

PRINCESS Participant Consent Form

Title of Study: Probiotics to Reduce Infections in CarE home reSidents.

Name of Participant: _____ Participant ID number:

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Please
INITIAL
beside each
statement

1. I confirm that I have read and understood the Participant Information Booklet/Pictorial Participant Information Booklet version 1.2 dated 04 October 2016 for the PRINCESS research study and I have had the chance to ask questions and discuss the study. I have received satisfactory answers to all of my questions. _____
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. _____
3. I understand that I will be given a daily capsule containing probiotic or a matched placebo and I will not know whether it contains the probiotic or placebo. _____
4. I understand that data relevant to this study will be collected from my care home records, from my GP and hospital notes. I give permission for the Cardiff University and Oxford University study team to have access to my records. _____
5. I understand that information about me (including name and address) will be held at SEWTU (Cardiff University) according to the 1998 Data Protection Act. I understand that this information will be kept strictly confidential and that no personal information will be used in the study report or other publications. _____
6. I agree to my General Practitioner being informed of my participation in this study. _____
7. I agree to remain in the study if I lose mental capacity and I agree for my next of kin or carer to be informed that I am taking part in this study. _____
8. I agree to take part in the above study. _____

Optional points 9-13: For each of the optional items, please INITIAL either the YES or NO boxes. You may still participate in the study even if you do not agree to point(s) 9-13.

9. Optional: I agree to donate blood samples when I start the study and 12 months later. I understand that I will not be given the test results. YES NO
10. Optional: I agree to donate saliva samples when I start the study, three and 12 months later. I understand that I will not be given the test results. YES NO
11. Optional: I agree to donate stool samples when I start the study, three and 12 months later. I understand that I will not be given the test results. YES NO
12. Optional: I agree to provide an extra blood sample four weeks after my flu vaccination. I understand that I will not be given the test results. YES NO
13. Optional: I agree that the tissue samples I donate may be used for future research projects in the UK. The samples will be stored and subsequently distributed to approved projects in accordance with the Human Tissue Act and ethical legislation. YES NO

Name of participant: _____ **Signature:** _____ **Date:** __/__/____
(print) (not needed if verbal consent)

Name of person taking consent: _____ **Signature:** _____ **Date:** __/__/____
(print)

Name of Witness to Verbal Consent (if needed): _____ **Signature:** _____ **Date:** __/__/____
(print)

When completed, please store white copy in site file, file yellow copy at local centre*, and give green copy to the participant.