Can patients understand research information leaflets and consent forms?

HRB-TMRN PhD scholar Lydia O' Sullivan's project aims to further our understanding of informed consent and identify how emerging technologies including electronic consent may be used to streamline clinical trials.

This project will include a comprehensive review of the current evidence with regard to both the effectiveness and challenges in informed consent, including quality of informed consent. The consent processes across ongoing clinical research studies will be evaluated, incorporating the perspectives of patients and staff. Strategies to improve the consent process, particularly the use of technology, will be identified. Finally, a study within a trial will be designed to evaluate impact of technology on improve the quality of informed consent.

Lydia has worked as a Clinical Trial Coordinator and a Clinical Research Associate and holds a BSc in Radiation Therapy and a post graduate diploma in Radiotherapy and Oncology.

Lydia is studying under the supervision of Prof Peter Doran (UCD School of Medicine) and Prof Eilish McAuliffe (UCD School of Nursing, Midwifery and Health Systems).

#informedconsent
#trialmethodology
@hrbtmrn @UCDClinRes

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Trials Methodology Research Network

HRB-TMRN PhD scholar Lydia O' Sullivan is looking to receive copies of patient information leaflets and informed consent forms from academic studies, hospital-based research and studies sponsored by pharmaceutical companies.

Rationale for the study: Informed consent is an integral part of maintaining high ethical standards when performing clinical research with human participants. Patient facing documents, including patient information leaflets (PILs) and informed consent forms (ICFs), form a crucial component of the informed consent process. However, the literature has shown that research PILs and ICFs are frequently written at an inappropriate readability level. In particular, research PILs and ICFs have increased in length and continue to do so following the implementation of the General Data Protection Regulations (GDPR). These factors may significantly hinder participants from understanding the relevant information and providing good quality informed consent.

Aim of the study: to assess the readability and understandability of a selection of clinical research PILs and ICFs using a series of validated criteria.

What kind of PILs and ICFs will be included?

In order to carry out a comprehensive analysis, all forms of clinical research documents will be included: interventional, non-interventional and observational studies. We hope to include PILs and ICFs from academic studies, hospital-based research and studies sponsored by pharmaceutical companies. We would be very grateful if you would agree to share with us any PILs and ICFs for any research studies that are ongoing or took place in the last 5 years within your company.

Will this information be kept private?

Documents will be held in the strictest confidence. As the study aims to analyse the PILs and ICFs at an aggregate level, no study, investigator or sponsor will be individually identified in the analysis or any subsequent publications. However, any participant or sponsor can receive a summary of the analysis for their documents upon request.

Who will I send the PILs and ICFs to?

PILs and ICFs can be sent, in pdf format, to **lydia.osullivan@ucdconnect.ie**

Many thanks for your assistance with this project, and if you have any queries, please do not hesitate to contact Lydia.

http://bit.ly/INFORMEDCONSENT2019