

## PRINCESS Consultee Declaration Form

Please  
**INITIAL**  
 beside each  
 statement

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

Name of Participant: \_\_\_\_\_ Participant ID number: \_\_\_\_\_

1. I [name of consultee] have been consulted about [name of resident] ]'s participation in the PRINCESS research study. I confirm that I have read the Information Sheet for Consultees, version 1.2, dated 04 October 2016. I confirm that I have had the chance to ask questions about the study and have had them answered. \_\_\_\_\_
2. In my opinion the person I am being consulted about would agree if they could decide for themselves (i.e. if they had 'capacity') to take part in the study. \_\_\_\_\_
3. I understand that the participation of the person I am being consulted about is voluntary, and I can request that they are withdrawn from the study at any time, without giving any reason, and without their medical care or legal rights being affected. \_\_\_\_\_
4. I understand that the person I am being consulted about will be given a daily capsule containing probiotic or a matched placebo, but will not be told whether the capsules they will be given contains the probiotic or placebo. \_\_\_\_\_
5. I understand that data relevant to this study, of the person I am consulting about, will be collected from their care home, GP and hospital notes. I understand the Cardiff University and Oxford University study team will have access to the medical records of the person I am representing. \_\_\_\_\_
6. I understand that information about the person I am being consulted about (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. \_\_\_\_\_
7. I understand that their General Practitioner will be notified that they are taking part in this study. \_\_\_\_\_

**For points 8-12: please INITIAL either the YES box if your advice is that they would agree to the optional points, or INITIAL the NO box if they would not agree (if they had capacity) to these points.**

8. Optional: In my opinion the person I am being consulted about would agree to donate blood samples when they start the study and 12 months later. I understand that they will not be given the test results. YES NO
9. Optional: In my opinion, they would agree to donate saliva samples when they start the study, three and 12 months later. I understand that they will not be given the test results. YES NO
10. Optional: In my opinion, they would agree to donate stool samples when they start the study, three and 12 months later. I understand that they will not be given the test results. YES NO
11. Optional: In my opinion, they would agree to provide an extra blood sample four weeks after their flu vaccination. I understand that they will not be given the test results. YES NO
12. Optional: I agree that the tissue samples they 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

**Consultee:**  
 (print name) \_\_\_\_\_ **Relationship to resident:** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_/\_\_/\_\_\_\_

**Additional Consultee (if applicable):**  
 (print name) \_\_\_\_\_ **Relationship to resident:** \_\_\_\_\_

**Signature:** \_\_\_\_\_ **Date:** \_\_/\_\_/\_\_\_\_

**Name of person taking consent:** \_\_\_\_\_ **Signature:** \_\_\_\_\_ **Date:** \_\_/\_\_/\_\_\_\_  
 (print)