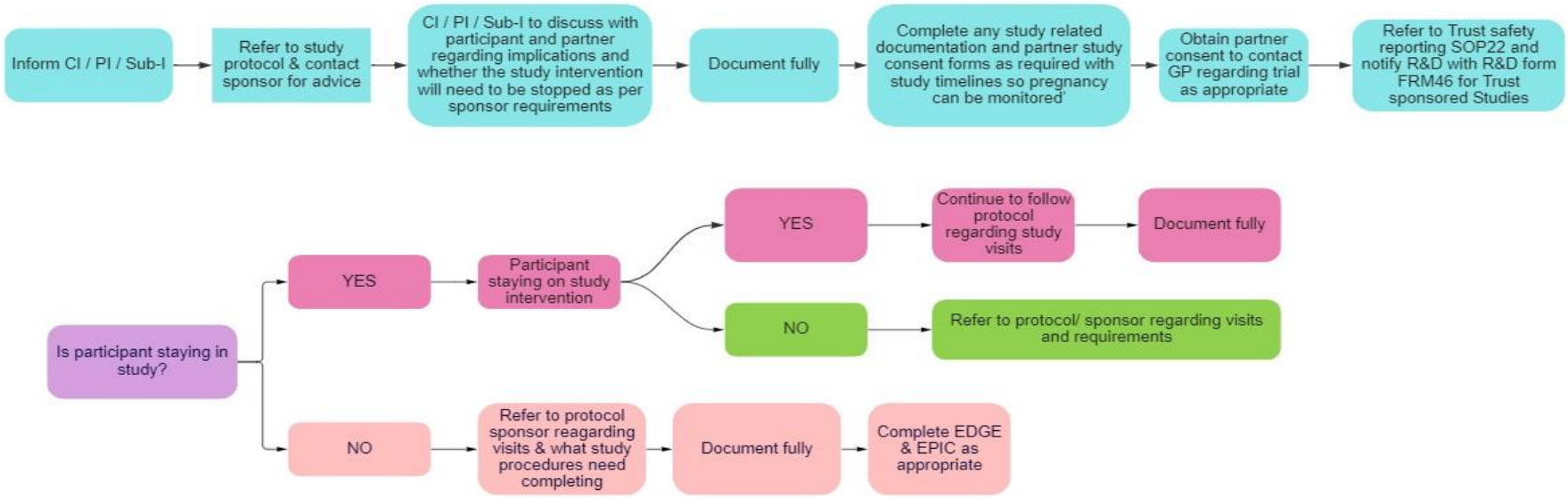
6.3 Study participant's partner becomes pregnant while on study



Any pregnancy complications during study:

> Ensure PI/SUB-I aware and providing guidance
> Document **FULLY**
> Inform sponsor - complete AE/SAE or other sponsor pregnancy notification form (whichever is applicable)
> Use FRM 47 to notify R&D in Trust sponsored Studies
> Inform local obsetric team/ GP
> Follow trust SOP22 - Safety reporting & report to Royal Devon as required
> Carry out any relevant study related procedures.

7. DISSEMINATION AND TRAINING

7.1 This WI and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

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

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS WI

8.1 In order to monitor compliance with this WI, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Pregnancy forms are available and accessible to the research delivery team.	Presence on the RDEResearch website.
2.	Should a participant become pregnant while taking part in an interventional trial, the participant should be withdrawn from the trial where pregnancy is an exclusion criterion.	Monitoring of the exclusion criteria referenced in the study protocol and study withdrawal log in the ISF/TMF/e-TMF.
3.	Pregnancy occurring in a female participant or in a female partner of a male participant in an interventional trial does require monitoring and follow up by the Investigator.	Monitoring the completion of the Pregnancy Notification and Follow-up forms.

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) 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 GOG.

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 RDE Research website.

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