

The UK PSC Study: Participant Consent Form version 4

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 confirm that I have read and understood the participant information sheet (version 7) for the UK PSC Study. I have been given the contact details of the study team. If I had any questions about the study, I was able to contact the study team and my questions were answered.

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

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3. I agree to join the UK PSC Study. I agree to donate a sample of blood, from which DNA will be extracted to determine if there are genes that cause PSC. I understand that my anonymised DNA sample will be stored indefinitely in an approved and properly regulated biorepository for further analysis in future, ethically-approved studies.

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4. I agree to donate a second blood sample, to measure markers in the blood associated with PSC, as outlined in the Participant information sheet (version 7). 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.

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5. I agree to be contacted by the study team, no more frequently than every twelve months, to be asked to provide a further blood sample and/or update my health information, as a follow-up of my PSC

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

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

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8. 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 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 me.

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9. If I have undergone 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, I will not be required to have a biopsy especially for the current study. If I have undergone 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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10. I understand that my donated samples and information collected about me 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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11. I understand that if I am found to have a particular genetic abnormality known to cause a particular disease, the study team will inform my liver doctor, who will discuss the finding with me. I give my permission for the study team to inform my 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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12. I give my permission for my 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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13. I give my permission for information collected about me to be shared with other researchers in the UK and abroad, subject to approval by a Data Access Committee.

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

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15. I give my permission to be contacted and invited to participate in other research studies based on information about me stored in the UK PSC database. (If you do not want to be contacted about other research studies, please leave this box empty.)

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Name of participant

Signature of participant

Date

Name of researcher (optional)

Signature of researcher (optional)

Date