# APPENDICES

## 32. INFORMED CONSENT MATERIALS

### PATIENT INFORMATION SHEET

You are being invited to participate in a research study. Before you take part, we would like to explain the study purpose is giving you a chance to ask questions. Please read carefully the information provided here. If you agree to participate, please sign the informed consent form. You will be given a copy of this document to take home with you.

### STUDY INFORMATION

#### DESCRIPTION OF YOUR CONDITION AND THE STUDY

You have been diagnosed with a condition called prostate cancer. The treatment with radiotherapy has been decided by your doctors. This is the standard treatment for your cancer along with hormonal therapy. During radiotherapy, normally the prostate gland is treated to a high dose with radiation with computer-based planning over a period of 5-6 weeks. There is an alternative schedule in which the treatment is delivered over a shorter time of 7-10 days. We intend to study these schedules and find out the side-effects and effectiveness of both the schedules.

**The present study:** The present research is comparing two different dose schedules of radiotherapy. It is to see whether the shorter duration of treatment results is as effective as the standard duration of treatment and thus possibly help to reduce the treatment time for patients. This will also hopefully reduce the associated cost involved in radiotherapy to patients. The study plans to include about 434 study participants.



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**STUDY PROCEDURES AND VISIT SCHEDULE**

If you agree to take part in this study, before you start treatment, basic tests like blood tests, scans and x-rays will be performed, if not already done. You will be then allocated to one of the treatments by a process known as randomization. Randomization means that the decision will be impartially done by a central computer and your study doctor cannot influence to which treatment you will be assigned. In group A, patients will receive radiotherapy in 25 sittings over 5 weeks. If allotted to group B, patients will receive radiotherapy over 1-2 weeks in 5 sittings. The radiotherapy will be given with the best possible and most advanced technique in both groups to decrease possible side effects and is similar in every way except the duration of treatment. Once the treatment is decided in any group, you will be called for planning of radiation treatment. This will involve undergoing a CT scan which will be done to accurately plan the radiotherapy. You will be followed up on a regular basis to monitor your condition and all other medicines will be similar in both groups. During the follow-up, routine examination and tests by your physician will be done. You will be asked to fill quality of life form regularly to help us to understand the side effects better. You will also be asked questions on your health care expenditure to understand the financial costs borne by you during the treatment. You will need to visit the doctor's clinic 3-6 monthly for 1$^{st}$ year and 6 monthly thereafter. The frequency of visiting the doctor's clinic is the same as normal follow-up visits outside the study.

**ALTERNATIVE TREATMENTS**

If you choose not to take part in this study, you will be offered RT outside the study over 5-6 weeks. This will be discussed with you in detail by your doctor.



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**POSSIBLE RISKS AND SIDE-EFFECTS OF RADIOTHERAPY**

You will be counselled regarding the possible side effects of radiation which are no different from that of routine radiotherapy. The technique of RT that we will employ will help in reducing the side effects. These include general symptoms like nausea, vomiting, fatigue, mild weakness and loss of appetite. Skin darkening in the treated area, diarrhoea, pain and/or bleeding on passing motion, urinary urgency, increased frequency of urination or bleeding on passing urine as immediate side effects during treatment. Late side effects include increased frequency of urination, burning in urine and mild bleeding from urine and stools. These expected side effects can be treated by simple medicines if needed. Those in the short treatment group may have slightly more side effects as mentioned above compared to those on the 5-week radiotherapy schedule. In case of severe side effects, which may occur in about 2% of patients, the RT may be temporarily stopped.

**COST OF TREATMENT AND SIDE EFFECTS**

If you are in the standard group with 5 weeks of treatment, the cost of treatment will be borne by you as would have done routinely. In case you are in the short treatment group of 1-2 weeks, the cost will not be charged to you. The doctor will discuss the approximate cost of treatment with you. There will be no extra scans or tests involved**.**

**REIMBURSEMENT FOR PARTICIPATION**

No financial reimbursement is planned for participation in the study.

**EMERGENCY MEDICAL TREATMENT**

In the unlikely event of any medical emergency arising due to the radiotherapy, you will be provided the best possible care as needed. You will have to pay for it in the standard longer treatment arm but not the shorter treatment arm.



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**POTENTIAL BENEFITS**

There may be no direct benefits to you due to participation in the trial. You will receive excellent quality treatment in both arms. If you are in the arm that has radiation with shorter duration of treatment, you may have less out of pocket expenditure and can return home quickly. There is no assurance however that you will benefit from this study. Nevertheless, your participation may contribute to the medical knowledge about the best way to treat patients with disease like yours. Please remember that the many of the most effective treatments used today are the result of clinical trials done in the past.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

The information in the study records will be kept confidential and the clinical charts will be housed in the TMH/CRS/ACTREC. Data will be stored securely and will be made available only to persons conducting the study and to the regulatory authorities. The data will not be made available to another individual unless you specifically give permission in writing. No reference will be made in oral or written reports which could link you to the study. Result of the project will not be communicated to the subject unless deemed necessary.

**COMPENSATION FOR PROTOCOL RELATED INJURY**

All subjects participating in the study will be covered under institutional insurance for any trial related injury or death.

**WHOM TO CONTACT IF YOU HAVE QUESTIONS**

If you have questions about this research study and your rights or in the case of any injuries during this study, you may contact the Principal Investigator:

Dr. Vedang Murthy

Department of Radiation Oncology,

Advanced centre for treatment, research and education for cancer (ACTREC),

Tata Memorial Centre, Navi Mumbai 410210, Tel: (022) 27405000

If you have questions about the study or your rights as a participant, you can call the IEC, which is the committee that reviewed and approved this study:

The Chairperson,

Dr R Mulherkar,

IEC III,

Advanced centre for treatment, research and education for cancer (ACTREC),

Tata Memorial Centre,

Navi Mumbai 410210,

Tel:(022)27405154

**INFORMED CONSENT FORM (ICF)**

Participation

Your participation in this study is voluntary; you may decline to participate at any time without penalty and without loss of benefits to which you are otherwise entitled.

If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your non-participation will not have any adverse effects on your subsequent medical treatment or relationship with the treating physician

If you withdraw from the study before data collection is completed, your data will not be entered in the study report.

Consent

Informed Consent form to participate in a clinical trial

Study Title:

Study Number:

Subject' Initials: _____ Subject's Name: _____

Date of Birth / Age: _____

1. I understand that I am being invited to take part in the research study. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand the risks and potential benefits of this research study that were explained to me. I freely give my consent to take part in research study described in this form.
4. I understand that the Sponsor of the research study, others working on the Sponsor's behalf, IEC and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
5. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
6. I agree to take part in the above study.

   I have read the above information and agreed to participate in this study. I have received a copy of this form.
7. **Informed consent form to participate in a biological sample study**

Study Title:

Study Number:

Participant' Initials: _____

Participant's Name: _____

Date of Birth / Age: _____

**Do you consent to biological sample study?**

☐ YES, I consent ☐ NO, I do not consent

1. I understand that I am being invited to take part in the research study. I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions.
2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
3. I understand the risks and potential benefits of this research study that were explained to me. I freely give my consent to take part in research study described in this form.



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4. I understand that the investigator of the research study, others working on the Investigator's behalf, IEC and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
5. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s).
6. I agree to take part in the above study.

| | |
|---|---|
| Participant's name (print): | |
| Participant's signature & date: | |
| Address:<br><br>Qualification (please attach supporting documentation):<br>_____<br>Occupation: Student / Self-Employed / Service /Housewife /Others (Please tick as appropriate) and attach supporting documentation<br><br>Annual Income of the subject (please attach supporting documentation):<br>_____ | |
| Phone Nos.: | |
| Legally Acceptable Representative name | |
| Legally Acceptable Representative signature & date: | |

| | |
|---|---|
| Address (capital letters):<br><br>Phone Nos.: | |
| Impartial Witness's name: | |
| Impartial Witness's signature & date: | |
| Address (capital letters):<br><br>Phone Nos.: | |
| Name of PI or Co-PI/Co-I: | |
| PI or Co-PI/Co-I & date: | |

**Appendix 1: Karnofsky Performance Scale**

100- Normal, no complaints, no evidence of disease
90 - Able to carry on normal activity: minor symptoms of disease
80 - Normal activity with effort: some symptoms of disease
70 - Cares for self: unable to carry on normal activity or active work
60 - Requires occasional assistance but is able to care for needs
50 - Requires considerable assistance and frequent medical care
40 - Disabled: requires special care and assistance
30 - Severely disabled: hospitalization is indicated, death not imminent
20 - Very sick, hospitalization necessary: active treatment necessary
10 - Moribund, fatal processes progressing rapidly

**Appendix 2: RTOG Acute Toxicity**

| **Organ** | **Grade 0** | **Grade 1** | **Grade 2** | **Grade 3** | **Grade 4** |
|---|---|---|---|---|---|
| LOWER G.I. INCLUDING PELVIS | No change | Increased frequency or change in quality of bowel habits not requiring medication/ rectal discomfort not | Diarrhea requiring parasympatholytic drugs (e.g., Lomotil)/ mucous discharge not necessitating sanitary pads/ rectal or abdominal pain requiring analgesics | Diarrhea requiring parenteral support/ severe mucous or blood discharge necessitating sanitary pags/abdominal distention (flat plate radiograph demonstrates | Acute or subacute obstruction, fistula or perforation; GI bleeding requiring transfusion; abdominal pain or tenesmus requiring tube |

| | | | | | |
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| | | requiring analgesics | | distended bowel loops) | decompression or bowel diversion |
| GU | No change | Frequency of urination or nocturia twice pretreatment habit/ dysuria, urgency not requiring medication | Frequency of urination or nocturia which is less frequent than every hour. Dysuria, urgency, bladder spasm requiring local anesthetic (e.g., Pyridium) | Frequency with urgency and nocturia hourly or more frequently/ dysuria, pelvis pain or bladder spasm requiring regular, frequent narcotic/gross hematuria with/ without clot passage | Hematuria requiring transfusion/ acute bladder obstruction not secondary to clot passage, ulceration or necrosis |

## Appendix 3: RTOG Late Toxicity

| Organ | Grade 0 | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|---|---|---|---|---|---|
| Small/ Large intestine | No change | Mild diarrhoea; mild cramping; bowel movement 5 times daily; slight rectal discharge or bleeding | Moderate diarrhoea and colic; bowel movement > 5 times daily; excessive rectal mucus or intermittent bleeding | Obstruction or bleeding, requiring surgery | Necrosis/ perforation fistula |
| Bladder | No change | Slight epithelial atrophy; minor telangiectasia (microscopic hematuria) | Moderate frequency; generalized telangiectasia; intermittent macroscopic hematuria | Severe frequency & dysuria; severe telangiectasia (often with petechiae); frequent hematuria; reduction in bladder capacity (<150 cc) | Necrosis/contracted bladder (capacity < 100 cc); severe hemorrhagic cystitis |

## Appendix 4: Common Terminology Criteria for Adverse Events (CTCAE V 4.03)

| **Gastro intestinal Disorder** | | | | | |
|---|---|---|---|---|---|
| CTCAE | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
| Constipation **Definition:** A disorder characterized by irregular and infrequent or difficult evacuation of the bowels. | Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema | Persistent symptoms with regular use of laxatives or enemas; limiting instrumental ADL | Obstipation with manual evacuation indicated; limiting self-care ADL | Life-threatening consequences; urgent intervention indicated | Death |
| Diarrhea **Definition:** A disorder characterized by an increase in frequency and/or loose or watery bowel movements | Increase of <4 stools per day over baseline; mild increase in ostomy output compared to baseline | Increase of 4 - 6 stools per day over baseline; moderate increase in ostomy output compared to baseline; limiting instrumental ADL | Increase of >=7 stools per day over baseline; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self-care ADL | Life-threatening consequences; urgent intervention indicated | Death |
| Fecal incontinence **Definition:** A disorder characterized by inability to control the escape of stool from the rectum | Occasional use of pads required | Daily use of pads required | Severe symptoms; elective operative intervention indicated | - | - |
| Proctitis **Definition:** A disorder characterized by inflammation of the rectum | Rectal discomfort, intervention not indicated | Symptomatic (e.g., rectal discomfort, passing blood or mucus); medical intervention indicated; limiting instrumental ADL | Severe symptoms; fecal urgency or stool incontinence; limiting self-care ADL | Life-threatening consequences; urgent intervention indicated | Death |
| Rectal hemorrhage **Definition:** A disorder characterized by bleeding from the rectal wall | Mild symptoms; intervention not indicated | Moderate symptoms; intervention indicated | Transfusion indicated; invasive intervention indicated; hospitalization | Life-threatening consequences; urgent intervention indicated | Death |

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| and discharged from the anus | | | | | |
| Rectal pain **Definition:** A disorder characterized by a sensation of marked discomfort in the rectal region | Mild pain | Moderate pain; limiting instrumental ADL | Severe pain; limiting self-care ADL | - | - |
| Rectal ulcer **Definition:** A disorder characterized by a circumscribed, erosive lesion on the mucosal surface of the rectum | Asymptomatic; clinical or diagnostic observations only; intervention not indicated | Symptomatic; altered GI function (e.g., altered dietary habits, vomiting, diarrhea) | Severely altered GI function; TPN indicated; elective invasive intervention indicated | Life-threatening consequences; urgent operative intervention indicated | Death |

| **Renal and Urinary Disorder** |
|---|

| CTCAE | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---|---|---|---|---|---|
| **Urinary Frequency** **Definition:** A disorder characterized by urination at short intervals | Present | Limiting instrumental ADL; medical management indicated | - | - | - |
| **Urinary incontinence** **Definition:** A disorder characterized by inability to control the flow of urine from the bladder | Occasional (e.g., with coughing, sneezing, etc.), pads not indicated | Spontaneous; pads indicated; limiting instrumental ADL | Intervention indicated (e.g., clamp, collagen injections); operative intervention indicated; limiting self-care ADL | - | - |
| **Urinary retention** **Definition:** A disorder characterized by accumulation of | Urinary, suprapubic or intermittent catheter placement not indicated; able to | Placement of urinary, suprapubic or intermittent catheter placement indicated; | Elective invasive intervention indicated; substantial loss of affected kidney function or mass | Life-threatening consequences; organ failure; urgent operative | Death |

| | | | | | |
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| urine within the bladder because of the inability to urinate | void with some residual | medication indicated | | intervention indicated | |
| **Urinary tract obstruction** **Definition:** A disorder characterized by blockage of the normal flow of contents of the urinary tract | Asymptomatic; clinical or diagnostic observations only; intervention not indicated | Symptomatic but no hydronephrosis, sepsis, or renal dysfunction; urethral dilation, urinary or suprapubic catheter indicated | Altered organ function (e.g., hydronephrosis or renal dysfunction); invasive intervention indicated | Life-threatening consequences; urgent intervention indicated | Death |
| **Urinary tract pain** **Definition:** A disorder characterized by a sensation of marked discomfort in the urinary tract | Mild pain | Moderate pain; limiting instrumental ADL | Severe pain; limiting self-care ADL | - | - |
| **Urinary urgency** **Definition:** A disorder characterized by a sudden compelling urge to urinate | Present | Limiting instrumental ADL; medical management indicated | - | - | - |

**Appendix 5: Out of pocket Expenditure: Data Collection Tool**

**General Information**

Case No: _____ Trial No: _____

Type of Radiotherapy: _____

1) Name of Patient _____

   Address of Patient

   Contact No.

   Email id_____

2) Name of Respondent/Caregiver _____

Relation with Patient _____

Contact No._____

3) Religion

a) Hindu b) Muslim c) Sikh

d) Christian f) Others

4) Locality

a) Urban b) Slum c) Rural

5) Educational status

a) Illiterate b) Primary c) Middle

d) Matric e) Senior secondary f) Graduation

g) Post graduation

6) Marital Status

a) Unmarried b) Married

c) Separated/Divorced d) Widow/Widower

7) Type of Insurance

a) BPL free/poor free b) Government employee

c) Private Insurance d) Any other, specify….

e) NO

8) Previous history of

a) Smoking b) Alcohol consumption

| | | |
|---|---|---|
| **Out of pocket expenditure**<br>**From To** | | **Date of Follow up visit:** |
| **No. of Care givers:** | | |
| **Travel expense (Rs):** | 1) Home town to Mumbai & Return Journey to Home town | |
| | 2) Local Residence to Hospital | |
| | 3) Other Travel related to treatment | |
| | 1) Hormone Therapy | |

| | | |
|---|---|---|
| **Medicine expense related to cancer or its treatment:** | 2) Urinary | |
| | 3) Rectal/ Bowel | |
| | 4) Others | |
| **Tests/ Labs expense:** | 1) PSA/testosterone/BMD/CBC, etc. | |
| | 2) Scans | |
| | 3) Others | |
| **Surgery Procedure expenses** | 1) Cystoscopy | |
| | 2) Sigmoidoscopy/APC | |
| | 3) Others | |
| **Food expense for patient + Care giver:** | | |
| **lodging expense for patient + Care giver:** | | |
| **Other Related Payments/ Consultancy fee** | | |
| **Total for the visit:** | | |

c) Tobacco chewing d) Any other e) No

Name: Signature:

**33. BIOLOGICAL SPECIMENS**

Blood and urine samples and tissue specimens will be collected and preserved for future research with due permission.



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