Access to United Kingdom Primary Sjogren's Syndrone Registry Biological Samples

Eligibility

The UKPSSR essentially aims to facilitate high quality research in pSS, therefore all types of research proposals from academic researchers and their industrial collaborating partners from within the UK and outside the UK will be considered with the following exceptions:

(i) animal research

(ii) research into termination of pregnancy or reproductive cloning

Application

(i) All researchers planning to use the samples for research must apply to the steering committee using a standardised application form.

(ii) A steering committee comprising 7 specialists in pSS from across the UK will review the research proposals. (since Sept 2011, 2 lay members have joined the committee)

(iii) The following criteria will be used to assess the research proposals

(a) Scientific merits of the proposed research

(b) Whether the proposed study addresses an unmet need in pSS research and treatment

(c) Whether the proposed research falls within the remits of the objectives of the UKPSSR

(d) Can the project be carried out on "any" pSS cohort?

(iv) All applications will be considered using the same criteria regardless of the types and locations of the research organisations.

(v) Formal approvals will only be granted after the steering committee received written evidence of sufficient funding support, research sponsorship and approvals from relevant regulatory bodies locally.

Samples released to other researchers

(i) No sample will be released to any researcher without a formal, written approval from the steering committee.

(ii) All samples will be released in an anonymised format to the researchers in order to ensure confidentiality and anonymity of the participants.

(iii) A Material Transfer Agreement will be arranged between the UKPSSR and the receiving organisations to ensure that

(a) the samples released to the researchers will be used solely for the specific study approved by the steering committee;
(b) the samples will not be used for other studies or be transferred to other researcher(s) without formal approval by the steering committee;

(c) No copy of the samples will be made by the researchers;

(d) the researcher will either return or destroy all un-used samples upon completion of the study according to the directions given by the UKPSSR;

(e) the researcher will destroy all un-used samples if a participant withdraws her/his consent;

(f) researchers receiving DNA samples will be asked to sign an additional confidentiality agreement to ensure that the use of such samples will be handled in accordance to the principles of the Data Protection Act (1998);

(g) the UKPSSR has the right to request a copy of the raw data generated by the researcher(s) using the samples of the UKPSSR to be added to the registry if the steering committee considers such data will add value or enhance the utility of the registry

(iv) A up-to-date record of samples released to other researchers will be kept by the senior research nurse/technician respectively.

(v) The details of all research projects covered under this application will be reported to the research ethics committee on an annual basis.

(vi) The quantity of samples to be released to each researcher will ideally be based on pilot data. If no pilot data were available, then samples may be released in stages, so that the quantity of samples required for the entire project can be more accurately determined.

(vii) All researchers using the samples must submit a written report to the steering committee within 6 months of the completion of the study. In addition, for research projects of 2 years or longer, an annual interim report on the progress of the project is required.