UKITPR STUDY INFORMED CONSENT AGREEMENT (6.05.1)

Site address and contact details here

Barts and The London School of Medicine and Dentistry

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Study Informed Consent Agreement

UK Adult Idiopathic Thrombocytopenia (ITP) Registry

Please initial boxes

1. I confirm that I have read and understand the ~~Prospective~~ Participant Information Sheet~~Overview~~ of the UK Adult Immune ~~Idiopathic~~ Thrombocytopenia (ITP) Registry (version 45.0) and have had the opportunity to address any questions or concerns that I had regarding the study.

2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time without giving any reason and without my medical care or legal rights being affected.

3. I understand ~~that ITP related~~ relevant sections of ~~information from~~ my medical records may be extracted by responsible individuals comprising my clinical care team or the chief investigator's study team. I give permission for these individuals to have access to my medical records.

4. As part of keeping my records complete and up-to-date at the registry, I give permission to the chief investigator's study team to obtain study-related information:

a. From my Summary Care Records

b. From my General Practitioner

c. Through the Data Linkage Services provided by the NHS's Health and Social Care Information Centre or NHS Digital.

5. The UK ITP Registry may collaborate with fellow researchers outside of Queen Mary University of London ~~if expertise and facilities not available at the University are required (e.g. certain DNA analysis, bioinformatics, etc)~~. If this collaboration is ~~deemed~~ necessary, I agree that the UK ITP Registry may enter into a data sharing agreement with these researchers where anonymised information may be shared for a defined period of time.

6. I agree to take part in the UK ITP Registry.

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7. I agree to donate 4-8 ml of blood ~~on one occasion~~ for genetic material extraction to allow genetic analysis including whole genome sequencing and RNA sequencing or any novel genomic technologies in the future. ~~for causes, treatment responses and disease associations of ITP.~~ Prior to genetic material extraction, blood will be stored at The Royal London Hospital. ~~Following extraction, any blood remaining will be disposed of in line with the Human Tissue Authority.~~ The donation of a blood sample may take place at a time after initial consent, according to practical convenience and considerations.

~~a.~~

I consent to the obtaining or transfer and storage of~~–~~ my previously obtained blood, or saliva ~~–~~in a research tissue bank for use in future studies.

a.

b. I agree that the ~~blood or saliva~~tissue as stated above ~~I have supplied~~ may be used for ~~future~~ genetic research

~~b. but not for research involving cloning or for the testing of inherited diseases without my express consent.~~

~~c.~~

~~d.~~ I am aware that I am free to withdraw my consent for the subsequent storage and use of my blood or saliva or other tissue at any time.

c.

8. I agree that the samples I have donated and the information gathered about me can be stored for use in future medical research studies aimed at identifying the interactions between genes, the environment and disease.

~~I understand that this research may include the participation of commercial companies and that I will not benefit financially if this research leads to new treatments or medical tests.~~

9. In the event that an abnormality that has ~~signficance~~significance for my care is picked up from tests carried out on my sample, I agree that my clinical care team or GP can be notified.

Optional Sub-study – Platelet and Immunological Investigation:

~~Royal London Hospital patients only:~~

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8.10. I agree to donate four blood samples of 50ml (10 teaspoons) ~~over a six month period~~ for the sub-study looking at the cells, metabolites, proteins in my blood ~~(optional)~~.

~~Name of Participant~~	~~Date~~	~~Signature~~
Name of Participant	Date	Signature
~~Name of researcher taking consent~~	~~Date~~	~~Signature~~
Name of researcher taking consent	Date	Signature

~~Name of Research Site~~

Name of Research Site

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