Essex Partnership University NHS Foundation Trust

Guidance for ‘Localising’ Patient Information Documentation for research studies

The following guidance is intended for localising patient documents that have already been ethically approved. If you require guidance on writing patient documentation from first principles, i.e. prior to initial submission to a Research Ethics Committee, please go to the Health Research Authority website for full guidance and templates. Please follow this link for more information: <http://www.hra-decisiontools.org.uk/consent/>

All patient documentation must be presented on Trust headed paper. Patient documentation normally includes:

* Participant Information Sheet
* Consent Form
* GP Letter

Occasionally studies may utilise posters & flyers to advertise the study, as well as other patient targeted documentation. Please consult the R&D department to find out if these need to be ‘localised’ as well.

The following guide is intended as generic information for researchers ‘localising’ their patient documents. Please consult the Research & Development Department if you require any guidance when completing Patient documentation. <https://eput.nhs.uk/about-us/research/>

R&D comments and guidance are in *green italics* throughout. Actual wording to be inserted is in normal black text.

*Trust Headers*

*Copy and paste the header into your patient document.*

*The full address must appear on Patient Information Sheets, Invitation Letters and GP letters. Only the header is required on Consent Forms.*



*Complaints details are usually given in ‘Part 2’ of the Patient Information Sheet.*

*Standard Complaints paragraph:*

The normal NHS complaints mechanism is available to you if you wish to complain about any aspect of the way you are approached or treated during the course of this study. Formal complaints should be addressed to:

Patient Experience Team

Essex Partnership University NHS Foundation Trust

Trust Headquarters

The Lodge

Lodge Approach

Wickford

Essex, SS11 7XX.

*Contact details for study:*

Principal Investigator: *Please enter PI name, title and contact telephone number (normally their secretary or research secretary)*

Study Nurse / Research assistant / Clinical Studies Officer / Research Delivery Coordinator : *Please enter name and title and contact telephone number*

*Independent Contact for information about taking part in research studies, paragraph:*

Independent information and advice about taking part in research studies is available from the Patient Experience Team office.

How to contact the Patient Experience Team:

1. **By phone:** 01245 546433

This helpline is open Monday to Friday 9am to 5pm. Please leave a message outside these hours and we will contact you as soon as possible.

1. **By email:** epunft.pals@nhs.net

Please do not include any confidential information about your health status or care in any email.

1. **By post:**

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*Consent Form*

*Insert the correct Trust Header at the top of the page. If the Consent form and the PIS are 1 document, please make sure you insert the Trust Header again at the top of the Consent Form. You don’t need to enter the address as well.*

*GP Letter*

*Please insert the correct Trust header and research site address to the GP letter (and any other patient correspondence as advised by the R&D office). Ensure that the Principal Investigator’s name, title and contact telephone number is provided at the bottom of the letter.*

*If you are in any doubt when ‘localising’ your patient documents, please do not hesitate to contact the R&D Department who will be happy to advise you.*