Online e-consent event – Questions and messages

27 January 2022
Hosted by UKTMN, MRC-NIHR TMRP and UKCRC CTU Network

National survey results	
Were there any concerns about inclusivity?	Yes, there were, especially around access to devices in different demographics
Do we have any idea about patient compliance with IMP after econsent compared to in-person amongst older people?	Short answer is no I don't think we do, certainly not from the survey work. There may well be people who can share experiences from their own CTIMPs. Not from the survey I am afraid, we did ask if trialists had an idea as to the effect on recruitment, retention and compliance, most people felt it was too early to tell
E-consent case studies	
How do you use REDCap to send text messages? Is it linked to another programme?	Yes, we did not make use of the inbuilt Twilio system. We do the same in Leeds. We use an in-house system to schedule and send SMS messages instead of relying on REDCAP's Twilio integration.
Is the email encrypted?	Not at the minute .... it is being worked on though
Our CTU also uses Redcap for econsent - I note you said you utilise REDCAP's repository feature for sites to access the PDF copies, however we've found the file repository can't be filtered by DAG so all consents can be viewed by all sites. How have you managed this?	Consent forms are downloaded through our study management system rather than directly through REDCap
How do you go about getting access to the e-consenting module of REDCAP?	Depending on version it is essentially toggled in the system
How do you send the participant a copy and verify the version of PIS consented to?	This can be done in the survey settings for the form
Has there been concern/problem at sites re using the iPad & the internet /system being allowed by the site IT dept? (Data protection etc)	A few sites haven't wanted an iPad because their Trust IT won't accept them but in general it has been well accepted From our studies, in the main no, some trusts have asked to have the device under their control but that is rare
How do you stop a participant submitted the form more than once? I've seen this happen a lot on another study	They can only submit it once the way we do it as the link in the email is linked to a study ID
How do you send the participant a copy and verify the version of PIS consented to?	The current PIS is always uploaded into REDCap and on the consent form, and a copy is sent with the email with the PDF of the consent form
How do you go about getting access to the e-consenting module of REDCAP?	From a site perspective we will create access on receipt of delegation log, training log and CV & GCP. From our perspective the IT team
How do you handle amendments which include a new version of the e-PIS/ICF when sites implement the new version on different dates?	We control when the updated version of REDCap is released, so we release it with the new version after the 35 days for sites to reject amendments has lapsed and release it to all sites on that date

Main discussion and group feedback	
Has the tick vs putting initials been an issue for anyone? Our e-consent has a tick and signature at the bottom	We use a tick in our e-consent form and that was approved without query - we actually also use a paper consent in which participants still initial too We've done the same in ours (tick and sig) We have tick (yes/ no as radio buttons). Only signature at the end. But non CTIMP.
Has anyone had any practical experience in implementing substantial amendments to Consent documentation whilst econsent is live? To ensure source copies pre amendment are not affected?	Yes, the original pdf generated for first consent was retained so no issue there really. there were other aspects I would have done differently but we managed to do it.
Is it easy to amend the ICF versions once new amendments are submitted/accepted?	As well as updating the Word doc form (if you have) you need to update your data matrix, get the updates programmed, tested, and released then you control when you release new version to sites
Has anyone used e-consent when working with GP practices? How did you find the experience?	Quite positive, though a bit of a learning curve originally! They liked fitting econsent alongside their normal videocall consultation (didn't need to bring the patient in) We are trying with dental practices - early days, but some are keen.
Were GP practices okay to use Redcap. Easy to train?	We had a bespoke system, not Redcap, but the teams got up to speed OK following CTU training and guidance documents. Sites may vary though, as always!
For our CTIMPS consent forms are archived for 25 years... whose responsibility will it be to ensure the electronic consent systems still be accessible in 25 years?	I think it's the same as any electronic archiving, it's up to the archivists to pre-empt anything that will not allow the econsent to be accessed in archives
Has anyone got experience of setting up e-Assent (for under 18yr olds) as well as consent?	Yes, we have a mental health trial where parent/carer gives e-consent and subsequently the young person gives e-assent
Have you got a further process after e-Assent that re-consents when they reach 18yrs old?	For this particular trial, the upper end of eligibility is 15 years and the follow up time is completed before the young person reaches 18 We're running an observational study in children from 0-18 years with 5 years follow up, and we've been asked to re-consent patients when they turn 16 during the follow up period
Does an e-Consent approach facilitate the sharing of results with participants at the end of the trial?	We ask VROOM patients if they want to receive the results by email or post, so in that respect it helps us know how to share the results We have the same on our consent form patients can chose text/post/email to receive the results at the point of consent. The difficult part was considerations about length of time before results were ready and keeping contact details up to date and it being appropriate to still send the results. We have a way for patients to update their contact details and preferences (and opt out of receiving the results) via our websites