Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE : UK

B TRIAL IDENTIFICATION

B.1 EudraCT number : 2007-005080-10
B.2 Sponsor's protocol code number: UHL 10467
B.3 Full title of the trial: Irregular vaginal bleeding with etonorgestrel contraceptive implant - A pilot randomised controlled trial of prophylactic down regulation with a Gonadotrophin releasing hormone analogue prior to implant insertion.

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	☐
C.1.1	Sponsor	X
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below:**	
C.1.4.1	Organisation : University Hospitals of Leicester MHS Trust	
C.1.4.2	Name of person to contact : Carolyn Maloney	
C.1.4.3	Address: R&D Office Leicester General Hospital Gwendolen Road Leicester LE5 4PW	
C.1.4.4	Telephone number : 0116 258 4109	
C.1.4.5	Fax number : 0116 258 4226	
C.1.4.6	E-mail carolyn.maloney@uhl-tr.nhs.uk	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	X
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
	• Co-ordinating investigator (for multicentre trial):	☐
	• Principal investigator (for single centre trial):	☐
C.2.5	**Complete below** :	
C.2.5.1	Organisation: University Hospitals of Leicester NHS Trust	
C.2.5.2	Name : Carolyn Maloney	
C.2.5.3	Address : R&D Office Leicester General Hospital Gwendolen Road Leicester LE5 4PW	
C.2.5.4	Telephone number :0116 258 4109	
C.2.5.5	Fax number :0116 258 4226	
C.2.5.6	E-mail : carolyn.maloney@uhl-tr.nhs.uk	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial?**
D.1.1	(YYYY/MM/DD): 2013/12/31

D.2	**Is it an early termination?[3]**	yes X no ☐

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.
2 According to national legislation.
3 Cf. Section 4.2. of the detailed guidance CT-1.

D.2.1	If yes, give date : 2013/12/31
D.2.1.1	Briefly describe in an annex (free text): The study originally opened in 2008. There have been set backs with recruitment including no personnel to run the study, and now the service has been moved to a different provider. In June 2013, the team were given a further six months to attempt to get the study off the ground, but there remains no recruitment. The Sponsor has therefore made the decision to close the study.
D.2.1.2	The justification for early termination of the trial; Zero recruitment since 2008.
D.2.1.3	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; Zero
D.2.1.4	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product. None as no recruitment

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[4]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1) ☑
E.2.1	Date : 9/1/14
E.2.2	Signature : Caby Maloney
E.2.3	Print name: CAROLYN MALONEY

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) : ☑
E.3.1	Date : 9/1/14
E.3.2	Signature : Caby Maloney
E.3.3	Print name: CAROLYN MALONEY,

[4] Section 4.3. of the detailed guidance CT-1.