Personal Legal Representative Consent Form

**VITDALIZE UK**

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| **Site name:** | | | | **Principal Investigator:** | | | |
| **Participant Trial Number:** | | | | **Please initial each question to confirm consent ↓** | | | |
|  | | | |  | | | |
| 1. | I am willing to act as a personal legal representative for my relative/friend | | | | | |  |
| 2. | I am able to do this because I am (please see page 2) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |  |
| 3. | 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. | | | | | |  |
| 4. | It is my belief that my relative/friend would not object to taking part in a screening programme to find out if they are eligible for participation in the main **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. | | | | | |  |
| 5. | I understand that my relative/friend’s participation in **VITDALIZE UK** is voluntary and that I am free to withdraw my relative/friend by informing the research team at any time, without giving a reason, and without my relative/friend’s medical care or legal rights being affected. | | | | | |  |
| 6. | 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 my relative/friend’s medical notes and information collected from the **VITDALIZE UK** Trial, due to my taking part in this research. I give permission for these individuals to have direct access to my relative/friends records. | | | | | |  |
| 7. | I agree to my relative/friends 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. | | | | | |  |
| 8. | Information collected that identifies my relative/friend 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. | | | | | |  |
| 9. | 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. | | | | | |  |
| 10. | For accurate follow-up of all participants, the **VITDALIZE UK** Research Team may need to contact other UK NHS bodies to provide information about your relative/friends 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 my relative/friend’s NHS number, Community Health Index (CHI) or Health & Care number (H&C), date of birth, post code, sex and trial number. | | | | | |  |
| 11. | I agree to my relative/friend to take part in the **VITDALIZE UK** Trial. | | | | | |  |
| **To continue participating in the VITDALIZE UK Study you MUST consent to points 1-12 above and initial the corresponding boxes. Point 12 and 13 are OPTIONAL please initial if you agree.**  **PLEASE CONTINUE TO NEXT PAGE** | | | | | | | |
| 12. | I understand that my friend/relative may not be able to answer questions needed as part of the **VITDALIZE UK** Trial because they are still unwell. If this occurs, I agree to be contacted to provide information as proxy about my relative/friends health for the **VITDALIZE UK** Trial. | | | | | |  |
| 13. | I believe that my relative/friend 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. | | | | | |  |
| 14. | If my relative/friend 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 relative/friends health specific for the **VITDALIZE UK** Trial. | | | | | |  |
|  | |  |  | |  |  | |
| Name of personal legal representative | |  | Date | |  | Signature | |

**For the researcher who is obtaining screening informed consent:**

|  |  |
| --- | --- |
| **1.** | I have explained the research project to the personal legal representative and have answered all their questions honestly and fully. |
| **2.** | I am not aware of any objection held by the proposed research participant to participate in this trial (for example, an advance directive). |
| **3.** | If at any time I am advised by the legal representative that the proposed research participant would object to being included in this research project, I will withdraw the person from the study immediately. |
| **4.** | If I become aware of any apparent resistance or objection from the proposed research participant, I will withdraw them from the study immediately. |

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| --- | --- | --- | --- | --- |
| Name of Researcher |  | Date |  | Signature |
| Name of witness *(witness only required if personal legal consent is obtained via telephone, videoconference or equivalent)* |  | Date |  | Signature |

# Additional information regarding personal legal representatives

# *Who can act as a personal legal representative for the purposes of obtaining consent for research participation?*

A carer/relative/friend who is willing to act on their behalf. Ideally it should be the person with the closest personal relationship with the potential subject who is capable him or herself of giving consent.

***What does a personal legal representative do?***

A personal legal representative consents to participation in medical research on behalf of a person who cannot consent for themselves. Deciding what the person would have wanted should take into account:

* the person’s values and preferences
* their physical and psychological health and well-being
* their quality of life
* their spiritual and religious welfare

Prior to reaching a decision on whether to give or withhold consent, the personal legal representative must be fully aware of the type of research, its purpose, risks, inconveniences and implications of the trial. A personal legal representative has the right to withdraw consent to participation.

***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***