Appendix 1

Interview Guide

Discussion of life situation in context of child’s illness

Understanding and awareness of parents about Palliative Care Unit

1. Pathways to palliative care – entry into treatment, time and quality of care, physical condition of child, severity and progression of the illness
2. Knowledge and compatibility of needs and services – awareness of existing unit, services available, usefulness of services
3. Expectations from unit – medical, financial, nursing, daily routine and others
4. Areas where support or help is perceived – arrangement of medicines, pain or wound management, other day to day requirements, emotional support and others
5. Felt advantages of unit – key service provider, as a team, unit, multi disciplinary team approach, home care services.

Influence of child’s condition on stress experienced by parents

1. Pre-illness stressful experiences – experienced stress before the illness in any domains – (financial, social, familial, inter personal relationship, illness and others)
2. Stress of witnessing the suffering of child in all domains (physical, psychological, familial, social relationships/activities, spiritual, health and others)
3. Influence of child’s resilience and coping on parental coping – understanding level of child about illness, prognosis and current situation, age, emotional, mental maturity and other factors
4. Sources of stress related to daily routine/everyday life and other factors that aggravate parental stress – pre-existing stress and distress related to current life situation and not related to illness
5. Effect of stress on the overall event – changes in perception, life style/routine/interactions and others
6. Interpersonal relationship and interaction within family – supportive, non supportive, openness, existing interaction patterns and others
Coping strategies adopted by parents

1. Internal and external factors responsible for parental coping – attribution, personal/familial meanings, availability of support system, ability of an individual to arrange for various resources satisfying current need
2. Need based changes in coping strategies – changes made in coping if the situation demands, flexibility in adopting coping strategies, types of strategies used, resources required for this
3. Factors of parental resilience across all domains that has guided the journey of parents from diagnosis to the current situation – same as above
4. Influence of spiritual, social and psychological factors on coping

Terminal Illness and parenting style

1. Factors related to the terminal stage of the illness that influences the family coping and parental styles – issues related to death and dying, preparation across various domains
2. Changes in parenting styles from one sibling to the other – regular parenting style regularly adopted by parents and changes due to the life limiting condition of child and changed life style on others
3. Past parental behavior and current condition- changes in approach, behavior because of the condition of child, disciplining patterns and others
4. Qualities of parenting that have facilitated and encouraged the child’s resilience - influence of factors like openness, control, warmth of parents, healthy interpersonal relationship, availability of parents at the time of need of child, strength/positive approach to handle the situation and others
5. Felt changes in parenting style by both (child and parents) after this life situation – changes in overall behaviour and approach to family members and child, changes in life style patterns (good or bad habits), changes in disciplining patterns, changes in level of acceptance regarding each others’ behaviour patterns and others
To,
Ms. Minu Marathe,
Principal Investigator,
TMH

Ref: Final Approval Project No. 698

Dear Ms. Marathe,

Human Ethics Committee reviewed and discussed your application dated 11.06.2009 to conduct the research study entitled "Resilience and Coping Adopted by Families of Children suffering from cancer in Palliative Care" during the HEC-II meeting held on 23.10.2009 at 9.30 a.m. in the Institutional Review Board Meeting Room, Main Bldg., 3\textsuperscript{rd} Floor, Tata Memorial Hospital.

The following documents were reviewed and approved:

1. Project Submission form.
2. Study protocol
4. Informed consent forms version 2 in English, Hindi and Marathi
5. Lay summary & questionnaire in English, Hindi and Marathi

The following members of the Human Ethics Committee-II (HEC-II) were present at the meeting held on 23.10.2009 at 9.30 a.m. in the Institutional Review Board Meeting Room, Main Bldg., 3\textsuperscript{rd} Floor, Tata Memorial Hospital.

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<tbody>
<tr>
<td>1</td>
<td>Mr. PK Rao</td>
<td>Acting Chairperson, Founder/ Trustee of JASCAP, Jeeol Association for support to Cancer patients since 1996</td>
<td>Male</td>
<td>Lay person</td>
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<tr>
<td>2</td>
<td>Dr. Medha Joshi</td>
<td>Member Secretary, Head, Digital Lib. Sc., Tata Memorial Hospital</td>
<td>Female</td>
<td>Library Information Sc</td>
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<tr>
<td>3</td>
<td>Dr. VR Joshi</td>
<td>Member, Head, Rheumatology, P.D. Hinduja Hospital &amp; Research Centre, Pathologist and Medico-legal Consultant, Sachana Pathology Laboratory, Medical Research Centre, Immunology Laboratory</td>
<td>Male</td>
<td>Clinician, Clinical research</td>
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<tr>
<td>4</td>
<td>Dr. R. Munagekar</td>
<td>Member, Clinical Pharmacologist, Male ACTREC, Clinical Pharmacologist</td>
<td>Male</td>
<td>Medicolegal expert</td>
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<tr>
<td>5</td>
<td>Dr. Vikram Gota</td>
<td>Alternate Member, Clinical Pharmacologist, Male ACTREC, Clinical Pharmacologist</td>
<td>Male</td>
<td>Clinical Pharmacologist</td>
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Project No. 098 Page 1 of 3
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<tr>
<td>6)</td>
<td>Dr. Reena Nair,</td>
<td>Professor, Dept. of Medical Oncology, TMH</td>
<td>Female</td>
<td>Medical Oncologist</td>
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<td>7)</td>
<td>Dr. A. Puri,</td>
<td>Associate Professor, Dept. of Bone &amp; Soft tissue, TMH</td>
<td>Male</td>
<td>Surgeon</td>
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<td>8)</td>
<td>Dr. M.A Muckaden,</td>
<td>Radiation Oncologist, OfC Palliative Care Services, TMH</td>
<td>Female</td>
<td>Radiation Oncologist</td>
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<td>9)</td>
<td>Ms. Munal Marathe</td>
<td>Medical Counselor</td>
<td>Female</td>
<td>Social Scientist</td>
</tr>
<tr>
<td></td>
<td>Alternate Member</td>
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The trial is approved in its presented form. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of annual status report.

Following points must be noted:

1. HEC should be informed of the yearly progress of the study.

2. HEC has approved recruitment of 30 patients on the study.

3. PI and other investigators should co-operate fully with data and safety monitoring sub-committee (DSMSC), who will monitor the trial from time to time.

4. The decision was arrived at through consensus. Neither PI nor any of proposed study team members was present during the decision making of the HEC.

5. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to HOD, DSMSC and extramural sponsors.

6. The HEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines.

7. In case of any new information or any SAE, which could affect any study, must be informed to HEC, DSMSC and sponsors. The PI should report SAEs occurred for HEC approved studies within 7 days of the occurrence of the SAE. If the SAE is ‘Death’, the IRB Secretariat will receive the SAE reporting form within 24 hours of the occurrence.

8. In the events of any protocol amendments, HEC must be informed and the amendments should be highlighted in clear terms as follows:
   a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
   b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted.
c. If the amendments require a change in the consent form, the copy of
revised Consent Form should be submitted to Ethics Committee for
approval.
d. If the amendment demands a re-look at the toxicity or side effects to
patients, the same should be documented.
e. If there are any amendments in the trial design, these must be
incorporated in the protocol, and other study documents. These revised
documents should be submitted for approval of the SRC and HEC, only
then can they be implemented.
f. Approval for amendment changes must be obtained prior to
implementation of changes. Without including all the above points, the
amendment is unlikely to be approved by the Ethics committee.
g. Any deviation/violation/waiver in the protocol must be informed to the
HEC.

Thanking You,

Yours Sincerely,

Dr. Medha Joshi,
Secretary,
Human Ethics Committee-II
Appendix 3

INFORMED CONSENT FORM

Resilience and Coping Adopted by Families of Children in Palliative Care

Mrunal Marathe (Ph.D. Scholar)

Dr Srilatha Juvva (Research Guide)

Dr. M.A. Muckaden and Prof. C.A.K. Yesudian (Dissertation Advisors)

The parents of cancer affected children undergo a variety of experiences, including psychological challenges, illness related and other issues. Cancer in the terminal stage adds distress to the parental stress level. Parents of the children use their own ways of coping. The factors affecting this process will be studied. The efficacy of the available support system will be studied comparing them with the expressed parental needs and expectations.

Information

This exploratory study will adhere to the paradigm of Qualitative Research Methodology

Unstructured interview will be conducted in a quiet room assuring privacy in the Palliative care clinic area by using Interview guide. Duration of the interview will be a minimum of thirty minutes and a maximum of two hours and will be arranged according to mutual convenience of the interviewer and the participants. Notes of the interview will be taken by the Principal Investigator and will be taped in a DVD recorder only on consent.

The information/data will be anonymous and access will be available only with the Principal Investigator. This data will be stored by the PI in a secure place, till the doctoral dissertation and viva voce examination process is completed. It will be used to prepare a document which can be published in a scientific journal or into a book. No part of this data can be traced back to you at any time.
### Risks

You may feel depressed while sharing your experiences regarding the terminal stage of your child’s disease. You have a right to ask to meet a counselor or a clinical psychologist for this purpose. The PI who is also a trained counselor will be able to identify this and make appropriate referrals. Please comply with the referrals so made.

### Reimbursement and Cost for travel

Interview will be arranged on the same day of your routine follow up. You will not be required to incur extra travel costs for the purpose of this study.

### Benefits

Your participation in this study will be highly valuable towards contributing to a model or package for intervention. Though sharing your experience may not benefit you directly, your needs, expectations can help us to understand the efficacy of the existing support system and modify it, if needed.

We hope that talking about your experiences will enrich the study and our intervention program.

### Contact for any information

If you have questions at any time about the study or the interview, you may contact the researcher, Mrunal Marathe by phone 98204 73490.

If you any doubt about your rights regarding your participation in the study, you can contact Secretary, Health Ethics Committee, I.R.B., Third Floor, Tata Memorial Hospital. Phone: 022-24177282
**Participation**

Your participation in this study is voluntary; you may decline to participate at anytime 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 symptomatic care and your non participation will not have any adverse effects on your subsequent care or relationship with the treating team.

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

I have read the above information and agree to participate in this study. I have received a copy of this form.

Participant's name (print) ________________________________

Participant's signature ________________________________

Address (in capital letters)

Date ______________

Witness’s name (print) ________________________________

Witness’s signature ________________________________

Tel No. _______________ Date _______________

PI or the person administering the consent:

Name (Print) & signature
Appendix 4

Participant Information Sheet

Lay Summary:

This is a qualitative research study exploring the factors helping parents to cope with psychosocial, emotional, spiritual and other type of distress related to the terminal stage of disease of their child. The resilience and coping mechanism is important to study and comparatively less studied in India with a focus on the issues related to death and dying of a child. The data will provide insight into the support systems and the professional services available in the field. This study will add value by modifying the existing services.

Fact Sheet:

- If your child is suffering from terminal stage of cancer, then you will be requested to participate in this study.
- Coping and resilience is a natural phenomenon and the factors affecting them are different for different individuals. We would like to collect the information on those factors.
- You might feel a little depressed during the conversation. We will help you through that feeling by discussing with you and by making appropriate referrals.
- Interview will be fixed as per your convenience on the same day of your routine follow up. The duration and number of sittings will be decided as per the mutual convenience.
- Data collected will be used to prepare scientific document for publication. This may help us to improve the existing support system that satisfies your needs at such difficult points of your life.
Appendix 5

Questionnaire to be given to the participant before administration of the Informed Consent Form

1. What is the purpose of this study?
2. Who is doing it?
3. How long will the study last?
4. How many other people are included?
5. Do you know why you are chosen to be part of the study?
6. What do you have to do?
7. What are the possible side effects?
8. Who will you contact if you face any problem?
9. How will the study affect your daily life?
10. Does the study involve extra time, costs and/or follow up visits?
11. Do you know that the information collected about yourself will be kept confidential?
12. What will happen if you do not agree to participate?