

IRAS Project ID: **298078**

REC reference: **21/WA/0229**

Short title: **What does research impact mean to participants?**

Date: **12/07/21**

Dear Wales REC 5 Team,

Many thanks for taking the time to review our research plan and for granting preliminary ethics approval. I have responded to the requests for further information, as outlined in the table below.

There have been no changes to the IRAS form or supporting documentation. I have amended the response to filter question 3, as described in the first row below.

Please do not hesitate to contact me if you require any additional clarification.

Many thanks,

Lisa Newington

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Assessment - Further Information Required	Response from the applicant
Question 3 in the project filter suggests that there are research sites in England, Wales, Scotland and Northern Ireland. However, A72 states that this is a single site study supported by NHS PICs in England. Please clarify the arrangements, as the main site in part C is a non-NHS site.	<p>Thank you for the opportunity to clarify the study site arrangements. The CI is based at Imperial College London (university) and Imperial College Healthcare NHS Trust, co-located on university infrastructure within the NHS site. The main site in Part C was listed as the university, because they are the study sponsor. The CI will also lead the Imperial NHS PIC, with support from the NHS lead nurse for research (Prof Mary Wells) and lead clinical academic for therapies (Dr Caroline Alexander).</p> <p>The aim is to include PICs across the NHS, and ideally within the four nations. These will be a combination of NHS (Health and Social Care Northern Ireland) and university sites. Agreement has been provided by the sites within England listed on the IRAS application, but the plan is to add additional PIC locations through a minor amendment as these are identified.</p>

Assessment - Further Information Required	Response from the applicant
	In project filter question 3, I specified the inclusion of all four nations within the UK as this is where I hope the PICs will be located. I have now changed this response to 'England' as the research site is in London. I misinterpreted this question to also include the PIC locations, apologies for the confusion.
Please justify why the demographics form collects name, email and phone number. The minimum amount of identifiable data should be collected to meet the study's aims. Please consider revising the demographic data collected.	The participant's name is needed to be able to address the individual appropriately in correspondence about the study, and when conducting in the interview. The planned correspondence method is by email, with the interviews conducted via video platform. It is desirable to have a phone number for all interviewees in case of issues with internet/video platforms on the day, to allow the interview to be swiftly converted to a phone interview. Participants will also have the option to choose a phone interview, in which case the phone number is essential. For these reasons we plan to collect name, email and phone number.
Clarify how audio recordings will be stored prior to transfer to the transcription company.	It is anticipated that the interviews will be recorded through the inbuilt recording systems on the CI's Imperial College computer. An external device will also be used as backup. Audio files will be stored under password protection on the Imperial College computer in a designated folder. If an external recording device is used, the files will be deleted from this device once uploaded. The upload is manual (by plugging the recording device into the computer).
Clarify how audio recordings will be securely transferred to the transcription company and back again to the CI.	The transcription company (PageSix) has a secure upload/download process via their website. This requires a personal account. The audio file will be uploaded from the Imperial College computer onto the CI's account within the PageSix web platform (https://www.pagesix.co.uk/).
Clarify how transcriptions will be transferred from the transcription company to the CI for pseudonymisation.	Once transcribed, the word document is downloaded using the process outlined above: the CI logs into the PageSix account and downloads the file from the account on to the Imperial College computer. The original transcript will be stored under password protection on the Imperial College computer, checked against the audio file and pseudonymised. The audio file and original transcript will then be securely deleted.