

A research study to determine the genetic causes of PSC and childhood autoimmune liver disease

Parent/Guardian Consent Form version 2

Chief Investigator: Dr Palak Trivedi, University of Birmingham

Please confirm that you agree with the statements below, by writing your initials in each box below and on page 2 overleaf. Please make sure in addition you print your name, sign your name and date the consent form.

**Please initial
box:**

1. I, the undersigned, am the parent or legal guardian of the child named below, and I have the authority to execute this Consent Form on behalf of the child.

2. I confirm that I have read and understood the Parent/Guardian Information Sheet (version 2,) for the UK Primary Sclerosing Cholangitis (PSC) Study (which includes children with autoimmune liver disease),, and that my child has read or had read to them the appropriate *Participant Information Sheet* for their age group. I have been given the contact details of the study team. If my child or I had any questions about the study, we were able to contact the study team and our questions were answered.

3. I understand that my child's participation is voluntary and that they are free to withdraw at any time, without giving any reason and without his/her medical care or legal rights being affected. I understand that if I withdraw my child from the study, I can request that my child's samples and clinical data are retained, or that my child's samples are destroyed and all clinical data on him/her is deleted. Following withdrawal from UK PSC, no new information about my child will be added to the research database, and we will not be contacted again.

4. I agree to my child joining the UK PSC Study. I agree to my child donating a sample of blood, from which DNA will be extracted to determine if there are genes that cause childhood autoimmune liver disease. I understand that my child's anonymised DNA sample will be stored indefinitely in an approved and properly regulated biobank for further analysis in future, ethically-approved studies.

5. I agree to my child donating a blood sample, to measure markers in the blood associated with childhood autoimmune liver disease, as outlined in the *Parent/Guardian Information Sheet* and *Participant information* sheets. I understand that my anonymised serum sample will be stored indefinitely in an approved and properly regulated biorepository for further analysis in future, ethically-approved studies.

6. I agree to be contacted no more frequently than every twelve months, to be asked that my child provides a further blood sample and/or updates their health information, as a follow-up of their autoimmune liver disease.

7. I understand that the study team will obtain information about my child's health and major life events from their medical records held by their hospital and GP surgery, and their medical records stored in NHS data centres. I understand that the study team will use my child's NHS (or CHI) number to obtain this information. I give my permission for the study team to have access to my child's medical records, now and in the future.

8. I understand that information collected about my child will be stored in the UK PSC Database. Identifiable information about my child (such as their name and NHS or CHI number) will be destroyed ten years after the study has ended. However, non-identifiable information about my child (such as results of medical investigations) will be retained indefinitely for further analysis in future, ethically-approved studies.

9. I understand that the database may be looked at by authorised members of the UK PSC research team, and by regulatory authorities for monitoring purposes (e.g. the Research and Development Department at my child's hospital or regulatory authorities from Cambridge University Hospitals NHS Foundation Trust). I give my permission for these authorised individuals to look at information

collected about my child.

10. If my child has had a liver biopsy in the past, I understand that the study team will request some of this tissue for analysis in the current study. However, my child will not be required to have a biopsy especially for the current study. If my child has had a liver biopsy in the past, I give my permission for the study team to request the report and some of this tissue, if available.

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11. I understand that my child's donated samples and information collected about my child are given to the UK PSC Study, as an absolute and non-returnable gift, meaning without conditions and without receiving payment.

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12. If the study team finds that my child has a genetic abnormality known to cause a particular disease, I understand that they will inform his/her liver doctor, who will discuss the finding with us. I give my permission for the study team to inform my child's liver doctor of particular genetic abnormalities they might find (If you do not want to be made aware of particular genetic abnormalities, please leave this box empty).

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13. I give my permission for my child's anonymised DNA samples and anonymised serum samples to be shared with other researchers in the UK and abroad, subject to approval by a Sample Access Committee

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14. I give my permission for information collected about my child to be shared with other researchers in the UK and abroad, subject to approval by a Data Access Committee.

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15. I give my permission for my child's anonymised genetic information to be stored indefinitely in the European Genome-phenome archive (EGA) and shared with other researchers in the UK and abroad, subject to approval by a Data Access Committee.

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16. I give my permission to be contacted, in order to invite my child to participate in other research studies based on information about him/her stored in the research database. My child and I will be provided with age-appropriate information about these studies. (If you do not want to be contacted about other research studies, please leave this box empty).

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Name of parent/guardian (PRINT)

Signature

Date

Relationship to child

Name of researcher (PRINT)

Signature

Date