

# UCD Fam-D-Bread Study

## Parent/Guardian Information Leaflet

### What is this research about and why are we doing it?

Vitamin D is an essential nutrient that has several health benefits. We can make vitamin D in our skin when the sun shines or we can get vitamin D from certain foods. In Ireland, we don't get enough sunshine, particularly from October to March, and most people are not eating enough foods that contain vitamin D to meet their requirements and so a large proportion of the population are at risk of low vitamin D. For this reason, it is important for us to look at ways to increase the amount of vitamin D we are getting from foods and therefore improve our year-round vitamin D levels. This study will examine if we can increase the amount of vitamin D we are eating and prevent low vitamin D levels in wintertime using a vitamin D fortified bread. We expect that outcomes from this research will inform policy and recommendations to improve vitamin D in our diets in Ireland.

### What will happen if I decide to take part in this research study?

#### **Screening (approx. 20 mins)**

If you decide to complete the screening questionnaire on behalf of your family, you will be asked questions related to your child's/children's age, medical conditions, medication use, supplement use, diet, and sun exposure (such as upcoming holidays or tanning bed use). Your child/children may be ineligible to take part if any of the screening questionnaire responses will impact study adherence (ability to consume bread daily) or outcomes (vitamin D status).

If your family is eligible based on the screening questionnaire, researchers from UCD will contact the lead participant (the parent/guardian who completed the screening questionnaire or another parent/guardian on behalf of the family) via phone or email to discuss next steps. Children will not be contacted directly by a researcher. If your family decides to take part, all participating family members will be asked to attend a visit at a UCD research centre on two occasions, 8 weeks apart. A study visit will take up to 2 hours to complete; however, if it is more convenient for you, we can complete some of these questionnaires at a home visit before the study site visit. If you choose the option to do some of the questionnaires at a home visit, then the study site visit will be 30 minutes.

#### **Baseline visit**

If your family decides to attend a full study visit at a UCD research centre, the study information will be discussed with all family members in age-appropriate language. Parents/guardians will be asked to provide informed parental consent for their child/dependent. Children (under the age of 18 years) will be asked to agree to their participation in the study. Your family will be randomly allocated to either the vitamin D fortified bread or the unfortified (control) bread study group, however, we (the researchers) or your family will know which group you are in.

During the full study visit, the following assessments will be collected from your child/children:

- Body measurements such as weight, height, waist and hip circumference (Can be collected during home visit or at a research centre)
- A small blood sample will be collected by a trained experienced research nurse (only able to be collected at a research centre). These samples will be frozen and analysed for nutrients and other health related markers.

Following blood collection, a snack will be provided. After the study visit, all family members will be asked to eat two slices of study bread for 8 weeks.

### **Endpoint data collection (Week 8)**

At the end of the 8-week study, you will be asked to return a UCD research centre for the endpoint data collection. As described above, your family will have the option for a home visit from a researcher or to have all data collected during a full study visit. Children's body measurements (weight, height, waist and hip circumference) can be collected either at home or at a research centre. A small blood sample will be collected again onsite at a research centre. A snack will be provided following blood sampling.

### What are the possible risks of taking part in this research study?

There is very low risk associated with taking part in this research. When giving blood, there is a chance children may experience discomfort, fainting, minor bruising, or some inflammation on the skin. To ensure this risk is kept to a minimum, all samples will be collected by a nurse who is trained and experienced in collecting blood samples. A standard protocol will be followed to ensure safe blood collection. If for any reason you do not wish for your child to provide a blood sample or if your child does not agree to blood sampling, you do not have to take part in this research.

### What are the benefits of taking part in this research study?

If you decide to take part, you will be contributing to research which is aiming to improve knowledge on vitamin D fortified foods among children, adolescents and adults in Ireland. Everyone who participates will be provided with bread throughout the 8-week study and information on other sources of vitamin D to help you make the recommended changes.

### What are the benefits to the researcher if I take part in this research study?

With this research, researchers aim to inform national policy to solve vitamin D deficiency in Ireland. If you decide to take part, the researchers can gather evidence to support this policy. This research project supports postgraduate students who will be able to analyse the anonymised data to answer research questions as part of their research degree theses and can then publish the analysis in academic papers in peer-reviewed journals. The investigators of this research will achieve the aims and objectives provided to the project's funder (the Department of Agriculture, Food and the Marine).

### How will my data be used?

If you provide parental consent and your child agrees to take part, your child will be assigned a study code number, and this code will be used to input the data collecting during the study. During the data collection phase of the study, study code number will be linked to names in a separate file and stored safely on a secure password protected database. Once data collection is complete, the file linking names and your child's study code number will be destroyed. From this point on, data will be anonymised so we will not know what data or samples belong to families. We will use your child's blood sample to measure their vitamin D levels and other health biomarkers. The anonymised data will be used in one or more scientific papers and reports and will be available for use by the study collaborators for future nutrition/vitamin D research projects. Archived data may be used by other researchers in future upon request from the study principal investigator. This data will be anonymised and used only for research purposes.

### How will my privacy be protected?

Any information collected will be kept completely confidential. Your child's information will be in a pseudonymised (coded) format and stored using a study code number. Any personal data which you provide to the University will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection Legislation. Following parental consent and assent, your child's data will be used for the purposes outlined in this participant information leaflet. All data will be stored securely on Multi-Factor Authentication protected files and your data and any remaining blood samples will be retained for 10 years or 5 years post publication. Some findings from the study will be presented and published at a later date, but these will describe the study population as a whole and not refer to individual people.

#### What is the legal basis for processing my data? Or why are you processing my data?

Any data provided to us during the course of this study will be processed fairly and lawfully. The General Data Protection Regulation (GDPR) allows us to process your data because the research is of substantial public interest (Articles 6(1) (e) and 9(2) (g) of the GDPR). Signing the Informed Consent Form means that your data and biological samples will be used for the purposes outlined in this document.

#### How will I find out what happens with this study?

When the study is finished and the data has been analysed, the researchers involved in the study will put together a summary of the study results. We will not be able to provide individual data as all analysis will be done using coded samples and data only. If you decide to take part in the study, you will sign a consent form. The consent form will include a statement that will give you the opt-in option to allow us to save your email or postal address so that we can share the summary report with you when complete.

#### Can I change my mind at any stage and withdraw from the study?

Decision to take part in this study is entirely voluntary. You and your child are able to ask questions or withdraw from the study at any time without having to provide an explanation. If your family decides to withdraw from the study early, your coded data collected from when you signed the consent form will be used for statistical analysis unless you also withdraw your consent for them to be used in this way. If a member of your family wishes to withdraw from the study, your remaining family members may choose to continue their participation if your family still meets study inclusion criteria (i.e. at least one parent/guardian and at least one child/dependent). If you withdraw your consent and request for your data to be removed, your data will be destroyed. However, this can only be done if you withdraw during the data collection period (after signing consent until your final onsite visit to UCD), as your data will be anonymised once data collection is complete. This means that we will use only a study code to save your data and therefore we will not be able to identify you. Following your withdrawal, no new data will be collected.

#### Who do I contact if I have any concerns about the protection of my data?

If you require further information regarding your data, please firstly contact the study's principal investigator, Prof Aifric O'Sullivan at [aifric.osullivan@ucd.ie](mailto:aifric.osullivan@ucd.ie). If you feel you require further assistance, you can contact the UCD Data Protection Officer Office of the DPO, Roebuck Castle, UCD, Belfield, Dublin 4, by email at [gdpr@ucd.ie](mailto:gdpr@ucd.ie) or phone on 01 716 8704. Alternatively, I understand I can direct complaints to a party independent to this study at [foodandhealth@ucd.ie](mailto:foodandhealth@ucd.ie).

#### Contact details and further information:

Please feel free to ask for further information before deciding if you will take part. If you want further information, you can contact the researchers at [vitamind@ucd.ie](mailto:vitamind@ucd.ie) or 01 716 2467.

Thank you for your interest in this study and for taking the time to read through this information leaflet.