Bradford Teaching Hospitals NHS
NHS Foundation Trust

SITE PRINCIPAL INVESTIGATOR/LOCAL COLLABORATOR

END OF STUDY DECLARATION REPORT

FOR ALL STUDIES

- *To be signed by the Principal Investigator/Local collaborator*
- *To be submitted to the Research Management & Support Office, Bradford Institute for Health Research, Bradford Royal Infirmary, within 15 days of the end of the study or early termination at the Trust; email bradfordresearch.monitoring@bthft.nhs.uk*
- ***Are you ready to submit this form?***

☐ *Yes, sponsor has confirmed study's end date at BTHfT (ie, no further data collection).*
The definition of the end of the study should be documented in the protocol. In most cases, this will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol If you are unsure, contact the sponsor to confirm that the study has ended at BTHfT.

1. Principal Investigator Details

Name:	
Department:	
Contact Details:	

2. Study Details

Short Title:	
Local project reference number (BTHFT No)	

3. **Study Metrics -** Please check the ***Details*** *page on EDGE at the* ***Project Site (Red) Level*** and complete the following chart (definitions below):

	Enter Current Dates on EDGE	Enter your corrections (if any)
Details		
Site Target Recruitment*		
Milestones		
SIV (if applicable)*		
Open to Recruitment*		
Recruitment End Date (Actual)*		
Closed Date*		

If you do not have access to EDGE, please contact x3468 to obtain this information.

**** Key Definitions:***

Site Target Recruitment: *Number of unique participants planned to provide informed consent and be deemed eligible (ie,. excluding screen failures) at the site for the study as jointly agreed between the sponsor and the site.*

SIV (Site Initiation Visit): *Arranged by the sponsor and is the date of a visit by Sponsor to site to initiate the site prior to commencement of recruitment. Formal visit with agenda that covers roles and responsibilities, staff training and review of the protocol procedures. It can be completed by teleconference or other acceptable means.*

Open to Recruitment: *Date that the site is ready to start (ie, recruit study participants, provide data or tissue) defined by all other requirements to start are satisfied.*

Recruitment End Date (Actual)*: Date that the study stopped recruiting participants at the Trust.*

Closed Date: *The date site actually closed, ie the study end date. This is usually the date of the last patient, last visit, or the date data collection ceased. It can also be the date the study ended prematurely and permanently by either the sponsor or the Trust.*

4. Recruitment Metrics

Please provide the following information. Please see ***Key Definitions*** *below*

Actual Recruitment (count): *Please ensure these recruits are uploaded onto EDGE before submitting this form or contact us to enter them in the legacy section if recruited before 1st April 2016 – The recruitment dates below must match what is on EDGE.*	
Date First Participant Consented:	
Date Last Participant Consented:	
First Participant Recruited (*if applicable)*	
Last Participant Recruited (if applicable)	

**** Key Definitions:***

Actual Recruitment: *Total number of study participants recruited into the study at the Trust. For studies that involve a screening process prior to entering the study, then each participant consented and screened and enters the study is counted as one 'recruit'. A participant who signs the consent form but does not progress from screening and does not enter the study is not counted as a 'recruit'. For studies that do not involve a screening process following consent, then all participants that sign the consent form are counted as recruits.*

Date First Participant Consented: *This is the date of the first signed consent form.*

Date Last Participant Consented: *This is the date of the last signed consent form.*

First Participant Recruited *The confirmation of the first participant recruited will be a retrospective verification as it will require the outcome of screening to ensure the participant is eligible for the study before this data point can be captured. Where a participant consents to both screening and entry into a study and they then fail to pass screening, their consent date cannot be used. The next date of consent to participate of an eligible participant will be defined as the first participant. This will more likely apply to studies that involve randomisation, for example, but not exclusively. Please provide the date of consent and not the date of randomisation or entry into the study.*

Last Participant Recruited: *The confirmation of the last participant will be a retrospective verification as it will require the outcome of screening to ensure the participant is eligible for the study before this data point can be captured. Where a participant consents to both screening and entry into a study and they then fail to pass screening, their consent date cannot be used. The previous date of consent to participate of an eligible participant will be defined as the last participant. This will more likely apply to studies that involve randomisation, for example, but not exclusively. Please provide the date of consent and not the date of randomisation or entry into the study.*

5. Recruitment of participants

Did you meet the recruitment target agreed with the sponsor?

☐ YES *Please continue from section 7*

☐ NO *Please complete section 6 and continue from section 7*

6. Reasons for not meeting the agreed recruitment target

Please provide the main reasons why you experienced difficulties in recruiting participants at the Trust below

7. Withdrawals/Completions

Number of participants completing the study at the Trust:	
Number of withdrawals: *(this does not refer to screen failures but participants who were taken off the study after having entered the study)*	
Number of participants withdrawing from the study at the Trust due to: (a) Lack of efficacy (b) Adverse events (c) Self-withdrawal (d) Non-compliance	

8. Early Termination

Did this study terminate prematurely?

☐ NO *Please continue from section 11*

☐ YES *Please complete section 9 & 10 and continue from section 11*

9. What is the justification for this early termination?

e.g. safety, difficulties recruiting participants, trial has not commenced, other reasons

10. Implications for research participants as a result of early termination.

What are the potential implications for research participants as a result of terminating the study prematurely?
Please describe the steps taken to address them below

11. Temporary Halt

Was there ever a temporary halt to the study?

☐ NO *Please continue from section 14*

☐ YES *Please complete sections 12 & 13 and continue from section 14*

12. Justification for the temporary halt

What was the justification for temporarily halting the study? *Please explain below:*

13. Implications for research participants as a result of this temporary halt

What are the potential implications for research participants as a result of temporarily halting the study?
Please describe these and the steps taken to address them below:

14. Safety of participants *(circle/highlight your answer)*

Have there been any serious adverse events (SAEs) to participants at the Trust?	YES / NO / Not applicable
Have these SAEs been notified to the Sponsor?	YES / NO / Not applicable
Have any concerns arisen about the safety or welfare of participants in this study at the Trust?	YES / NO / Not applicable *If yes, give details below and say how the concerns have been addressed.*

15. Study's Essential Documentation

Who is responsible for the site file, case report forms and other essential documentation?	
Where is the site file, CRFs and the essential documentation stored? Please provide full postal address & contact details of the archive.	
How long will the site file, CRFs, and the essential documentation, be kept for? (minimum of 5 years and thereafter as agreed with sponsor)	
Are you aware you should have an up-to-date archiving log?	YES / NO

16. Study Dissemination and translation into practice

How will research findings be disseminated? (Tick all that apply)	☐ Peer reviewed journal ☐ Scientific conference abstract ☐ Scientific conference poster ☐ Printed press ☐ Internet articles ☐ Project website ☐ Written feedback to participants and other interested groups or communities ☐ Participant Event ☐ Newsletter ☐ Databank ☐ Public Database ☐ Other (please specify):
What was the purpose of this research project (Tick all that apply)	☐ To increase knowledge & evidence of the subject ☐ To change standard clinical care practice ☐ To enable further research ☐ To undertake a PHD or other educational qualification ☐ Other (please specify):

Are you aware that you should forward any current or future publications arising from this study to the Medical Library?	YES / NO library.service@bthft.nhs.uk

17. Other issues

Have there been any other developments in the study that you wish to report to the Research Management & Support Office?

☐ YES *Please attach a separate statement with details.*
☐ NO

Are there any legal or resource issues on which further advice is required?

☐ YES *Please attach a separate statement with details.*
☐ NO

18. Sponsorship

Is Bradford Teaching Hospitals NHS FT the Sponsor of this study?

☐ YES *Please submit the HRA Declaration of the End of a Study to the HRA and to R&D as well so that we can update the green level in EDGE*
☐ NO *Please continue to the final Declaration in section 19*

Please note that our site end date should not be after the study end date that you will report to the HRA in their Declaration of the End of a Study.

19. Declaration

I confirm that the information provided in this form and on EDGE is complete and true and correspond with each other.

Signature of Principal Investigator/ Local Collaborator	
Print Name	
Date of completion of this report	