IPPOSI

DISCUSSION PAPER

Informed consent

Date of Discussion: June 20th, 2016

Location: Patient and Public Involvement Summer School, University of Limerick, Ireland

Simply but powerfully stated, patient involvement in informed consent is essential to ensure that the process is meaningful for patients. Only by involving patients can the correct conditions be created in which patients have the opportunity, inclination and ability to ask the questions which are important for them and their future health.

Informed consent is a legal requirement, but patient involvement stops consent being treated as a tick-box exercise and opens up a space for dialogue between the patient and the researcher. Within this space, patients and researchers can work together to agree the appropriate approach, language, tone, presentation and dissemination of informed consent. It was also suggested that other patients and researchers might be able to co-learn from experts in the fields of adult literacy and communication.

Managing expectations was identified as an important part of clinical research management, and establishing relationships based on respect and honesty is likely to reduce the need for clarifications at a later date or the emergence of misunderstandings between parties. All too often informed consent perceives the patient as a passive subject, rather than as a potential partner, with the rights of patients taking a back-seat to the research being undertaken.

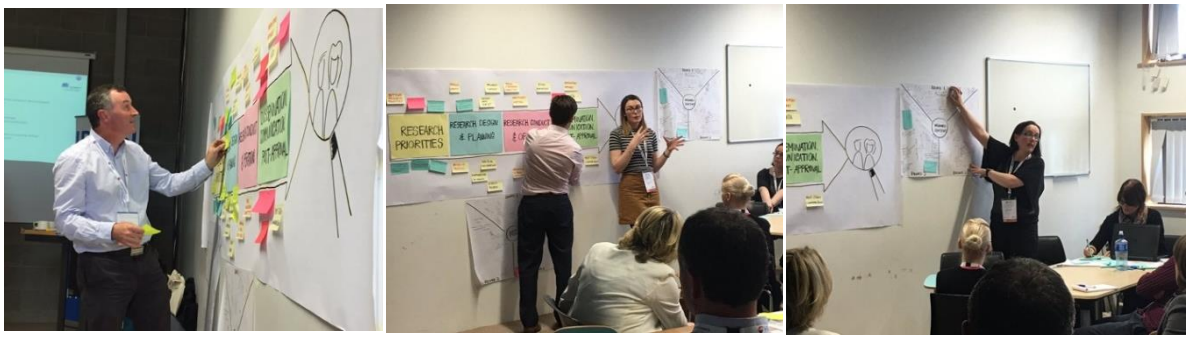
Looking towards the future, it was agreed that a change in the research culture is needed, and careful consideration given to the benefits patients can bring to the research process in general. Many emphasised that by involving patients in the very early research phases, issues around informed consent and other subsequent stages of clinical research may be less likely to happen.

To ignite a change in culture, it was suggested that patients and researchers might agree 'guiding principles' in the form of an Informed Consent Charter which outlines the different rights and responsibilities of both the patient and the researcher. As an example, it was suggested that the Charter might provide more definition around an 'appropriate timeframe' in order to ensure that patient are given sufficient time to review and consider informed consent forms before signing.

This discussion paper was produced from an IPPOSI-facilitated workshop that took place at the PPI Summer School in the University of Limerick, organised by the University's Health Research Institute in June 2016. The workshop was facilitated by Laura Kavanagh and Derick Mitchell of IPPOSI, with three EUPATI fellows: Damien Peelo, COPD Support Ireland; Caitriona Dunne, Fighting Blindness; Rachel Lynch, FibroIreland. Participants included patient and community organisations, health researchers, public research funders and postgraduate students.

Building on this idea, all agreed on the need to abolish tokenism and to embrace meaningful engagement; with *co*-writing informed consent forms *with* patients being put forward as a practical way to overcome current challenges. It was suggested that patients might contribute towards the creation of informed consent summaries and of more interactive ways of exploring informed consent issues, for example using graphics or videos.

Finally, the volunteerism of the patient should be central, and informed consent should incorporate procedures for when patients want to change their consent or withdraw. It was suggested that informed consent be considered as an ongoing and continuous process, not an isolated event. Many underlined the need for repeat explanations and for different support networks including the important role played by clinical trial nurses. A call was made for changes to informed consent forms to be clearly tracked. The conditions of consent should be clear and patients should know whether their consent is for current and/or future research. Some even suggested testing patients to see if they correctly understand the consent they are giving.



Useful resources:

- All outputs from the 2016 workshop are available at the link below: http://www.ipposi.ie/patient-experts-action
- The Irish Platform for Patient Organisations, Science and Industry (IPPOSI) http://ipposi.ie/
- The European Patients' Academy on Therapeutic Innovation (EUPATI) https://eupati.eu

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