Graham Roberts Study (Roberts Study)

Patient Questionnaire

Through the Roberts Study, we are learning about why some bladder cancers respond better to treatment than others. This will help us to develop new and better ways of predicting recurrence and progression of bladder cancer in the future, as well as new interventions that can improve quality and quantity of life. Your participation is a critical contribution toward this goal.

This questionnaire is confidential. We will be taking every step to ensure that your answers to the interview questions are stored securely and are not shared with anyone outside the study team.

If you need any help with any of the questions, please feel free to ask the study team.

Roberts Study (IRAS: 231052) Questionnaire Version 3.0 11/10/2018

Participant number: _____

Date of Birth: _____

Date of Questionnaire: _____

Is this the first time you have filled in this questionnaire? Yes/No

*If this is not the first time you have filled in the questionnaire, please skip **section 1 and 2** and proceed immediately to **section 3** below.*

Section 1 – Personal details and medical history

1. **How would you describe your race / ethnic background?**

   White/Caucasian ☐ Black/Afro-Caribbean ☐ Asian ☐ Other ☐

   If other, please specify.....

2. **What is your current marital status?**

   Married ☐ Divorced/Separated ☐ Widowed ☐ Never married ☐

3. **What is your current living arrangement?**

   Alone ☐ With partner ☐ With other family ☐

   Assisted Living ☐ Nursing Home ☐ Other ☐

4. **What is your current work status?**

   Full-time ☐ Part-time ☐ Retired ☐

   Disabled ☐ Unemployed ☐

5. **What is your highest level of education?**

   Primary school ☐ Higher education (e.g. University) ☐

   Secondary school ☐ Other ☐

For the following questions please circle or tick the appropriate answer:

6. **Have you ever had any type of cancer (except for non-melanoma skin cancer)?**

   YES NO
   If you answered yes, please specify: _____

7. **Were any of your immediate blood relatives, that is, your mother, or father, or sister(s), or brother(s), or son(s), or daughter(s), ever diagnosed as having any type of cancer?**
   - □ Yes
   - □ No – please continue to question 8
   - □ I prefer not to answer
   - □ I don't know

   Who was/were diagnosed as having cancer, that is, what was his or her relationship to you?
   - □ Mother
   - □ Father
   - □ Brother(s)
   - □ Sister(s)
   - □ Son(s)
   - □ Daughter(s)
   - □ I prefer not to answer
   - □ I don't know

   You indicated that at least one of your immediate blood relatives was diagnosed with cancer. Was he/she, or at least one of them (if more than one), diagnosed with **bladder cancer**?
   - □ Yes
   - □ No
   - □ I prefer not to answer
   - □ I don't know

8. **Did you ever have a bladder infection with at least one of the following symptoms: frequent urination or pain or burning when urinating?**
   - □ Yes
   - □ No
   - □ I prefer not to answer
   - □ I don't know

   How many times did you have this kind of infection? Would you say:
   - □ 1 or 2 times,
   - □ 3 or 5 times,
   - □ 6 or 10 times,
   - □ 11 or more times?
   - □ I prefer not to answer
   - □ I don't know

   How old were you when you first had this type of infection?
   When I was _____ years old
   - □ I prefer not to answer
   - □ I don't know

9. Did you ever have a kidney infection diagnosed by a physician?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

How many times did you have this kind of infection? Would you say:

- □ 1 or 2 times,
- □ 3 or 5 times,
- □ 6 or 10 times,
- □ 11 or more times?
- □ I prefer not to answer
- □ I don't know

10. Before 1 year ago, did you ever have renal or nephritic colic, or kidney or renal stones?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

11. Before 1 year ago, did you ever have urinary bladder stones?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

12. Before 1 year ago, did you ever have a growth removed from your urinary bladder?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

13. Did you ever have any of the following symptoms when urinating: difficulty starting, difficulty stopping or increased frequency during the night?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

14. If you are a man, please answer the following question: Did your doctor ever tell you that you had an enlarged prostate?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

[Women only] The next group of questions are about your reproductive history. Firstly, how old were you when you had your first menstrual period?

[ ] years old

- □ I prefer not to answer
- □ I don't know

Have you had at least one menstrual period in the past 12 months?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

Are you pregnant or breastfeeding?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

Have you had surgery to remove your uterus (hysterectomy)?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

Have you had any of your ovaries surgically removed (oophorectomy)?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

How many of your ovaries were removed?

- □ One
- □ Both
- □ I prefer not to answer
- □ I don't know

Have you ever taken birth control pills?

- □ Yes
- □ No
- □ I prefer not to answer
- □ I don't know

At what age did you first start taking birth control pills?

_____ year old

- □ I prefer not to answer
- □ I don't know

How long did you take birth control pills?

_____ years _____ months

- □ I prefer not to answer
- □ I don't know

How many times have you been pregnant?

- □ Never
- □ _____ times
- □ I prefer not to answer
- □ I don't know

How many of your pregnancies ended in a live birth?

_____

- □ I prefer not to answer
- □ I don't know

Section 2 – History of tobacco consumption

Please tick the most appropriate answer:

1. **During your entire lifetime, have you smoked a total of 100 cigarettes or more, which is 5 or more packs?**
   - □ Yes
   - □ No
   - □ I prefer not to answer
   - □ I don't know

2. **Did you ever smoke cigarettes regularly, that is, at least one per day for six months or longer?**
   - □ Yes
   - □ No
   - □ I prefer not to answer
   - □ I don't know

3. **Think about all the years that you smoked cigarettes, how many cigarettes per day did you usually smoke?**
   - □ Less than one
   - □ _____
     [please enter a number if it is more than 1, but less than 95]
   - □ More than 95
   - □ I prefer not to answer
   - □ I don't know

4. **How old were you when you first started smoking at least one cigarette per day?**
   years old
   - □ I prefer not to answer
   - □ I don't know

5. **How old were you when you last smoked cigarettes?**
   _____ years old
   - □ I still smoke
   - □ I refuse to answer
   - □ I don't know

6. **When you smoked cigarettes, would you say that you usually inhaled only into your mouth, into your mouth and throat or into your chest?**
   - □ Mouth only
   - □ Mouth and throat
   - □ Chest
   - □ I do not inhale
   - □ Cannot say, but not deeply into the chest
   - □ I prefer not to answer
   - □ I don't know

7. **Have you ever smoked at least one cigar per week for six months or longer?**
   - □ Yes
   - □ No
   - □ I prefer not to answer
   - □ I don't know

8. **How old were you when you first started smoking at least one cigar per week?**
   _____ years old
   - □ I refuse to answer
   - □ I don't know

9. **How old were you when you last smoked cigars?**
   _____ years old
   - □ I still smoke cigars
   - □ I refuse to answer
   - □ I don't know

10. **For how many years altogether have you smoked/did you smoke cigars? Please do not include any periods during which you may have quit.**
    _____ years _____ months
    - □ I don't know
    - □ I prefer not to answer

11. **Thinking about all the years that you smoked cigars, how many cigars did you usually smoke in a week?**
    - □ Less than one
    - □ _____
    [please enter a number if it is more than 1 but less than 95]
    - □ More than 95
    - □ I refuse to answer
    - □ I don't know

12. **Have you ever smoked at least one pipe of tobacco per week for six months or longer?**
    - □ Yes
    - □ No
    - □ I prefer not to answer
    - □ I don't know

13. **How old were you when you first started smoking at least one pipe of tobacco per week?**
    _____ years old
    - □ I refuse to answer
    - □ I don't know

14. **How old were you when you last smoked a pipe?**
    _____ years old
    - □ I still smoke a pipe
    - □ I refuse to answer
    - □ I don't know

Section 3 – Current medical conditions and medications

1. **Have you been diagnosed with any of the following medical conditions?'**

(a) High blood pressure	YES	NO
(b) Diabetes mellitus	YES	NO
(c) High cholesterol	YES	NO
(d) Myocardial infarction (heart attack)	YES	NO
(e) Angina pectoris	YES	NO
(f) Atrial fibrillation	YES	NO
(g) Congestive heart failure	YES	NO

2. **Have you regularly taken any of these medications *in the last two years*?**

(a) Non-steroidal anti-inflammatory drugs (NSAIDs)

(i) Aspirin	YES	NO
(ii) Ibuprofen (e.g. Advil, Nurofen, Nuprin, Medipren)	YES	NO
(iii) Other: _____	YES	NO

(b) "Statin" cholesterol-lowering drugs

(i) Lovastatin (e.g. Mevacor, Altocor)	YES	NO
(ii) Simvastatin (e.g. Zocor)	YES	NO
(iii) Pravastatin (e.g. Pravachol, Pravigard)	YES	NO
(iv) Atorvastatin (e.g. Lipitor)	YES	NO
(v) Other: _____	YES	NO

(c) Beta blocker drugs

(i) Metoprolol (e.g. Lopressor, Toprol)	YES	NO
(ii) Atenolol (e.g. Tenormin)	YES	NO
(iii) Nadolol (e.g. Corgard)	YES	NO
(iv) Other: _____	YES	NO

(d) Antidepressants: Selective serotonin reuptake inhibitors (SSRIs)

(i) Citalopram (e.g. Celexa)	YES	NO
(ii) Escitalopram (e.g. Lexapro)	YES	NO
(iii) Fluoxetine (e.g. Prozac)	YES	NO
(iv) Paroxetine (e.g. Paxil)	YES	NO
(v) Sertraline (e.g. Zoloft)	YES	NO
(vi) Fluvoxamine (e.g. Luvox)	YES	NO
(vii) Other: _____	YES	NO

(e) Other antidepressants

(i) Amitriptyline (e.g. Elavil, Endep)	YES	NO
(ii) Imipramine (e.g. Tofranil)	YES	NO
(iii) Nortriptyline (e.g. Pamelor)	YES	NO
(iv) Other: _____	YES	NO

(f) Sleeping tablets

(i) Diazepam (e.g. Valium)	YES	NO
(ii) Alprazolam (e.g. Xanax)	YES	NO
(iii) Lorazepam (e.g. Ativan)	YES	NO
(iv) Chlordiazepoxide (e.g. Librium)	YES	NO
(v) Other: _____	YES	NO

(g) Diabetes medications

(i) Insulin	YES	NO
(ii) Metformin	YES	NO
(iii) Rosiglitazone (e.g. Avandia)	YES	NO
(iv) Pioglitazone (e.g. Actos)	YES	NO
(v) Other: _____	YES	NO

(h) Are you on any other long-term medication? _____

Section 4 – Current smoking behaviour, alcohol consumption and other environmental/occupational exposures

Please circle the most appropriate answer:

1. **Do you currently smoke cigarettes, a pipe or cigars? If you answered YES, how many cigarettes, pipe refills or cigars do you smoke per day?**

	Cigarettes	Pipe	Cigars
Currently smoke?	YES NO	YES NO	YES NO
If yes, how many per day?	1-4 5-14 15-24 25-34 35-44 45 or more	1-4 5-10 10 or more	1-4 5-10 10 or more

2. **In a typical week over the past three months, on how many days did you consume an alcoholic drink of any type?**

No days *1 day per week* *2 days per week* *3 days per week*

4 days per week *5 days per week* *6 days per week* *7 days per week*

3. **In a typical month, what is the largest number of drinks of beer, wine and / or spirits you have in one day?**

None *1-2 drinks per day* *3-5 drinks per day*

6-9 drinks per day *10-14 drinks per day* *15 or more drinks per day*

4. **On a typical day, what is the total number of alcoholic and non-alcoholic drinks combined you have in one day?**

1*-2 pints per day* *3-5 pints per day*

6-9 pints per day *10-14 pints per day* *15 or more pints per day*

5. **On a typical day, how many cups of coffee do you drink in one day?**

None 1*-2 cups per day* *3-5 cups per day*

6-9 cups per day *10 or more cups per day*

6. **Have you ever worked in the production of rubber or aluminium or were you exposed to aromatic amines (eg. printing or dye industry) for five years or more?** YES NO

7. **Do you get your drinking water from a private well?** YES NO

Section 5 – Quality of Life (FACT-BI)

Below is a list of statements that other people have said are important**. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please mark this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

Please circle or mark one number per line to indicate your response as it applies to the past 7 days.

	ADDITIONAL CONCERNS	Not at all	A little bit	Some-what	Quite a bit	Very much
BL1	I have trouble controlling my urine	0	1	2	3	4
C2	I am losing weight	0	1	2	3	4
C3	I have control of my bowels	0	1	2	3	4
BL2	I urinate more frequently than usual	0	1	2	3	4
C5	I have diarrhoea	0	1	2	3	4
C6	I have a good appetite	0	1	2	3	4
C7	I like the appearance of my body	0	1	2	3	4
BL3	It burns when I urinate	0	1	2	3	4
BL4	I am interested in sex	0	1	2	3	4
BL5	(For men only) I am able to have and maintain an erection	0	1	2	3	4
Q2	Do you have an ostomy appliance? No___ Yes___ If yes, answer the following two items: ↓					
C8	I am embarrassed by my ostomy appliance	0	1	2	3	4
C9	Caring for my ostomy appliance is difficult	0	1	2	3	4

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Section 6 – Fatigue (FACIT - Fatigue)

Below is a list of statements that other people have said are important**. Please circle or mark one number per line to indicate your response as it applies to the past 7 days.**

		Not at all	A little bit	Some-what	Quite a bit	Very much
HI7	I feel fatigued	0	1	2	3	4
HI12	I feel weak all over	0	1	2	3	4
An1	I feel listless ("washed out")	0	1	2	3	4
An2	I feel tired	0	1	2	3	4
An3	I have trouble starting things because I am tired	0	1	2	3	4
An4	I have trouble finishing things because I am tired	0	1	2	3	4
An5	I have energy	0	1	2	3	4
An7	I am able to do my usual activities	0	1	2	3	4
An8	I need to sleep during the day	0	1	2	3	4
An12	I am too tired to eat	0	1	2	3	4
An14	I need help doing my usual activities	0	1	2	3	4
An15	I am frustrated by being too tired to do the things I want to do	0	1	2	3	4
An16	I have to limit my social activity because I am tired	0	1	2	3	4

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Section 7 – Anxiety and Depression (PHQ-9)

Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not At all	Several Days	More Than Half the Days	Nearly Every Day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed or hopeless	0	1	2	3
3. Trouble falling asleep, staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself - or that you're a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or, the opposite - being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
Column Totals	_____ +	_____ +	_____	
Add Totals Together	_____			

10. If you checked off any problems, how difficult have those problems made it for you to Do your work, take care of things at home, or get along with other people?

☐ Not difficult at all ☐ Somewhat difficult ☐ Very difficult ☐ Extremely difficult

Section 8 – Health Questionnaire (EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

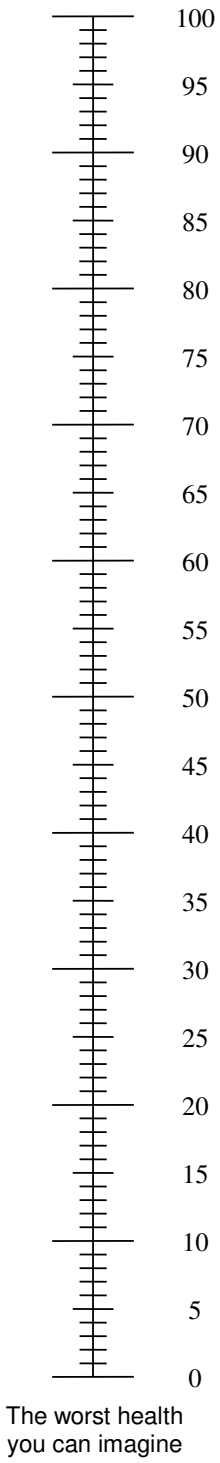
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Section 9 – Physical activity

Think about an average week in the past months. Please indicate **how many days per week** you performed the following activities, how much time on average you were engaged in this, and (if applicable) how strenuous this activity was for you?

	Days per week	Average time per day	Effort (circle please)
Walking	days	hours minutes	slow/moderate/fast
Bicycling	days	hours minutes	slow/moderate/fast
Other physical activity (e.g. swimming, gym, gardening)	days	hours minutes	slow/moderate/fast

If you wear a pedometer on a regular basis, on average how many steps a day to you take?

<2500 steps *2500-4999 steps* *5000-9999 steps*

10000 or more steps *N/A – do not use*

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Section 10 – Diet (Hertfordshire Short Questionnaire)

The section below asks you about how often over the past 3 months you have eaten particular foods.

	FOOD AND AMOUNTS	AVERAGE USE IN PAST 3 MONTHS									
		Never	Less than once/month	1-3 per month	Once a week	2-4 pe week	5-6 week	Once a day	2-3 per day	4-5 pe day	6+ per day
1	White bread (one slice)										
2	Brown and wholemeal bread (one slice)										
3	Biscuits eg digestive (one)										
4	Apples (one fruit)										
5	Bananas (one fruit)										
6	Melon, pineapple, kiwi and other tropical fruits (medium serving)										
7	Green salad eg lettuce, cucumber, celery										
8	Garlic – raw and cooked dishes										
9	Marrow and courgettes										
10	Pepper – cooked and fresh										
11	Yogurt (125g pot)										
12	Egg as boiled, fried, scrambled, etc (one egg)										
13	White fish eg cod, haddock, plaice, sole (not in batter/crumbs)										
14	Oily fish, eg mackerel, tuna, salmon										
15	Bacon and gammon										
16	Meat pies, eg pork pie, pasties, steak & kidney, sausage rolls										
17	Boiled, mashed and jacket potatoes (one egg size potato)										
18	Chips										
19	Pasta eg spaghetti, macaroni										
Which is the main spreading fat you have used for example on bread or vegetables?											
20	Spreading fat (teaspoon) _____										

ADDITIONAL DIETARY QUESTIONS

Q21 Which types of milk have you used regularly in drinks and added to breakfast cereals over the past three months? Circle all that apply.

1. Whole pasteurised
2. Semi-skimmed pasteurised (include 1% milks)
3. Skimmed pasteurised
4. Whole UHT
5. Semi-skimmed UHT
6. Skimmed UHT
7. Other: _____ (please specify)
8. None (go to Q23)

Of the above, which are the three types of milk that you drink most commonly?

Number ____ (Milk A)

Number ____ (Milk B)

Number ____ (Milk C)

Q22 On average over the past three months how much of the above have you consumed per day?

Milk A ___ . _____ pints

Milk B ___ . _____ pints

Milk C ___ . _____ pints

Q23 Have you added sugar to tea and coffee or breakfast cereals in the past three months?

No

Yes (go to Q24)

Q24 Approximately how many teaspoons of sugar have you added each day? _____