Changes in informed consent as a result of the COVID-19 pandemic: examples from two neurology studies

Mark Baker
Research Nurse
Swansea Bay University Health Board
Introduction

BIOJUME
BIOLOGY OF JUVENILE MYOCLONIC EPILEPSY

MND REGISTER
England, Wales & Northern Ireland
Method

**Biology of Juvenile Myoclonic Epilepsy (BIOJUME)**

- Protocol Version 1.9 1st July 2020
- Funder reference: CIHR MOP 142405
- IRAS ID: 199351

- reviewed project protocols before January 2020 and subsequent amendments to BIOJUME in July 2020 and the MND Register in February 2021

- lack of face to face meetings with potential participants, threatened to seriously impact project recruitment during lockdowns.

- new processes were required!
Results – pre COVID PANDEMIC
Results – MND Register

- Section 251 of the NHS Act 2006 was implemented
- Means the MND Register can use patient identifiable data for research and audit without individual patient consent
- GDPR and the Data Protection Act 2018 classifies the data as a “special category” for the use in scientific research in the public interest
- Essentially an opt in / opt out consent model
- In SBUHB we ask the participant’s permission to use their data
- Outside SBUHB patients must state that they wish to opt out
Results – BIOJUME
Conclusion

• examples from non COVID projects that had to modify the consent process

• opt in / opt out model suitable for studies with a very low risk of harm to the participant but is controversial

• multiple consent processes give patients more options

• the studies demonstrate innovation and subsequent resilience of the research delivery team

• We are brilliant professionals!!!!!!!
THE END