

**Vitamin D Supplementation Trial**  
**1 Month / 2<sup>nd</sup> Visit CRF**

Date of 2<sup>nd</sup> visit

**TO BE COMPLETED BY RESEARCHER**

1. Is the participant's urine ca:cr ratio from visit 1 within the acceptable range?\*      Yes       No

2. Is the participant's serum calcium from visit 1 within the acceptable range?\*      Yes       No

**Researcher's signature and ID****Date****iSTAT results**

3. POC ionised calcium (mmol/l)\*\*      1<sup>st</sup>      2<sup>nd</sup> – if required      3<sup>rd</sup> – if required

●     
●     
●

**Researcher's signature and ID****Date**

4. Other study bloods      Collected?      Yes       No

Site of procedure (e.g. left arm)

5. Urine sample (for ca:cr ratio)      Collected?      Yes       No

**Researcher's signature and ID****Date**

6. Is the participant's ionised calcium from this visit within the acceptable range?\*      Yes       No

**Researcher's signature and ID****Date**

7. Have there been any changes in the participant's health in the last 4 weeks?      Yes       No

7a. If yes, please complete the table below and an AE or SAE form if applicable.

Change in health	Date	Time	Description	Adverse Event / Serious Adverse Event form completed? (Y/N)
	dd/mmm/yyyy	hh : mm		
	dd/mmm/yyyy	hh : mm		
	dd/mmm/yyyy	hh : mm		
	dd/mmm/yyyy	hh : mm		
Researcher's signature and ID			Date	

**8. Date and time of administration of study medication** (please ensure acceptable safety readings before administering).

Date: d d / m m m / y y y y

Comments: d d / m m m / y y y y

Time: H H : m m

h h : m m

Researcher's signature and ID

Date d d / m m m / y y y y

**9. Any comments / actions taken?**

Researcher's signature and ID

Date d d / m m m / y y y y

#### Additional notes

\* Ensure the safety measurements collected at the previous visit are within the acceptable ranges before proceeding with this visit (serum calcium <2.65mmol/l; urine ca:cr <1). If the measurements are found not to be acceptable the participant cannot proceed in the trial.

\*\*Ensure the iSTAT measurement is within the acceptable range before proceeding with this visit (ionised calcium <1.3mmol/l). If the measurement is found not to be acceptable repeat the measurement. If the second measurement is within the acceptable range, take a third measure. If two of three measurements are normal proceed with this visit. If two of three measurements fall outside of the acceptable ranges do not proceed with this visit. If the second test is unacceptable, as well as the first, do not carry out a third test. The participant cannot proceed in the trial.

If the participant cannot continue in the trial, collect a blood sample to enable laboratory analysis of serum calcium for reporting to the participant's GP as appropriate. There is no need to collect the other trial bloods.