

Baseline SURVEY- start of trialStudy ID: **PROSDXXXX****Appendix 1****A Randomised Control Trial of Vitamin D Supplementation in Prostate Cancer Cases (PROSD)**

This randomised control trial aims to see if oral vitamin D supplementation can prevent prostate cancer progression. This survey covers a range of questions on factors that may, or may not, be connected with your cancer and how you cope with it. Your answers are important to us, so please answer every question. If you are not sure of the right dates or ages, your best guess is better than leaving it blank.

The information that we collect is confidential. Please be assured, that all the information collected from this study will be stored in a secure place and your name will be removed from it and it will not be used for any purpose other than for this study.

We thank you for your cooperation in completing this survey.

You can complete this survey online by going to <https://webmail.nswcc.prosD.xxxxxx>

Instructions on how to complete this survey.

- Please answer **ALL** questions about yourself and your own experience by placing a cross (X) in the appropriate box(es) that is adjacent to your choice of response.
- Please write clearly using BLACK or BLUE ink.
- Please write numbers in appropriate boxes e.g. 2nd Dec 1942--0 2 /1 2 /1 9 4 2
- If you make a mistake or change your mind please draw a line through that answer and write the correct answer next to it e.g. ~~25~~ 36

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Baseline SURVEY- start of trialStudy ID: **PROSDXXXX****PERSONAL DETAILS**Today's date: / /

Family Name: _____

First Given name: _____

Other Given names: _____

Date of birth: / / Address

Street no: _____

Street name: _____

Suburb: _____

State: _____

Post code: Medicare Number:

Confirm contact details:

- Home telephone _____
- Work telephone _____
- Mobile _____
- Email _____

Baseline SURVEY- start of trialStudy ID: **PROSDXXXX****GENERAL QUESTIONS ABOUT YOU**

Q1 How tall are you without shoes (please give to the nearest centimetre or inch)?

- Feet: _____ Inches: _____ **or**
- Meters: _____ Centimetres: _____

Q2 How much do you currently weigh?

- ___ kg **or**
- ___ stones **or**
- ___ pounds

Q3 What is the highest qualification you have completed? (please put one cross (X) in the most appropriate box)

- ☐ No school certificate or other qualifications
- ☐ School or intermediate certificate (or equivalent)
- ☐ Higher school or leaving certificate (or equivalent)
- ☐ Trade/apprenticeship (e.g. hairdresser, chef)
- ☐ Certificate/diploma (e.g. child care, technician)
- ☐ University degree or higher

Q4 What is your current work status? (you can cross more than one box)

- ☐ In full time paid work/self-employed
- ☐ In part time paid work/doing unpaid work
- ☐ Completely retired/pensioner
- ☐ Partially retired looking after home/family
- ☐ Disabled/sick/unemployed
- ☐ Other

Q5 What best describes your current situation? (please cross one box)

- ☐ Single
- ☐ Married
- ☐ De facto/living with a partner
- ☐ Widowed
- ☐ Divorced
- ☐ Separated

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Q6 Which of the following do you have? (excluding Medicare)

- ☐ Private health insurance – with extras
- ☐ Private health insurance – without extras
- ☐ Department of Veterans' Affairs white or gold card
- ☐ Health care concession card
- ☐ None of these

Q7 Do you currently smoke cigarettes, cigars, pipes or any other tobacco products:

- ☐ Daily
- ☐ At least weekly (not daily)
- ☐ Less often than weekly
- ☐ Not at all

Q8 Over your lifetime would you have smoked at least 100 cigarettes or a similar amount of tobacco?

- ☐ Yes
- ☐ No

QUESTIONS ABOUT HEALTH*The following are general questions related to your health.*

Q9 Have any of your first degree relatives ever been diagnosed with prostate cancer? By 'first degree relative', I mean your father, son or brother.

- ☐ Yes
- ☐ No
- ☐ Don't know

Q10 Has a doctor EVER told you that you have:

(Circle 'Yes' where needed)

- Cancer, other than prostate cancer (please describe type of cancer) -Yes
- Heart failure (heart failure, weak heart, enlarged heart) -Yes
- Atrial fibrillation -Yes
- High blood pressure -Yes
- Stroke -Yes

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- Diabetes -Yes
- Blood clot (thrombosis) -Yes
- Enlarged prostate -Yes
- Asthma -Yes
- Hay fever -Yes
- Osteoarthritis -Yes
- Depression -Yes
- Anxiety -Yes
- Parkinson's disease -Yes
- **None of these** -Yes

Q11 How many times in the **LAST 4 MONTHS** have you visited your general practitioner (this does not include visits to your urologist or specialists about your prostate cancer)?

_____ Times

Q12 During the **PAST MONTH**, how many times have you fallen to the floor or ground?
(put "0" if you haven't fallen in the past month)

_____ Times

Q13 Have you had a broken/fractured bone in the last month?

- ☐ Yes
- ☐ No

QUESTIONS ABOUT YOUR PSYCHOLOGICAL DISTRESS

*The following questions are a list of comments made by men about their prostate cancer. Please **CIRCLE** the score that indicates on how frequently these comments were true for you **during the past week**;*

(Scores: 0=Not at all; 1=Rarely; 2=Sometimes; 3=Often)

No.	Question	Score
14	Any reference to prostate cancer brought up strong feelings in me	0 1 2 3
15	Even though it's a good idea, I found that getting the PSA test scared me	0 1 2 3
16	Whenever I heard about a friend of public figure with prostate cancer, I get more anxious about my having prostate cancer	0 1 2 3

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- | | | |
|----|---|----------------|
| 17 | When I thought about having a PSA test, I got more anxious about my having prostate cancer | 0 1 2 3 |
| 18 | Other things kept making me think about prostate cancer | 0 1 2 3 |
| 19 | I felt kind of numb when I thought of prostate cancer | 0 1 2 3 |
| 20 | I thought about prostate cancer even though I did not mean to | 0 1 2 3 |
| 21 | I had a lot of feelings about prostate cancer, but I didn't want to deal with them | 0 1 2 3 |
| 22 | I had more trouble falling asleep because I couldn't get thoughts of prostate cancer out of my mind | 0 1 2 3 |
| 23 | I was afraid that the results from my PSA test would show that my disease was getting worse | 0 1 2 3 |
| 24 | Just hearing the words 'prostate cancer' scared me | 0 1 2 3 |

*For the next three questions, please indicate how frequently these situations have **EVER** been true for you.*

(Scores: 0=Not at all; 1=Rarely; 2=Sometimes; 3=Often)

- | No. | Question | Score |
|------------|---|----------------|
| 25 | I have been so anxious about my PSA test that I have thought about delaying it | 0 1 2 3 |
| 26 | I have been so worried about my PSA test result that I have thought about asking my doctor to repeat it | 0 1 2 3 |
| 27 | I have been so concerned about my PSA test result that I have thought about having the test repeated at another lab to make sure they were accurate | 0 1 2 3 |

*The following are a number of statements concerning a person's beliefs about their own health. In thinking about the **past week**, please indicate how much you agree or disagree with each statement: strongly agree, agree, disagree, or strongly disagree. Please circle the number of your answer.*

(Scores: 0= Strongly agree; 1= Agree; 2= Disagree; 3= Strongly disagree)

- | No. | Question | Score |
|------------|--|----------------|
| 28 | Because cancer is unpredictable, I feel I cannot plan for the future | 0 1 2 3 |

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- | | | | | | |
|----|---|---|---|---|---|
| 29 | My fear of having my cancer getting worse gets in the way of my enjoying life | 0 | 1 | 2 | 3 |
| 30 | I am afraid of my cancer getting worse | 0 | 1 | 2 | 3 |
| 31 | I am more nervous since I was diagnosed with prostate cancer | 0 | 1 | 2 | 3 |

Note: Brief Symptom Inventory (BSI18) questions (Q32-Q49) are not shown due to licencing restrictions.

QUESTION ON PHYSICAL ACTIVITY

*The following questions are about any physical activities that you may have done in the **LAST WEEK:***

Q50 In the **last week**, how many times have you **walked** continuously, for at least 10 minutes, for recreation, exercise or to get to or from places?

*(This must be **continuous** walking, i.e. for at least 10 minutes without stopping).*

_____times per week.

Q51 What do you estimate was the total time that you spent **walking** in this way in the last week?

(e.g. If you walked on Monday, how long did you spend walking? If you walked on Tuesday, how long did you spend walking?...do this for the rest of the week then add up your hours and /or minutes walked)

In hours and/or minutes

_____hours

_____minutes

The next questions exclude household chores, gardening or yard work:

Q52 In the last week, how many times did you do any **vigorous** physical activity which made you breathe harder or puff and pant?

(e.g. jogging, cycling, aerobics, competitive tennis, football (of all types), hockey, squash, cross-country skiing, cross-country hiking (i.e. rough or steep terrain), weight lifting,

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boxing, rock climbing, basketball, netball, gymnastics, using a rowing machine, martial arts, high-impact and step aerobics).

_____times

Q53 What do you estimate was the total time that you spent doing this **vigorous** physical activity in the last week?

(e.g. If you walked on Monday, how long did you spend walking? If you walked on Tuesday, how long did you spend walking?...do this for the rest of the week then add up your hours and /or minutes doing vigorous physical activity)

In hours and/or minutes

_____hours

_____minutes

Q54 In the last week, how many times did you do any other more **moderate** physical activities that you have not already mentioned?

(e.g. gentle swimming, social tennis, golf, dancing, badminton, table tennis, horseback riding, canoeing, kayaking, volleyball, cricket, baseball or softball, downhill skiing, cross-training, surfing and windsurfing).

_____times

Q55 What do you estimate was the total time that you spent doing these **moderate** activities in the last week?

In hours and/or minutes

_____hours

_____minutes

QUESTIONS ON DIETARY CHANGE

The following questions are related to possible changes you may have made to your diet. These are changes that you are **CURRENTLY** using to help with your prostate cancer and/or its side effects.

Q56 Are you **CURRENTLY** eating differently to help with your prostate cancer?

- ☐ Yes (if **YES**, please complete question 57)
- ☐ No (if **NO**, please go to question 58)

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Q57 (please put a cross (X) for where a change in your diet was made)

- ☐ -Increasing a particular type of fat or oil (please describe)_____
- ☐ -Increased soy products
- ☐ -Increased fruit in general
- ☐ -Increased vegetables in general
- ☐ -Increased a particular type of food (s) (please list)_____
- ☐ -Increased a particular type of drink (s)(please list)_____
- ☐ -Decreased fats, oils or fried foods (please describe)_____
- ☐ -Decreased red meat
- ☐ -Decreased processed meats, for example ham, salami, bacon
- ☐ -Decreased dairy products
- ☐ -Decreased a particular type of food (s) (please list)_____
- ☐ -Decreased a particular type of drink (s) (please list)_____
- ☐ -Special diet for example vegetarian or macrobiotic (please describe)_____
- ☐ -Other changes (please describe)_____

QUESTIONS ON YOUR SUPPLEMENT INTAKE

Q58 Did you supplement your diet with **VITAMINS/MINERALS** &/OR **HERBAL SUPPLEMENTS** during the past 16 weeks?

- ☐ YES
- ☐ NO

If **YES**, please list items consumed below:

Brand	Type	Dose (eg 5mg)	How often

Baseline SURVEY- start of trialStudy ID: **PROSDXXXX****QUESTIONS ON MEDICATIONS TAKEN**

Q59 Did you take any medications regularly during the past 16 weeks (prescribed or over the counter)?

- ☐ YES
☐ NO

If **YES**, please list below:

Medication	Dose (eg 25mg)	How Often (eg twice daily)	Condition being treated	For how long did you take them during the past 16 weeks?

QUESTIONS ON YOUR SUN SENSITIVITY

The following questions on sun sensitivity are related to your body's ability to produce vitamin D and your susceptibility to sun damage.

Q60 Which colour best describes the colour of the skin on the inside of your upper arm, that is, your skin colour without any tanning?

- ☐ Very fair
☐ Fair
☐ Light olive
☐ Dark olive
☐ Brown
☐ Black

Q61 What would happen to your skin if it was repeatedly exposed to bright sunlight in summer without any protection? Would it:

- ☐ Go very brown and deeply tanned
☐ Get moderately tanned
☐ Get mildly or occasionally tanned
☐ Get no suntan at all or
☐ Only get freckled

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QUESTIONS ON YOUR RECENT SUN EXPOSURE

Q62 Please tell us about the time you have spent **OUTDOORS (between 8 AM and 5 PM)** in the past 16 weeks (i.e. about 4 months). It will help if you start by writing the date 4 MONTHS AGO (just take today's date and count back to the 4th month before it), and TODAY'S DATE in the given places below.

- **Column A:** write the **first place in which you lived for 1 week or more** in the past 16 weeks. Give Town or city, State if in Australia, and give name of Country if not Australia.
- **Column B:** write what your **main activity** was when you were in this location.
Eg. Working in a job, living at home, on holiday, or other (say what it was)
- **Column C:** write the first date you were in this location.
- **Column D:** write the duration of your stay in this location.
- **Columns E and F:** write the number of hours/day you spent outdoors, and not under any shade between 9am and 5pm while living at this place.
- Now fill in columns A and B on a new row for each time you changed for **1 week or more** the place you lived or your main activity, until you have covered the whole 16 weeks (4 month) period. If you need additional lines, you can write in the space below the table or add another sheet of paper.

Date 4 months ago: / /

A	B	C	D	E	F
Places lived for one week or more.	Main activity at this location	Approximate start date at this location	# weeks at this location	Number of hours spent outdoors at this location	
				On week days (or working days)	On weekend days (or days off)
Eg. Barcelona, Spain	Working	16 th Dec 15	4 weeks	Half an hour	4 hours
Eg. Fraser Island	Holiday	15 th Jan 16	2 weeks	6 hours	6 hours
Eg. Sydney	At home	1 st Feb 16	10 weeks	Half an hour	1 hours

Today's Date: / /

THIS IS THE END OF THE SURVEY.

Thank you for your cooperation in answering these questions. Please return these forms in the pre-paid envelope.

SURVEY12 month follow-upStudy ID: **PROSDXXXX****A Randomised Control Trial of Vitamin D Supplementation in Prostate Cancer Cases (PROSD)**

This randomised control trial aims to see if oral vitamin D supplementation can prevent prostate cancer progression. This is a follow-up survey on a range of questions for information that have previously provided us at the start of the study. Your answers are important to us, so please answer every question. If you are not sure of the right dates or ages, your best guess is better than leaving it blank.

The information that we collect is confidential. Please be assured, that all the information collected from this study will be stored in a secure place and your name will be removed from it and it will not be used for any purpose other than for this study.

We thank you for your cooperation in completing this survey.

You can complete this survey online by going to <https://webmail.nswcc.prosD.xxxxxx>

Instructions on how to complete this survey.

- Please answer ALL the questions about yourself and your own experience by placing a cross (X) in the appropriate box(es) that is adjacent to your choice of response.
- Please write clearly using BLACK or BLUE ink.
- Please write numbers in appropriate boxes e.g. 2nd Dec 1942--0 2 /1 2 /1 9 4 2
- If you make a mistake or change your mind please draw a line through that answer and write the correct answer next to it e.g. ~~25~~ 36

Please complete the following information and return to us in the pre-paid envelope.

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SURVEY12 month follow-upStudy ID: **PROSDXXXX****PERSONAL DETAILS**Today's date: / /

Family Name: _____

First Given name: _____

Other Given names: _____

Date of birth: / / Address

Street no: _____

Street name: _____

Suburb: _____

State: _____

Post code: Medicare Number:

Confirm contact details:

- Home telephone _____
- Work telephone _____
- Mobile _____
- Email _____

SURVEY12 month follow-upStudy ID: **PROSDXXXX****GENERAL QUESTIONS ABOUT YOU**Q1 How much do you currently weigh?

- ☐ ___ kg **or**
- ☐ ___ stones **or**
- ☐ ___ pounds

Q2 What is your current work status? (you can cross (X) more than one box)

- ☐ In full time paid work/self-employed
- ☐ In part time paid work/doing unpaid work
- ☐ Completely retired/pensioner
- ☐ Partially retired looking after home/family
- ☐ Disabled/sick/unemployed
- ☐ Other

Q3 What best describes your current situation? (please cross one box)

- ☐ Single
- ☐ Married
- ☐ De facto/living with a partner
- ☐ Widowed
- ☐ Divorced
- ☐ Separated

Q4 Which of the following do you have? (excluding Medicare)

- ☐ Private health insurance – with extras
- ☐ Private health insurance – without extras
- ☐ Department of Veterans' Affairs white or gold card
- ☐ Health care concession card
- ☐ None of these

Q5 Do you currently smoke cigarettes, cigars, pipes or any other tobacco products:

- ☐ Daily
- ☐ At least weekly (not daily)
- ☐ Less often than weekly
- ☐ Not at all

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Q6 Over your lifetime would you have smoked at least 100 cigarettes or a similar amount of tobacco?

☐ Yes☐ No

QUESTIONS ABOUT HEALTH

Q7 How many times in the **LAST 12 MONTHS** have you visited your general practitioner (this does not include visits to your urologist or specialists about your prostate cancer)?

 Times

Q8 During the **LAST MONTH**, how many times have you fallen to the floor or ground? (put "0" if you have not fallen in the last month)

 Times

Q9 Have you had a broken/fractured bone in the last month?

☐ Yes☐ No

Q10 In the **LAST 12 MONTHS**, has a doctor EVER told you that you have:

(Circle 'Yes' where needed)

- Cancer, other than prostate cancer (please describe type of cancer) -Yes
- Heart failure (heart failure, weak heart, enlarged heart) -Yes
- Atrial fibrillation -Yes
- High blood pressure -Yes
- Stroke -Yes
- Diabetes -Yes
- Blood clot (thrombosis) -Yes
- Enlarged prostate -Yes
- Asthma -Yes
- Hay fever -Yes
- Osteoarthritis -Yes
- Depression -Yes
- Anxiety -Yes
- Parkinson's disease -Yes
- **None of these** -Yes

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QUESTIONS ABOUT YOUR PSYCHOLOGICAL DISTRESS

*The following questions are a list of comments made by men about their prostate cancer. Please **CIRCLE** the score that indicates on how frequently these comments were true for you **during the past week**:*

(Scores: 0=Not at all; 1=Rarely; 2=Sometimes; 3=Often)

No.	Question	Score
11	Any reference to prostate cancer brought up strong feelings in me	0 1 2 3
12	Even though it's a good idea, I found that getting the PSA test scared me	0 1 2 3
13	Whenever I heard about a friend of public figure with prostate cancer, I get more anxious about my having prostate cancer	0 1 2 3
14	When I thought about having a PSA test, I got more anxious about my having prostate cancer	0 1 2 3
15	Other things kept making me think about prostate cancer	0 1 2 3
16	I felt kind of numb when I thought of prostate cancer	0 1 2 3
17	I thought about prostate cancer even though I did not mean to	0 1 2 3
18	I had a lot of feelings about prostate cancer, but I didn't want to deal with them	0 1 2 3
19	I had more trouble falling asleep because I couldn't get thoughts of prostate cancer out of my mind	0 1 2 3
20	I was afraid that the results from my PSA test would show that my disease was getting worse	0 1 2 3
21	Just hearing the words 'prostate cancer' scared me	0 1 2 3

*For the next three questions, please indicate how frequently these situations have **EVER** been true for you.*

(Scores: 0=Not at all; 1=Rarely; 2=Sometimes; 3=Often)

No.	Question	Score
22	I have been so anxious about my PSA test that I have thought about delaying it	0 1 2 3
23	I have been so worried about my PSA test result that I have thought about asking my doctor to repeat it	0 1 2 3

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- 24 I have been so concerned about my PSA test result that I have **0 1 2 3**
 thought about having the test repeated at another lab to make sure
 they were accurate

*The following are a number of statements concerning a person's beliefs about their own health. In thinking about the **past week**, please indicate how much you agree or disagree with each statement: strongly agree, agree, disagree, or strongly disagree. Please circle the number of your answer.*

(Scores: 0= Strongly agree; 1= Agree; 2= Disagree; 3= Strongly disagree)

No.	Question	Score
25	Because cancer is unpredictable, I feel I cannot plan for the future	0 1 2 3
26	My fear of having my cancer getting worse gets in the way of my enjoying life	0 1 2 3
27	I am afraid of my cancer getting worse	0 1 2 3
28	I am more nervous since I was diagnosed with prostate cancer	0 1 2 3

Note: Brief Symptom Inventory (BSI18) questions (Q29-Q46) are not shown due to licencing restrictions.

QUESTION ON PHYSICAL ACTIVITY

*The following questions are about any physical activities that you may have done in the **LAST WEEK**:*

Q47 In the **last week**, how many times have you **walked** continuously, for at least 10 minutes, for recreation, exercise or to get to or from places?

*(This must be **continuous** walking, i.e. for at least 10 minutes without stopping).*

_____ times per week.

Q48 What do you estimate was the total time that you spent **walking** in this way in the last week? (e.g. If you walked on Monday, how long did you spend walking? If you walked on Tuesday, how long did you spend walking?...do this for the rest of the week then add up your hours and /or minutes walked)

In hours and/or minutes

_____ hours

_____ minutes

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The next questions exclude household chores, gardening or yard work:

Q49 In the last week, how many times did you do any **vigorous** physical activity which made you breathe harder or puff and pant? (*e.g. jogging, cycling, aerobics, competitive tennis, football (of all types), hockey, squash, cross-country skiing, cross-country hiking (i.e. rough or steep terrain), weight lifting, boxing, rock climbing, basketball, netball, gymnastics, using a rowing machine, martial arts, high-impact and step aerobics*).

_____times

Q50 What do you estimate was the total time that you spent doing this **vigorous** physical activity in the last week? (*e.g. If you walked on Monday, how long did you spend walking? If you walked on Tuesday, how long did you spend walking?...do this for the rest of the week then add up your hours and /or minutes doing vigorous physical activity*)

In hours and/or minutes

_____hours

_____minutes

Q51 In the last week, how many times did you do any other more **moderate** physical activities that you have not already mentioned? (*e.g. gentle swimming, social tennis, golf, dancing, badminton, table tennis, horseback riding, canoeing, kayaking, volleyball, cricket, baseball or softball, downhill skiing, cross-training, surfing and windsurfing*).

_____times

Q52 What do you estimate was the total time that you spent doing these **moderate** activities in the last week?

In hours and/or minutes

_____hours

_____minutes

QUESTIONS ON DIETARY CHANGE

The following questions are related to possible changes you may have made to your diet. These are changes that you are **CURRENTLY** using to help with your prostate cancer and/or its side effects.

Q53 Are you **CURRENTLY** eating differently to help with your prostate cancer?

☐ Yes (if **YES**, please complete question 54)

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- ☐ No (if **NO**, please go to question 55)

Q54 (please put a cross (X) for where a change in your diet was made)

- ☐ -Increasing a particular type of fat or oil (please describe)_____
- ☐ -Increased soy products_____
- ☐ -Increased fruit in general_____
- ☐ -Increased vegetables in general_____
- ☐ -Increased a particular type of food (s) (please list)_____
- ☐ -Increased a particular type of drink (s) (please list)_____
- ☐ -Decreased fats, oils or fried foods (please describe)_____
- ☐ -Decreased red meat_____
- ☐ -Decreased processed meats, for example ham, salami, bacon_____
- ☐ -Decreased dairy products_____
- ☐ -Decreased a particular type of food (s) (please list)_____
- ☐ -Decreased a particular type of drink (s) (please list)_____
- ☐ -Special diet for example vegetarian or macrobiotic (please describe)_____
- ☐ -Other changes (please describe)_____

QUESTIONS ON YOUR SUPPLEMENT INTAKE

Q55 Did you supplement your diet with **VITAMINS/MINERALS &/OR HERBAL**

SUPPLEMENTS during the past 16 weeks?

- ☐ YES
- ☐ NO

If **YES**, please list items consumed below:

Brand	Type	Dose (eg 5mg)	How often

QUESTIONS ON MEDICATIONS TAKEN

Q56 Did you take any medications regularly during the past 16 weeks (prescribed or over the counter)?

- ☐ YES
- ☐ NO

SURVEY12 month follow-upStudy ID: **PROSDXXXX**If **YES**, please list below:

Medication	Dose (eg 25mg)	How Often (eg twice daily)	Condition being treated	For how long did you take them during the past 16 weeks?

QUESTIONS ON YOUR SUN SENSITIVITY

The following questions on sun sensitivity are related to your body's ability to produce vitamin D and your susceptibility to sun damage.

Q57 Which colour best describes the colour of the skin on the inside of your upper arm, that is, your skin colour without any tanning?

- ☐ Very fair
- ☐ Fair
- ☐ Light olive
- ☐ Dark olive
- ☐ Brown
- ☐ Black

Q58 What would happen to your skin if it was repeatedly exposed to bright sunlight in summer without any protection? Would it:

- ☐ Go very brown and deeply tanned
- ☐ Get moderately tanned
- ☐ Get mildly or occasionally tanned
- ☐ Get no suntan at all or
- ☐ Only get freckled

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QUESTIONS ON YOUR RECENT SUN EXPOSURE

Q59 Please tell us about the time you have spent **OUTDOORS (between 8 AM and 5 PM)** in the past 16 weeks (i.e. about 4 months). It will help if you start by writing the date 4 MONTHS AGO (just take today's date and count back to the 4th month before it), and TODAY'S DATE in the given places below.

- **Column A:** write the **first place in which you lived for 1 week or more** in the past 16 weeks. Give Town or city, State if in Australia, and give name of Country if not Australia.
- **Column B:** write what your **main activity** was when you were in this location.
Eg. Working in a job, living at home, on holiday, or other (say what it was)
- **Column C:** write the first date you were in this location.
- **Column D:** write the duration of your stay in this location.
- **Columns E and F:** write the number of hours/day you spent outdoors, and not under any shade between 9am and 5pm while living at this place.
- Now fill in columns A and B on a new row for each time you changed **for 1 week or more** the place you lived or your main activity, until you have covered the whole 16 weeks (4 month) period. If you need additional lines, you can write in the space below the table or add another sheet of paper.

Date 4 months ago: / /

A	B	C	D	E	F
Places lived for one week or more.	Main activity at this location	Approximate start date at this location	# weeks at this location	Number of hours spent outdoors at this location	
				On week days (or working days)	On weekend days (or days off)
Eg. Barcelona, Spain	Working	16 th Dec 15	4 weeks	Half an hour	4 hours
Eg. Fraser Island	Holiday	15 th Jan 16	2 weeks	6 hours	6 hours
Eg. Sydney	At home	1 st Feb 16	10 weeks	Half an hour	1 hours

Today's Date: / /

THIS IS THE END OF THE SURVEY.

Thank you for your cooperation in answering these questions. Please return these forms to us in the pre-paid envelope.

SURVEY-24 month follow-upStudy ID: **PROSDXXXX****A Randomised Control Trial of Vitamin D Supplementation in Prostate Cancer Cases (PROSD)**

This randomised control trial aims to see if oral vitamin D supplementation can prevent prostate cancer progression. This is a follow-up survey on a range of questions for information that have previously provided us at the start of the study, which will be your last. Your answers are important to us, so please answer every question. If you are not sure of the right dates or ages, your best guess is better than leaving it blank.

The information that we collect is confidential. Please be assured, that all the information collected from this study will be stored in a secure place and your name will be removed from it and it will not be used for any purpose other than for this study.

We thank you for your cooperation in completing this survey.

You can complete this survey online by going to <https://webmail.nswcc.prosD.xxxxxx>

Instructions on how to complete this survey.

- Please answer ALL the questions about yourself and your own experience by placing a cross (X) in the appropriate box(es) that is adjacent to your choice of response.
- Please write clearly using BLACK or BLUE ink.
- Please write numbers in appropriate boxes e.g. 2nd Dec 1942--0 2 /1 2 /1 9 4 2
- If you make a mistake or change your mind please draw a line through that answer and write the correct answer next to it e.g. ~~25~~ 36

Please complete the following information and return to us in the pre-paid envelope.

Questions**Page no.**

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QUESTIONS ON MEDICATIONS TAKEN	29
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SURVEY-24 month follow-upStudy ID: **PROSDXXXX****PERSONAL DETAILS**Today's date: / /

Family Name: _____

First Given name: _____

Other Given names: _____

Date of birth: / / Address

Street no: _____

Street name: _____

Suburb: _____

State: _____

Post code: Medicare Number:

Confirm contact details:

- Home telephone _____
- Work telephone _____
- Mobile _____
- Email _____

SURVEY-24 month follow-upStudy ID: **PROSDXXXX****GENERAL QUESTIONS ABOUT YOU**Q1 How much do you currently weigh?

- ☐ ___ kg **or**
- ☐ ___ stones **or**
- ☐ ___ pounds

Q2 What is your current work status? (you can cross (X) more than one box)

- ☐ In full time paid work/self-employed
- ☐ In part time paid work/doing unpaid work
- ☐ Completely retired/pensioner
- ☐ Partially retired looking after home/family
- ☐ Disabled/sick/unemployed
- ☐ Other

Q3 What best describes your current situation? (please cross one box)

- ☐ Single
- ☐ Married
- ☐ De facto/living with a partner
- ☐ Widowed
- ☐ Divorced
- ☐ Separated

Q4 Which of the following do you have? (excluding Medicare)

- ☐ Private health insurance – with extras
- ☐ Private health insurance – without extras
- ☐ Department of Veterans' Affairs white or gold card
- ☐ Health care concession card
- ☐ None of these

Q5 Do you currently smoke cigarettes, cigars, pipes or any other tobacco products:

- ☐ Daily
- ☐ At least weekly (not daily)
- ☐ Less often than weekly
- ☐ Not at all

SURVEY-24 month follow-upStudy ID: **PROSDXXXX**

Q6 Over your lifetime would you have smoked at least 100 cigarettes or a similar amount of tobacco?

☐ Yes☐ No**QUESTIONS ABOUT HEALTH**

Q7 How many times in the **LAST 12 MONTHS** have you visited your general practitioner (this does not include visits to your urologist or specialists about your prostate cancer)?

_____ Times

Q8 In the **LAST MONTH**, how many times have you fallen to the floor or ground? (put "0" if you have not fallen in the last month) _____ Times

Q9 Have you had a broken/fractured bone in the last month?

☐ Yes☐ No

Q10 In the **LAST 12 MONTHS**, has a doctor EVER told you that you have:

(Circle 'Yes' where needed)

- Cancer, other than prostate cancer (please describe type of cancer) -Yes
- Heart failure (heart failure, weak heart, enlarged heart) -Yes
- Atrial fibrillation -Yes
- High blood pressure -Yes
- Stroke -Yes
- Diabetes -Yes
- Blood clot (thrombosis) -Yes
- Enlarged prostate -Yes
- Asthma -Yes
- Hay fever -Yes
- Osteoarthritis -Yes
- Depression -Yes
- Anxiety -Yes
- Parkinson's disease -Yes
- **None of these** -Yes

SURVEY-24 month follow-up

Study ID: PROSDXXXX

QUESTIONS ABOUT YOUR PSYCHOLOGICAL DISTRESS

*The following questions are a list of comments made by men about their prostate cancer. Please **CIRCLE** the score that indicates on how frequently these comments were true for you **during the past week**:*

(Scores: 0=Not at all; 1=Rarely; 2=Sometimes; 3=Often)

No	Question	Score
11	Any reference to prostate cancer brought up strong feelings in me	0 1 2 3
12	Eventhough it's a good idea, I found that getting the PSA test scared me	0 1 2 3
13	Whenever I heard about a friend of public figure with prostate cancer, I get more anxious about my having prostate cancer	0 1 2 3
14	When I thought about having a PSA test, I got more anxious about my having prostate cancer	0 1 2 3
15	Other things kept making me think about prostate cancer	0 1 2 3
16	I felt kind of numb when I thought of prostate cancer	0 1 2 3
17	I thought about prostate cancer even though I did not mean to	0 1 2 3
18	I had a lot of feelings about prostate cancer, but I didn't want to deal with them	0 1 2 3
19	I had more trouble falling asleep because I couldn't get thoughts of prostate cancer out of my mind	0 1 2 3
20	I was afraid that the results from my PSA test would show that my disease was getting worse	0 1 2 3
21	Just hearing the words 'prostate cancer' scared me	0 1 2 3

For the next three questions, please indicate how frequently these situations have EVER been true for you.

(Scores: 0=Not at all; 1=Rarely; 2=Sometimes; 3=Often)

No	Question	Score
22	I have been so anxious about my PSA test that I have thought about delaying it	0 1 2 3
23	I have been so worried about my PSA test result that I have thought about asking my doctor to repeat it	0 1 2 3

SURVEY-24 month follow-up

Study ID: PROSDXXXX

- 24 I have been so concerned about my PSA test result that I have **0 1 2 3**
 thought about having the test repeated at another lab to make sure
 they were accurate

*The following are a number of statements concerning a person's beliefs about their own health. In thinking about the **past week**, please indicate how much you agree or disagree with each statement: strongly agree, agree, disagree, or strongly disagree. Please circle the number of your answer.*

(Scores: 0= Strongly agree; 1= Agree; 2= Disagree; 3= Strongly disagree)

No.	Question	Score
25	Because cancer is unpredictable, I feel I cannot plan for the future	0 1 2 3
26	My fear of having my cancer getting worse gets in the way of my enjoying life	0 1 2 3
27	I am afraid of my cancer getting worse	0 1 2 3
28	I am more nervous since I was diagnosed with prostate cancer	0 1 2 3

Note: Brief Symptom Inventory (BSI18) questions (Q29-Q46) are not shown due to licencing restrictions.

QUESTION ON PHYSICAL ACTIVITY

*The following questions are about any physical activities that you may have done in the **LAST WEEK**:*

Q47 In the **last week**, how many times have you **walked** continuously, for at least 10 minutes, for recreation, exercise or to get to or from places?

*(This must be **continuous** walking, i.e. for at least 10 minutes without stopping).*

_____ times per week.

Q48 What do you estimate was the total time that you spent **walking** in this way in the last week? (e.g. If you walked on Monday, how long did you spend walking? If you walked on Tuesday, how long did you spend walking?...do this for the rest of the week then add up your hours and /or minutes walked)

In hours and/or minutes

_____ hours

_____ minutes

SURVEY-24 month follow-upStudy ID: **PROSDXXXX**

The next questions exclude household chores, gardening or yard work:

Q49 In the last week, how many times did you do any **vigorous** physical activity which made you breathe harder or puff and pant? (*e.g. jogging, cycling, aerobics, competitive tennis, football (of all types), hockey, squash, cross-country skiing, cross-country hiking (i.e. rough or steep terrain), weight lifting, boxing, rock climbing, basketball, netball, gymnastics, using a rowing machine, martial arts, high-impact and step aerobics*).

_____times

Q50 What do you estimate was the total time that you spent doing this **vigorous** physical activity in the last week? (*e.g. If you walked on Monday, how long did you spend walking? If you walked on Tuesday, how long did you spend walking?...do this for the rest of the week then add up your hours and /or minutes doing vigorous physical activity*)

In hours and/or minutes

_____hours _____minutes

Q51 In the last week, how many times did you do any other more **moderate** physical activities that you have not already mentioned? (*e.g. gentle swimming, social tennis, golf, dancing, badminton, table tennis, horseback riding, canoeing, kayaking, volleyball, cricket, baseball or softball, downhill skiing, cross-training, surfing and windsurfing*).

_____times

Q52 What do you estimate was the total time that you spent doing these **moderate** activities in the last week?

In hours and/or minutes

_____hours _____minutes

QUESTIONS ON DIETARY CHANGE

The following questions are related to possible changes you may have made to your diet. These are changes that you are **CURRENTLY** using to help with your prostate cancer and/or its side effects.

Q53 Are you **CURRENTLY** eating differently to help with your prostate cancer?

- ☐ Yes (if **YES**, please complete question 54)
- ☐ No (if **NO**, please go to question 55)

SURVEY-24 month follow-upStudy ID: **PROSDXXXX**

Q54 (please put a cross (X) for where a change in your diet was made)

- ☐ -Increasing a particular type of fat or oil (please describe)_____
- ☐ -Increased soy products_____
- ☐ -Increased fruit in general_____
- ☐ -Increased vegetables in general_____
- ☐ -Increased a particular type of food (s) (please list)_____
- ☐ -Increased a particular type of drink (s) (please list)_____
- ☐ -Decreased fats, oils or fried foods (please describe)_____
- ☐ -Decreased red meat_____
- ☐ -Decreased processed meats, for example ham, salami, bacon_____
- ☐ -Decreased dairy products_____
- ☐ -Decreased a particular type of food (s) (please list)_____
- ☐ -Decreased a particular type of drink (s) (please list)_____
- ☐ -Special diet for example vegetarian or macrobiotic (please describe)_____
- ☐ -Other changes (please describe)_____

QUESTIONS ON YOUR SUPPLEMENT INTAKEQ55 Did you supplement your diet with **VITAMINS/MINERALS** &/OR **HERBAL****SUPPLEMENTS** during the past 16 weeks?☐ Yes☐ NoIf **YES**, please list items consumed below:

Brand	Type	Dose (eg 5mg)	How often

QUESTIONS ON MEDICATIONS TAKEN

Q56 Did you take any medications regularly during the past 16 weeks (prescribed or over the counter)?

☐ Yes☐ NoIf **YES**, please list:

SURVEY-24 month follow-upStudy ID: **PROSDXXXX**

Medication	Dose (eg 25mg)		How Often (eg twice daily)	Condition being treated	For how long did you take them during the past 16 weeks?

QUESTIONS ON YOUR SUN SENSITIVITY

The following questions on sun sensitivity are related to your body's ability to produce vitamin D and your susceptibility to sun damage.

Q57 Which colour best describes the colour of the skin on the inside of your upper arm, that is, your skin colour without any tanning?

- ☐ Very fair
- ☐ Fair
- ☐ Light olive
- ☐ Dark olive
- ☐ Brown
- ☐ Black

Q58 What would happen to your skin if it was repeatedly exposed to bright sunlight in summer without any protection? Would it:

- ☐ Go very brown and deeply tanned
- ☐ Get moderately tanned
- ☐ Get mildly or occasionally tanned
- ☐ Get no suntan at all or
- ☐ Only get freckled

Survey- 24 month follow-up

Study ID:

QUESTIONS ON YOUR RECENT SUN EXPOSURE

Q59 Please tell us about the time you have spent **OUTDOORS (between 8 AM and 5 PM)** in the past 16 weeks (i.e. about 4 months). It will help if you start by writing the date 4 MONTHS AGO (just take today's date and count back to the 4th month before it), and TODAY'S DATE in the given places below.

- **Column A:** write the **first place in which you lived for 1 week or more** in the past 16 weeks. Give Town or city, State if in Australia, and give name of Country if not Australia.
- **Column B:** write what your **main activity** was when you were in this location.
Eg. Working in a job, living at home, on holiday, or other (say what it was)
- **Column C:** write the first date you were in this location.
- **Column D:** write the duration of your stay in this location.
- **Columns E and F:** write the number of hours/day you spent outdoors, and not under any shade between 9am and 5pm while living at this place.
- Now fill in columns A and B on a new row for each time you changed **for 1 week or more** the place you lived or your main activity, until you have covered the whole 16 weeks (4 month) period. If you need additional lines, you can write in the space below the table or add another sheet of paper.

Date 4 months ago: / /

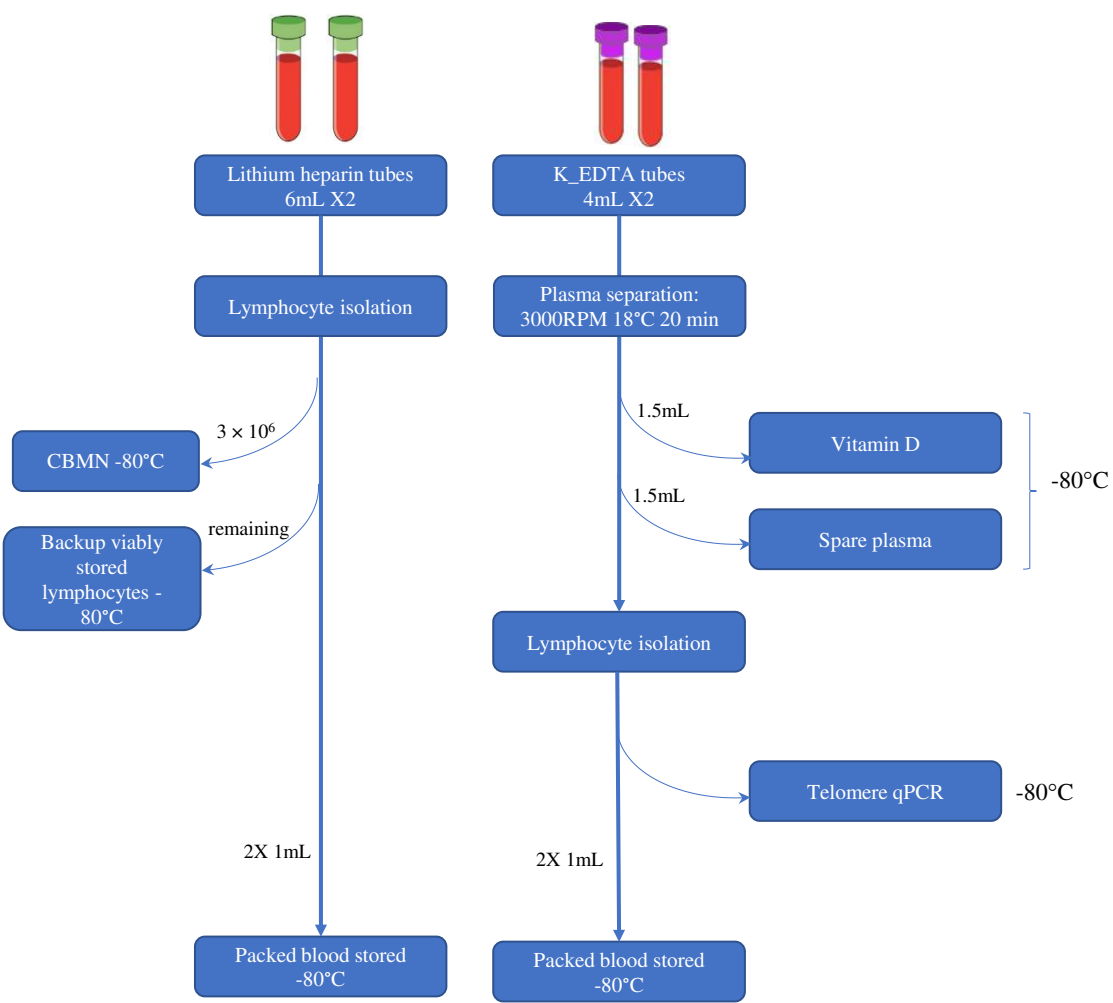
A	B	C	D	E	F
Places lived for one week or more.	Main activity at this location	Approximate start date at this location	# weeks at this location	Number of hours spent outdoors at this location	
				On week days (or working days)	On weekend days (or days off)
Eg. Barcelona, Spain	Working	16 th Dec 15	4 weeks	Half an hour	4 hours
Eg. Fraser Island	Holiday	15 th Jan 16	2 weeks	6 hours	6 hours
Eg. Sydney	At home	1 st Feb 16	10 weeks	Half an hour	1 hours

Today's Date: / /

THIS IS THE END OF THE SURVEY.

Thank you for your cooperation in answering these questions. Please return these forms to us in the pre-paid envelope.

Appendix 2. Flow Diagram for Blood Sample Processing in ProsD Study



Appendix 3



Participant Information Sheet and Consent Form

STUDY TITLE: A PHASE II RANDOMISED CONTROLLED TRIAL OF HIGH-DOSE VITAMIN D IN LOCALISED PROSTATE CANCER CASES WITH INTERMEDIATE RISK OF PROGRESSION.

Short Title	ProsD
Protocol Number	MQ_GUR_ProsD1
Local Project Sponsor	Macquarie University
Lead Investigator	Professor Howard Gurney
Urologist	
Location	

High dose vitamin D supplementation may reduce the progression of prostate cancer. Although it is approved to treat conditions relating to vitamin D deficiency, its use is not approved to treat prostate cancer due to insufficient evidence. This is a two year clinical trial which aims to see if vitamin D can prevent disease progression in men with prostate cancer who have chosen to be on active surveillance. It also aims to also establish the safety of its use in these men.

This trial is led by Professor Howard Gurney from Macquarie University, in conjunction with researchers at Cancer Council NSW, and a team of Australian urologists, geneticists and vitamin D experts.

This trial is funded by the Movember Clinical Trial Award (PCFA-CTA 1315) through the Prostate Cancer Foundation of Australia.

This Participant Information and Consent Form provides you information about this trial and explains all trial requirements. Knowing what is involved, will help you decide if you want to participate in this trial.

There will be no costs associated with participating in this research project. You will not be paid for participating in this trial.

Participation in this trial is voluntary. Whatever your decision, it will not affect your relationship with the staff caring for you. You will receive the best possible care whether or not you take part.

If you choose to participate, you will be kept informed of any significant new findings that may affect your willingness to continue in the trial. If you wish to withdraw from the trial once it has started, you can notify us of your decision. All information already collected will be retained.

Please read this information carefully. If you have any questions, please contact your urologist or the trial coordinator. Their contact details are provided at the end of this document.

Eligibility for trial participation

All men with prostate cancer, who have intermediate risk of disease progression, and who are being managed by active surveillance, and who have been diagnosed in the past 4 months, will be considered eligible to participate in this trial. You have been asked to participate because you appear to fit these criteria.

Intervention

We aim to recruit 120 participants to this trial. All participants will be randomly assigned to either, receive vitamin D for those in the intervention arm (total of 80 men in this group), or receive placebo (tablet with no active ingredient) tablets for those in the control arm (total of 40 men in this group). All participants and study investigators will be blinded to the content of the tablets, where neither party will be told which arm of the trial the participants are in; this ensures best scientific methods are used. This information, which will be held by the Clinical Trials Centre, will only be disclosed to the investigators at the end of the trial.

At the start of the trial, all participants will be asked to take 10 tablets over a period of 12 hours. From then on, all participants will be asked to take one tablet a month for the remaining 23 months. Supplements for this trial have been specifically designed and manufactured for the purpose of this trial. They cannot be purchased from the pharmacy, as the doses sold at pharmacies are lower than trial dosage.

Purpose of initial loading dose at the start of trial

The initial loading dose aims to boost blood levels of vitamin D, while the monthly dose will maintain required levels.

Managing side effects

Two other Australian based studies have previously used high dose Vitamin D supplements in this way. The Mel-D study which is a clinical trial in melanoma patients, and the D-Health study, which is an Australian study of ~20,000 men and women. Neither of these studies reported any unusual health effects in their participants. Nevertheless your blood and urine samples will be monitored closely for any signs of abnormalities.

Blood and urine collection

We will require your blood sample at 5 different time points, for the purpose of this trial, and that is, before commencement of intervention, and again at 6, 12 and 24 months. We will also require a blood and urine sample 24 hours after taking initial supplement. We will coordinate blood collection for the purpose of your routine clinical care, as requested by your doctor, at 3, 6, 9, 12, 18, and 24 months.

We will aim to coincide blood collection for the trial with that required by your doctor for your routine clinical care, to minimise your visits to the pathology centre. You will be given specific instructions to go to a pathology provider to have your blood drawn.

At the back of the form will be a list of pathology providers that you can choose for your convenience.

Purpose of multiple blood samples and urine sample

For the purpose of your safety and wellbeing, we will be collecting blood samples and urine to monitor renal function to ensure there are no adversities, 24 hours after commencing the trial. For the purpose of monitoring prostate specific antigen (PSA) levels, by your doctor, blood samples will be collected at 3, 6, 9, 12, 18 and 24 months; your doctor will continue to monitor your renal function to ensure there are no adversities. The results from these tests will be forwarded to your treating urologists, and a copy will be sent to the ProsD trial coordinator.

For the purpose of the trial, blood samples will also be collected at the start of the trial, and again at 6, 12, and 24 months, which will be used to determine if high levels of vitamin D are attained and also maintained thereafter. These blood samples will also be used to determine if there are overall changes to your gene profile following vitamin D supplementation.

All blood samples collected for the purpose of the trial will be stored in a -80C freezer at a laboratory specialising in specimen storage and analysis, and only be analysed at the end of the trial. These samples will be identified by a study identification number, not by name.

Prostate biopsy

You will not be required to have any additional biopsies for this trial. All biopsies that you will undertake will be according to standard clinical practice, as advised by your urologist. All pathology information that we will require for the trial will be collected from your clinical records. We will require a sample of your biopsy to assay for genome damage markers.

Tests conducted on your samples

We will analyse your blood and tissue biopsy samples for vitamin D levels, and also assess overall changes to your gene profile, from baseline to the end of the trial.

Blood test results

All test results will remain confidential. Only your doctor and the researchers will have access to any information about you. If any results have direct implications for your health, the trial team will inform your doctor and your doctor will discuss them with you.

Magnetic Resonance Imaging (MRI) scans

MRI scans take detailed pictures of your prostate and can indicate if your disease is progressing. Your diagnostic scan which would have been done before you were recruited to this trial, will establish your disease status. We will require you to have additional scans at 12 and 24 months, to determine if your disease has progressed. We will require copies of your diagnostic and follow-up scans.

We will cover all costs of these additional scans done at 12 and 24 months. We are unfortunately unable to reimburse any scans done before you were recruited into this trial.

Survey

You will be asked to complete a survey on your general health, demographic, diet, and lifestyle factors, your supplementation and medications use, and about your recent time spent outdoors, at the start of the study, and again at 12 and 24 months. We will mail you a copy of this survey which can be returned to us in a reply-paid envelope upon completion, or it can be completed online (details will be provided to you).

Changes to lifestyle

You will have to refrain from taking any vitamin D supplements while on this trial.

Benefits of taking part

We cannot guarantee that you will receive any benefits from this research. However, possible benefits may include a delay in your prostate cancer disease progression which means you will be able to remain on active surveillance longer. This may delay the uptake of more radical treatment and its possible side effects.

If this trial indicates that high dose vitamin D supplementation reduces disease progression, this will lead to a Phase III trial involving a larger group of men. If a Phase III trial is able to substantiate these findings, then results of the trial will be provided to prostate cancer organisations and policy makers at State and Territory, and Commonwealth levels to include high dose vitamin D supplementation in Australian clinical guidelines for the management of men on active surveillance.

Risks and disadvantages of taking part

High dose vitamin D supplementation is unlikely to cause significant side effects, as observed in two other Australian vitamin D based trials. There is a low risk of the blood calcium level becoming high. This will be monitored by the blood tests on the study and if it occurs, the vitamin D supplementation will be stopped. There is also a low risk of kidney stones if a high calcium level is not corrected by stopping the medication. If you do show signs of any new or unusual symptoms please do not hesitate to contact your treating urologists immediately.

Although your blood is drawn by professional health care professional, there is still a low risk of complications which may include fainting, dizziness, bruising at the puncture site, nerve injury and arterial puncture. If you have previously experienced any of these complications please bring this to the attention of the healthcare professional at time of your blood draw.

There are no proven long-term risks related to mpMRI scans and it is considered to be safe when performed at a centre with appropriate procedures. You will lie on a table inside the MRI scanner which will record information about your prostate. It will be important that you are in a comfortable position so that you can keep still. The scanner is very noisy and you may be given earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you. The magnetic field generated by the MRI will attract metal objects and therefore you will be instructed to remove all metallic belongings. This magnetic field can also pull on any metal containing object in your body such as medicine pumps and aneurysm clips, or result in overheating of some of the older style medical implants. Many new medical implants are designed to be MRI-compatible. Every MRI facility will have a comprehensive screening procedure to ensure the safe use of the MRI.

If you suffer any injury from participating in this study, the parties involved in this research project have agreed to cover any costs involved with ensuring the safety of all study participants. Any participants showing indications of any adverse event, adverse reaction or serious adverse event will be immediately withdrawn from the study and closely monitored by a clinician to ensure there are no further complications, at no cost to the study participant. If you wish to obtain a copy of the Medicines Australia compensation guidelines please contact the Trial coordinator on 1800 789 622 (FreeCall).

Access to clinical records

We will need to access your clinical records during the duration of this trial, and in the follow-up phase thereafter to determine long term effects. We will require your consent for us to access your clinical records.

De-identification of personal information

By signing the consent form you consent to your doctor and relevant trial staff collecting and using personal information about you for the research project. You will be assigned a unique identification number, and be referred to hereafter (i.e. blood sample tubes) by this unique identification number. Any identifiable information that is collected about you in connection with this study will be recoded to this identification number. It will remain confidential and will be disclosed only with your permission, or except as required by law. Only the investigators will have access to your details and results that will be held securely at Cancer Council NSW.

The results from this trial will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be presented in such a way that you cannot be identified.

Results from the trial

Individual results will not be provided to participants, as the analyses of these de-identified samples will only commence at the end of the trial, when all trial participants have completed the trial. The overall findings from this trial will be mailed to you in a newsletter.

Managing Adverse Effects

If you suffer any adverse effects, or complications as a result of this trial, you should contact your doctor as soon as possible and you will be assisted with arranging appropriate medical treatment.

Ethical review of this trial

All research in Australia involving humans is reviewed the Human Research Ethics Committee (HREC). This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies. The ethical aspects of this research project have been approved by the HRECs of Macquarie University, and Bellberry Limited, which is a national, private non-for-profit organisation providing high quality, independent scientific and ethical review of human research projects across Australia.

Utility of blood and tissue samples after the trial is complete

Your samples will be retained by the investigators for 15 years after the end of the trial. However since these samples are highly valuable, and may be extremely useful in future research, we seek your consent to retain these samples for longer than 15 years for cancer-related research in future. These samples may be used by future researchers, however no blood, tissue or health information will be released to a third party unless it is to carry out research that has been approved by a Human Research Ethics Committee.

All samples will be analysed simultaneously at the completion of this trial. All unused samples will be stored at -80°C, and may be used for research projects, only with the approval of a Human

Research Ethics Committee. If you do not agree to your specimen being stored beyond 15 years, then these samples will be destroyed.

What does participation in this trial involve?

Participation in this research involves taking monthly supplements, completing surveys, giving bloods, giving us consent to access your tissue biopsy and having Magnetic Resonance Imaging (MRI) scans. In addition, the researchers would like to have access to selected medical records about your prostate cancer tests, treatment and further results to obtain information relevant to the study.

If you agree to take part in this trial then:

- (i) You will agree to take 10 tablets over a period of 12 hours, at the start of the trial
- (ii) You will agree to have a urine test 24 hours after taking the first dose of supplementation, at the start of the study.
- (iii) You will agree to take 1 tablet every month for the remaining 23 months.
- (iv) You will agree to give ~twenty millilitres (~20mL), or ~one tablespoon, of blood at time of recruitment, 24 hours after taking the first dose of supplementation, at 6, 12, and 24 months each.
- (v) You will provide us consent to access your prostate cancer biopsy samples from the pathologist.
- (vi) You will agree to complete a survey (either paper survey or web-survey) at time of recruitment, and again at 12 and 24 months each.
- (vii) You will agree to have a MRI scan at 12 and 24 months (cost will be covered by the trial).
- (viii) You will consent to the use of your personal and health information.
- (ix) You will agree not to take additional vitamin D supplementation during this trial, although you can continue to take any medication as advised by your doctor

Participation in this study is voluntary. It is completely up to you whether or not you participate. Whatever your decision, it will not affect your relationship with the staff caring for you.

If you choose to participate, you will be kept informed of any significant new findings that may affect your willingness to continue in the study. If you wish to withdraw from the study once it has started, you can notify us of your decision, without having to give a reason. However all information already collected will be retained.

What to do next

If you agree to take part in this trial, please take these forms with you on your next visit to your urologist.

By signing it, you are telling us that you understand what you have read and consent to:

- taking part in this trial
- taking an initial high dose of oral vitamin D supplement
- taking a monthly dose of oral vitamin D supplements for 23 months
- giving urine and blood samples at specified time points at a pathology provider located near your residence
- Completing surveys at required time points
- having MRI scans at 12 and 24 months

- allowing researchers access your prostate biopsy samples
- allowing researchers to access your health information

You will be given a copy of this Participant Information and Consent Form to keep. Your urologist will keep one copy and return to us the third signed copy in the reply-paid envelope supplied.

After we have received your signed consent, we will send you further information about the blood collection and interview, which will be done before you are randomised to start the trial.

Remember: Participation in the study is entirely voluntary. You may withdraw at any time after you have agreed to participate.

Advice and Information

The person you may need to contact will depend on the nature of your query. If you have any medical problems which may be related to your involvement in this trial (for example any side effects) you can contact your urologist. If you want any further information concerning this project you can contact the Trial coordinator.

ProsD Study Team Contact Persons	
>Insert Urologist name<	Dr Visalini (Lini) Nair-Shalliker
Urologist	Trial Coordinator
Telephone: <Insert number>	Telephone: 1800 789 622 (FreeCall)
Email <Insert email add>	Email: enquiriesProsD@nswcc.org.au

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Bellberry Human Research Ethics Committee
HREC Executive Officer	Bellberry HREC
Telephone	(08) 8361 3222
Email	bellberry@bellberry.com.au

The Bellberry Human Research Ethics Committee has reviewed and approved this study in accordance with the National Statement on Ethical Conduct in Human Research (2007) – incorporating all updates. This Statement has been developed to protect the interests of people who agree to participate in human research studies. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Committee Chair, Bellberry Human Research Ethics Committee on 08 8361 3222.

CONSENT TO PARTICIPATE IN RESEARCH

Title: A Phase II randomised controlled trial of high-dose vitamin D in localised prostate cancer cases with intermediate risk of progression

Principal Investigator: Professor Howard Gurney

Declaration by Participant

1. I understand that the researcher will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.
2. I acknowledge that I have read, or have had read to me the Participant Information Sheet relating to this study. I acknowledge that I understand the Participant Information Sheet. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been provided to me by the Trial Coordinator and I, being over the age of 18 acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.
3. I acknowledge that I have been given time to consider the information and to seek other advice.
4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.
5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.
6. I acknowledge that this research has been approved by the Bellberry Human Research Ethics Committee.
7. I acknowledge that I have received the Participant Information Sheet and a copy of this consent form, which I have signed.
8. I acknowledge that regulatory authorities may have access to my medical records relevant to this study to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

Name of Participant (PRINT) _____	
Signature _____	Date _____

Declaration by Study Doctor:

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor (PRINT) _____	
Signature _____	Date _____

PARTICIPANT TO KEEP THIS FOR THEIR RECORDS

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Name of Study Doctor (PRINT) _____	
Signature _____	Date _____

DOCTOR TO KEEP THIS FOR THEIR RECORDS

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Name of Study Doctor (PRINT) _____	
Signature _____	Date _____

PLEASE SIGN AND RETURN IN REPLY PAID ENVELOPE

