

Amendment	Date of REC Favourable Opinion	Document	Description
Amend 1: AM01	17/11/2015	Consent Form V1.2	<ul style="list-style-type: none"> Amendment to reference Couples Information Leaflet Version 2.0 (12/11/2015)
Amend 2: AM02	29/01/2016	Consent Form V1.3 E-Freeze Posters V2.0	<ul style="list-style-type: none"> The terminology in the Consent Form was refined to ensure relevance for Scottish participants. The ISRCTN number has also been added and the explanation for longer term follow-up was condensed to avoid repetition. E-Freeze Poster Version 1.0 (09/09/2015) was given ethical approval as an undesigned version. The poster has now been designed and the wording has been amended slightly to include eligibility criteria and the interventions. The poster has been designed as both a white and green version.
Amend 3: AM03	20/07/2016	GP Letter V1.1 Economic Questionnaire V1.2 Emotions Questionnaire V2.0 Couples Flowchart V1.0 E-Freeze Postcard V1.0 E-Freeze Banner V1.0	<ul style="list-style-type: none"> Three new documents; the Couples Flowchart, E-Freeze Postcard and E-Freeze Banner were approved as part of substantial amendment AM03. The REC Reference was added to the GP Letter. A data logging box was added to the E-Freeze Economic Questionnaire. Minor amends have been made to the E-Freeze Emotions Questionnaire including typographical corrections and a tick box for 'first and second questionnaire' and a logging box on the front page to assist with data entry at the Co-ordinating Centre.
Amend 4: AM04	15/09/2016	Invitation email v1.0 CV for new PI	<ul style="list-style-type: none"> Use of already approved Invitation Letter in email format Change of PI at St Bartholomew's Hospital
Amend 5: AM05	19/12/2016	Joint Endometrial Scratch & E-Freeze Patient Invitation Letter V1.0 Joint Endometrial Scratch & E-Freeze Patient Invitation Letter V1.0 E-Freeze and Endometrial Scratch patient summaries V1.0	<ul style="list-style-type: none"> In several of the E-Freeze recruiting sites a competing NIHR funded trial called Endometrial Scratch is also taking place. This trial is recruiting a similar patient population. The E-Freeze and the Endometrial Scratch teams have created three new joint documents for use with couples in these centres.

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Amend 6: AM06	03/03/2017	E-Freeze Protocol V2.0 Couples Information Leaflet V3.0 E-Freeze Consent Form V2.0 E-Freeze Poster (Green and White) V3.0 E-Freeze Banner V2.0 Couples Flowchart V2.0 E-Freeze Postcard V2.0 E-Freeze Invitation Letter V2.0 E-Freeze Invitation Email V2.0 E-Freeze CCG Letter V2.0 E-Freeze GP Letter V2.0 E-Freeze Pregnancy Card V1.0 Notification of New PIC Site (Leighton)	<ul style="list-style-type: none"> The eligibility criteria for the E-Freeze trial have been amended, couples going through their second and third egg collection will now also be able to take part. The E-Freeze Protocol and several of the supporting documents for the trial have been updated to reflect the new eligibility criteria. A new document called the Pregnancy Card has been created, this is to be provided to couples that have a positive pregnancy test to inform them of the dates when they will be contacted for follow-up data collection. Leighton Hospital will be acting as a Participant Identification Centre.
Amend 7: AM07	06/04/2017	N/A	<ul style="list-style-type: none"> Change to PI at Liverpool Women's Hospital Addition of new centre, Queen's Hospital Romford
Amend 8: AM08	04/09/2017	N/A	<ul style="list-style-type: none"> Change of PI at Princess Anne, Southampton
Amend 9: AM09	05/12/2017	N/A	<ul style="list-style-type: none"> Addition of new centre, Countess of Chester
Amend 10: AM10	06/12/2017	N/A	<ul style="list-style-type: none"> Extension of recruitment end date
Amend 11: AM11	09/01/2018	E-Freeze Couples Podcast Interview Guide V1.0 Podcast Invitation Email V1.0 Podcast Card V1.0 Podcast Return Slip V1.0	<ul style="list-style-type: none"> Documents inviting couples that have completed E-Freeze and had a baby, to take part in a podcast about what it is like participating in the study.
Amend 12 AM 12	19/03/2018	N/A	<ul style="list-style-type: none"> Change of PI at Birmingham Women's and Children's Hospital
Amend 13 AM13	27/07/2018	E-Freeze Couples Podcast V1.0	<ul style="list-style-type: none"> Approval of E-Freeze Couples Podcast, for use on the E-Freeze trial website.
Amend 14 AM14	02/10/2018	N/A	<ul style="list-style-type: none"> Addition of new centre, ULCH.
Amend 15: AM15	N/A	N/A	<ul style="list-style-type: none"> Change of Trial Manager from Christina Cole to Fiona Goodgame Minor amendments do not require REC approval
Amend 16: AM16	N/A	N/A	<ul style="list-style-type: none"> Notification of HTA approval for contract variation for a 12 month funded follow up. E-Freeze end date extended from 31/07/2019 to 31/07/2020 Minor amendments do not require REC approval

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Amend 17: AM17	N/A	N/A	<ul style="list-style-type: none"> Change of Trial Manager from Fiona Goodgame to Vasha Bari Minor amendments do not require REC approval
Amend 18 AM18	N/A	N/A	<ul style="list-style-type: none"> Notification of 6 month extension to grant end date from 31/07/2020 to 31/01/2021. Minor amendments do not require REC approval