

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



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Introduction

BIOJUME
BIOLOGY OF JUVENILE MYOCLONIC
EPILEPSY



Method

Biology of Juvenile Myoclonic Epilepsy (BIOJUME)

Protocol Version 1.9 1st July 2020
Funder reference: CIHR MOP 142405

IRAS ID: 199351

MND Register for England, Wales and Northern Ireland
IRAS Project ID: 282429
V2.0 dated 23.02.2021



- 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

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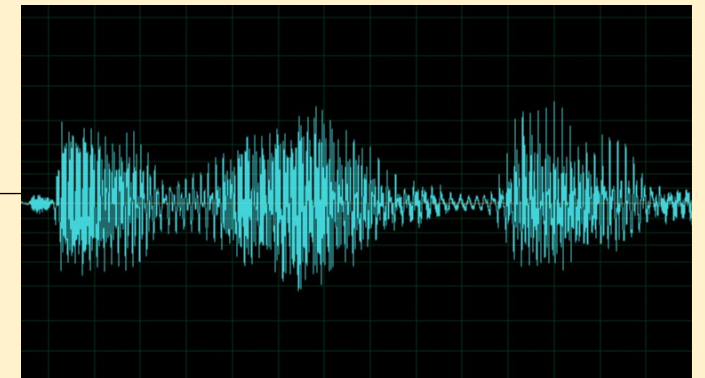
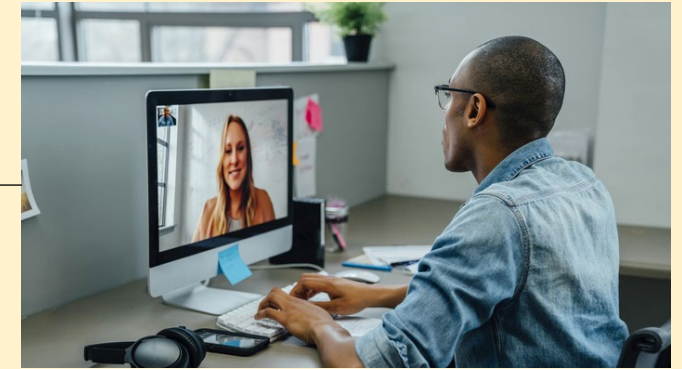
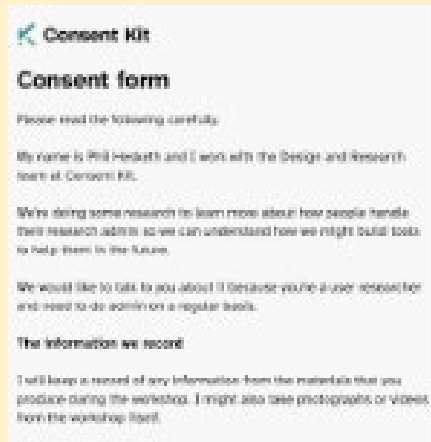


National Health
Service Act 2006

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!!!!!!**

