Drug-induced Liver Injury Study

Participant Consent Form

Version: COST template Date: 13-10-19

Pro-Euro-DILI Registry: Creation of a multicenter and multidisciplinary European registry of prospective drug-induced liver injury cases (Pro-Euro-DILI Registry)

Principal Investigator:

Patient Study ID: _____ Initials: _____

Patient initial each box:

1. I confirm that I have read and understand the information sheet dated _____ (version ___) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that if I withdraw from the above study, some anonymised samples and data already processed and used may still be used in the final analyses. ☐
3. I consent to the collection and storage of my personal information and health data and follow-up for the purposes of this International study. I understand that any information that could identify me will be kept strictly confidential and that no identifiable personal information will be shared or included in the study report or publications. I give permission for anonymized data collected to be stored in the secure Pro-Euro-DILI registry databases and used in future research by collaborators worldwide. I understand that my medical records may be looked at by authorised individuals from the Regulatory Authority, the Sponsor for the study and the study governance/audit team in order to check that the study is being carried out correctly. ☐
4. I consent to donate my blood and will also provide urine and stool samples, if possible, for analysis (urine and stool samples are optional). ☐
5. I consent to the use of any residual liver tissue or blood samples if leftover after my medical diagnosis is completed (if applicable). (This is optional). ☐
6. I agree that my DNA in the samples can be analysed to investigate genetic features (This is optional). ☐
7. I give consent for my anonymized biological samples and anonymized data to be ☐

stored for use in future research projects after the study ends. I give permission for any un-used samples to be transferred to custodianship of the University of Nottingham and stored in the HRA approved NDDC-BRU research tissue bank after the study ends. These will be stored at the University of Nottingham (Nottingham Digestive Diseases Centre) for up to 10 years and can be used for future projects. If you later withdraw your consent, we will notify the research tissue bank and database administrators of your study ID code and they will destroy any remaining samples and stored data (however, some samples and data may have already been utilized). (This is optional).

8. I consent to my personal details being kept in the research database held at the recruiting centre so that I can be contacted about other appropriate research studies. (This is optional). ☐

9. I agree to take part in the study. ☐

| --- | --- | --- |
| Name of participant (print) | Signature | Date |

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| Name of person taking consent (print) | Signature | Date |

Original to be retained and filed in the site file. 1 copy to patient, 1 copy to be scanned and filed in patient's notes