

UKITP README (2.1)

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Readme: Instructions for Filing for Local R&D Approval *UK Adult Immune Thrombocytopenic Purpura (ITP) Registry*

We would like to thank you for your interest in taking part in the UK Adult Immune Thrombocytopenic Purpura (ITP) Registry. The London Research Ethics Committee (REC) has exempted this study from site-specific assessment (SSA), so local R&D committees will simply be confirming that the submitted study documentation is complete and ensuring that appropriate resources are in place to conduct the proposed investigation. We anticipate that such a review will take approximately four weeks. The process for obtaining local R&D approval is straightforward and entails the following steps.

- (1) Download, save, and print the following study documents
 - (a) **NRES Application**
 - (b) **Study Protocol 2.2**
 - (c) **Prospective Participant Overview 3.1**
 - (d) **Haematologist Overview 2.4**
 - (e) **Initial Information Sheet 2.3**
 - (f) **Follow Up/Update Information Sheet 1.8**
 - (g) **Study Informed Consent Agreement 4.3**
 - (h) **Subsequent Tissue Usage Informed Consent Agreement 1.6**
 - (i) **BLT Sponsorship Approval**
 - (j) **Provisional R&D Approval**
 - (k) **Final R&D Approval**
 - (l) **Provisional London REC Approval**
 - (m) **Final London REC Approval**
- (2) Download, save, and open the **UKITP Cover Letter Template 1.8**. Insert centre, consultant, and R&D committee specific information in the relevant highlighted fields in blue. Save, print, and sign this document. *Note: Feel free to disregard this template and to use your own cover letter*
- (3) Mail this paperwork to your local R&D committee
- (4) Fax a copy of the signed cover letter to our Lead Epidemiologist, Mr Umesh Doobaree, at +44 (0) 203 246 0230

Should you have any questions or concerns, please do not hesitate to contact the registry's Data Manager and Study Coordinator, Mr Raghava Nandigam, via email (uk-itp.registryteam@nhs.net) or phone +44 (0) 207 377 7000, extension 61114. Once again, thank you for your participation. We look forward to registering your patients once your local R&D committee has issued its approval.

Yours sincerely,

The UK Adult ITP Registry Team

Revised 22nd February 2017