

## Welcome to the Integrated Research Application System

## IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

**Please enter a short title for this project** (maximum 70 characters)  
United Kingdom Adult Idiopathic Thrombocytopenic Purpura(ITP) Registry

**REC details:**

Name of main REC:  
NRES Committe London - Central

REC Reference Number:  
07/H0718/57

NRES form lock code:

**1. Select one category from the list below:**

- Clinical trial of an investigational medicinal product
- Study only involving data or tissues not identifiable to the researcher

**If your work does not fit any of these categories, select the option below:**

- Other study

**2. Does the study involve the use of any ionising radiation?**

- Yes  No

**3. In which countries of the UK will the research sites be located?(Tick all that apply)**

- England
- Scotland
- Wales
- Northern Ireland

**3a. In which country of the UK will the lead NHS R&D office be located:**

- England
- Scotland
- Wales
- Northern Ireland
- This study does not involve the NHS

**4. Do you plan to include any participants who are children?** Yes  No**5. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity?** Yes  No

*Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.*

**6. Is the study or any part of it being undertaken as an educational project?** Yes  No

**NOTICE OF SUBSTANTIAL AMENDMENT**

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).

The form should be completed by the Chief Investigator using language comprehensible to a lay person.

**Details of Chief Investigator:**

	Title Forename/Initials Surname
	Dr Vickie McDonald
Work Address	Pathology and Pharmacy Building 80 Newark Street London
PostCode	E1 2ES
Email	Vickie.McDonald@bartshealth.nhs.uk
Telephone	02032460338
Fax	02032460230

<b>Full title of study:</b>	United Kingdom Adult Idiopathic Thrombocytopenic Purpura (ITP) Registry: An Investigation of disease progression, treatment effectiveness and co-morbid conditions.
<b>Lead sponsor:</b>	Barts Health NHS Trust
<b>Name of REC:</b>	NRES Committe London - Central
<b>REC reference number:</b>	07/H0718/57
<b>Name of lead R&amp;D office:</b>	JRMO Barts Health
<b>Date study commenced:</b>	17/10/2007
<b>Protocol reference (if applicable), current version and date:</b>	UKITPR Study Protocol, version 2.3, 16/05/2018
<b>Amendment number and date:</b>	Amendment 6, 16/05/2018

**Type of amendment**

(a) Amendment to information previously given in IRAS

Yes  No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.  
completed below

(b) Amendment to the protocol

Yes  No

If yes, please submit *either* the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

revised protocol is attached

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

Yes  No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

revised documents attached

#### Is this a modified version of an amendment previously notified and not approved?

Yes  No

If yes, please explain the modifications made under "Summary of changes" below

N/a

#### Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

1. Change of Chief investigator
2. Removal of option to consent via invitation pack from the registry team at the Royal London Hospital, consent will be taken by the local site
3. GP data collection and entry by the local site rather than the registry team
4. Addition of the pregnancy database with Dr Sue Robinson as sub-investigator for this section
5. Simplification of the number of forms and information sheets
6. Reduction in amount of blood to be collected (from 15ml to 4-8ml/single EDTA tube)
7. Only patients from the Royal London Hospital will be invited to take part in a sub-study looking at platelet functionality and immunological profiling

#### Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

Nil

#### List of enclosed documents

Document	Version	Date
UKITPR Substantial Amendment 6_Cover Letter	-	16/05/2018
1 UKITPR Study Protocol	2.3	16/05/2018
2 UKITPR Prospective Participant Overview	3.2	16/05/2018
3 UKITPR Pregnancy Prospective Participant Overview	1.0	16/05/2018
4 UKITPR Study Informed Consent Agreement	4.4	16/05/2018
5 UKITPR Pregnancy Study Informed Consent Agreement	1.0	16/05/2018
6 UKITPR Initial Data Collection Sheet	2.5	16/05/2018
7 UKITPR Follow-up Information Sheet	1.9	16/05/2018
8 UKITPR General Practitioner Letter template	1.2	16/05/2018

9 UKITPR GP Proforma (Data Collection Sheet)	1.2	16/05/2018
10 UKITPR Pregnancy Registration Sheet	1.0	16/05/2018
11 UKITPR Pregnancy Status and Outcome Sheet	1.0	16/05/2018
12 UKITPR Local Participant Log (April 2018)	-	16/05/2018
13 UKITPR Centre Delegation Log (April 2018)	-	16/05/2018
14 ITPR Prospective Control Participant Overview UK	1.0	16/05/2018
15 ITPR Control Informed Consent Agreement UK	1.0	16/05/2018

**Declaration by Chief Investigator**

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*

2. *I consider that it would be reasonable for the proposed amendment to be implemented.*

Date of submission: 18/05/2018 .....

Signature:  .....

**Declaration by the sponsor's representative**

*I confirm the sponsor's support for this substantial amendment.*

Signature: .....

Print Name: .....

Post: .....

Organisation: Barts Health NHS Trust

Date: (dd/mm/yyyy)

**Does this amendment involve new types of exposure or increased exposure to ionising radiation?**

Yes     No

*If Yes, please provide details below:*

**Does this amendment involve inclusion of adults lacking capacity or a change to the arrangements relating to adults lacking capacity?**

Yes  No

*If Yes, please provide details below:*

**Declaration by Sponsor's Representative**

This section was signed electronically by Dr Mays Jawad on 18/05/2018 10:19.

Job Title/Post: Director of Research Services and Business Development

Organisation: Barts Health NHS Trust

Email: sponsorsrep@bartshealth.nhs.uk