Participant Informed Consent Form

VITDALIZE UK

Site name: **Principal Investigator:**

Participant Trial Number: **Please initial each question to confirm consent ↓**

1. I confirm that I have read and understood the Participant Information Sheet, dated _ _ / _ _ / _ _ _ _, version number __. __ for the **VITDALIZE UK** Trial. I have considered the information, asked questions, and have had these answered satisfactorily.

2. I understand that I will take part in a screening programme to find out if I am eligible for participation in the **VITDALIZE UK** Trial and that data collected at screening, may be used as part of this research even if I am found to be ineligible.

3. I understand that my participation in **VITDALIZE UK** 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. I understand that data collected up to my time of withdrawal may be used as part of the trial.

4. 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 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 records.

6. I agree to my GP being informed of my 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 me 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 your 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 NHS number, Community Health Index (CHI) or Health & Care number (H&C), date of birth, post code, sex and trial number.

10. I agree to take part in the **VITDALIZE UK** Trial.

To continue participating in the VITDALIZE UK Trial you <u>MUST</u> consent to points 1-10 above and initial the corresponding boxes. Point 11 is <u>OPTIONAL</u> please initial if you agree.

11. I agree to have blood samples taken and stored for future biochemical tests to help understand how my body responds to high dose vitamin D treatment. This is on the understanding that the investigations are for medical research only and my 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.

12. If I am transferred to another hospital for further treatment, I agree for the **VITDALIZE UK** research team to contact the hospital where I am receiving treatment, to request some information about my health specific to the **VITDALIZE UK** Trial.

Name of participant	Date	Signature **PLEASE CONTINUE TO PAGE 2**
Name of person receiving consent	Date	Signature
Name of witness *(witness only required if patient is physically unable to sign)*	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