Professional Legal Representative Consent Form

**VITDALIZE UK**

A doctor who is unconnected with the VITDALIZE UK Trial should complete this consent form. This could be the doctor primarily responsible for the medical treatment of the participant, or a person appointed by the relevant healthcare provider. This is to be completed in situations where the participant is temporarily unable to provide informed consent for themselves, and if there is no relative/friend/partner willing and capable to act as the personal legal representative.

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| **Site name:** | | **Principal Investigator:** | |
| **Participant Trial Number:** | | **Please initial each question to confirm consent ↓** | |
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| 1. | I have been consulted about \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ participation in the **VITDALIZE UK** Trial. I have had the opportunity to ask questions and understand what is involved. | |  |
| 2. | I confirm that I have read and understood the Legal Representative Information Sheet, dated  \_ \_ / \_ \_ / \_ \_ \_ \_, version number\_\_. \_\_ for the **VITDALIZE UK** Trial. I have considered the information, asked questions, and have had these answered satisfactorily. | |  |
| 3. | I understand that the participant will take part in a screening programme to find out if they are eligible for participation in the **VITDALIZE UK** Trial and that data collected at screening, may be used as part of this research even if they are found to be ineligible. | |  |
| 4. | I understand that participation in **VITDALIZE UK** is voluntary and that I am free to withdraw the participant at any time, without giving any reason, and without their medical care or legal rights being affected. I understand that data collected up to their time of withdrawal may be used as part of the trial. | |  |
| 5. | I understand that individuals from the **VITDALIZE UK** research team at site, representatives of the Sponsor, the National Coordinating Centre, regulatory authorities, or from the NHS Trust/ Health Board may look at relevant sections of the participant’s medical notes and information collected from the **VITDALIZE UK** Trial, due to their participation in this research. I give permission for these individuals to have direct access to the participant’s records. | |  |
| 6. | I agree to the participants GP being informed of their participation in the **VITDALIZE UK** Trial and that they may be contacted by members of the research team for follow-up information. | |  |
| 7. | Information collected that identifies the participant by name, e.g. Informed Consent Forms as well as contact address and email, will be transferred from where it is collected and stored at the University of Birmingham during the trial and then at a specialist, secure archiving facility, in compliance with current regulations, after the trial. I agree to the transfer and storage of this information. | |  |
| 8. | I understand that international collaborators in the European Union will use data collected as part of the **VITDALIZE UK** Trial that includes coded data e.g. participant trial number, gender and age, in compliance with current data transfer regulations. I give permission for these individuals to have access to this information for the **VITDALIZE UK** Trial. | |  |
| 9. | For accurate follow-up of all participants, the **VITDALIZE UK** Research Team may need to contact other UK NHS bodies to provide information about the participant’s health. I give consent for the use of information held and maintained by e.g. the Health and Social Care Information Centre and other central UK NHS bodies to contact participants or provide information about their health by using the participants NHS number, Community Health Index (CHI) or Health & Care number (H&C), date of birth, post code, sex and trial number. | |  |
| 10. | I understand that if the participant becomes able to give informed consent during the course of the trial, their consent or refusal to continue participating will override my opinion. | |  |
| 11. | In my opinion, it is the presumed will that the participant would agree to take part in the **VITDALIZE UK** Trial. | |  |

**PLEASE CONTINUE TO PAGE 2**

**To continue participating in the VITDALIZE UK Trial you MUST consent to points 1-11 above and initial the corresponding boxes. Point 12 is OPTIONAL please initial if you agree.**

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| 12. | I believe that the participant would not object to have blood samples taken and stored for future biochemical tests to help understand how the body responds to high dose vitamin D treatment and critical illness. This is on the understanding that the investigations are for medical research only and the results will be kept confidential. Any trial on this material is subject to Research Ethics Committee approval. I understand that these samples will be analysed in research laboratories outside this hospital, in the UK. |  |
| 13. | If my patient is transferred to another hospital for further treatment I agree for the **VITDALIZE UK** Trials Team to contact the hospital to request information about my patients health specific for the **VITDALIZE UK** Trial. |  |

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| Name of professional legal representative |  | Date |  | Signature |
|  |  |  |  |  |
| Name of person receiving consent |  | Date |  | Signature |

***Original to be filed in the Investigator’s Site File; 1 copy for patient; 1 copy to be kept with patient’s hospital record; 1 copy to be sent to BCTU***