

## CFHealthHub Audio Consent Form

Title of Project: CFHealthHub Data Observatory

Participant Screening Number:

Name of Researcher:

CFHealthHub ID:

**Note:** Prior to the consent process, the researcher will have confirmed that the participant has a copy of the study information sheet to hand (if not, this can be read to them) and answers any questions raised. Instructions for the researcher are underlined. Text in italics is to guide discussion with the participant.

**Introduction and discussion:** Before I can take consent I need to confirm with you that you understand what is involved and whether or not you agree to take part. Firstly, can you confirm that you have received the participant information sheet dated 19 March 2020 (version 7), do you have any initial questions about the study based on this?

I'd just like to take you through the key aspects of the study, please ask any questions you may have.

Researcher to summarise the key aspects of the study and answer any questions ensuring the following themes are covered:

- *Brief overview of the study*
- *What is expected of the participant and what will happen if they take part*
- *Potential risks and benefit*
- *How clinical care will be affected*
- *Who has access to their data*
- *What to do if they have any problems or wish to withdraw*

**Taking consent:** I am now going to read some statements to you. After each one, please answer 'yes' if you agree with the statement; or, 'no' if you do not agree with the statement.

	<b>Enter response</b>
1. I confirm that I have read and understand the information sheet dated (Version 7.0 18March2020) for this research study and have had the opportunity to ask questions. ( <u>Wait for response</u> )	<input type="text" value="Y/N"/>
2. I understand CFHealthHub will store my personal details, data related to CF, medication adherence, CFHealthHub usage data and any additional information I provide related to my condition. ( <u>Wait for response</u> )	<input type="text" value="Y/N"/>
3. I understand this data will undergo procedures to remove my personal identifiable information (pseudonymised) to people outside of the research study. ( <u>Wait for response</u> )	<input type="text" value="Y/N"/>
4. I understand my data will be shared with and analysed by the Clinical Trial Unit at the University of Sheffield. ( <u>Wait for response</u> )	<input type="text" value="Y/N"/>
5. I understand and agree that data from my existing nebuliser and medical notes, such as my NHS number and information relevant to CF will be stored securely in CFHealthHub. ( <u>Wait for response</u> )	<input type="text" value="Y/N"/>
6. I consent for the CF team to contact me via mobile phone (calls and texts), emails, and Skype to discuss the study and my adherence. ( <u>Wait for response</u> )	<input type="text" value="Y/N"/>

**When completed: 1 copy for participant; 1 (original) to be kept in Site file and 1 photocopy to be sent to Sheffield Clinical Trials Unit.**

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- |   |                              |
|---|------------------------------|
| 7. Within CFHealthHub I will be given the option to share my identifiable data with my local CF clinical team for use in my care. I understand that I am in control of this data sharing and that I can choose to turn this on/ off at any time. ( <u>Wait for response</u> )   | <input type="checkbox"/> Y/N |
| 8. I consent for my data stored within CFHealthHub to be grouped at centre level and shared with CF centres participating in the study across the UK. I understand I cannot be identified from this data. ( <u>Wait for response</u> )  | <input type="checkbox"/> Y/N |
| 9. I understand that my CF Registry data will be added to CFHealthHub. ( <u>Wait for response</u> )   | <input type="checkbox"/> Y/N |
| 10. I understand that my CFHealthHub data may be shared with the CF Registry and my GP will be informed of my participation in the study/ ( <u>Wait for response</u> )  | <input type="checkbox"/> Y/N |
| 11. I understand that I can use CFHealthHub as part of my ongoing CF care and I consent to any existing data within CFHealthHub to be retained as part of this study. ( <u>Wait for response</u> )  | <input type="checkbox"/> Y/N |
| 12. I understand that my participation is voluntary and I can consent to any or none of the optional consent items below. I can update or withdraw my consent at any time, without giving any reason, and without consequence. ( <u>Wait for response</u> )   | <input type="checkbox"/> Y/N |
| 13. I agree to take part in the above study. ( <u>Wait for response</u> )   | <input type="checkbox"/> Y/N |
| 14. (OPTIONAL) I consent for my pseudonymised data within CFHealthHub to be used for future research related to CF which has been ethically approved. I give permission for my contact details to be stored securely at the University of Sheffield for this purpose.   | <input type="checkbox"/> Y/N |
| 15. (OPTIONAL) I consent to be included for selection in future research studies which have been ethically approved. I understand when I meet the desired characteristics for the study I may be selected by chance to receive a new treatment. When I am not selected to receive the new treatment I consent to sharing my pseudonymised data without further notification. If I am selected to receive the new treatment I understand that I will be contacted and will have the opportunity to decline participation in the new study. I give permission for my contact details to be stored securely at the University of Sheffield for this purpose. | <input type="checkbox"/> Y/N |

*(If all responses to non-optional questions are 'yes' proceed as follows)*

Thank you. Now I need you to state your name for me so that it is recorded with this consent information (wait for response and print name)

                     The date today is:   

Please can you confirm that this is the date on which you have given your permission (wait for response and complete the section below).

<input style="width: 95%;" type="text"/>	d	d	m	m	y	y	y	y	<input style="width: 95%;" type="text"/>	
Name of person taking audio consent	Date						Signature			

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