

Appendix 1:

LAURENTIAN UNIVERSITY ETHICAL REVIEW FORM FOR RESEARCH INVOLVING HUMAN SUBJECTS

(Submit Original and **seven** (7) copies of form and all relevant documentation to Research Office, L-335A. Append pages as necessary.)

DATE: October 5, 2005 FILE NUMBER: _____

I agree to conduct this research in an ethical manner, and as approved by the REB. Any changes in the approved procedure will be reported to this REB immediately, with reasons. Such changes will require additional approval from this REB, and I agree to having the REB review my plans should such changes become necessary.

PRINCIPAL/STUDENT INVESTIGATOR(s)	DEPT	EXT.	E-MAIL	
<u>Raymond W. Pong</u> print name	_____ signature	<u>CRaNHR</u> _____	<u>4357</u> _____	<u>rpong@laurentian.ca</u>
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TITLE OF RESEARCH:

Using Telehealth to Augment Delivery of Mental Health Services by Family Health Teams: Potential Barriers and Possible Solutions

FUNDING AGENCY(if applicable):

Ontario Ministry of Health and Long-Term Care & Ontario Mental Health Foundation

PROJECT DATES: ESTIMATED START: October 2005 FINISH: February 2006

(Note: allow sufficient time for project to be completed. A new Ethical review will be required after the finish date.)

REPORT DATES: February 2006 or every _____ months.

(Reports must be scheduled at least once per year.)

A. ABSTRACT OF PROPOSED RESEARCH:

Briefly and concretely describe the purpose of the research. Be sure to include sufficient detail so that the REB understands clearly **WHAT** you are proposing to do.

If the research is part of a larger project, describe its relationship with the larger project.

****For Clinical trials, please request the specific form for that type of research.**

Telehealth continues to gain in prominence and support as evidenced by numerous telehealth initiatives, pilot projects and programs (e.g., NORTH Network, CHIPP). Many health care commissions and task forces have supported the wider use of telehealth, particularly in northern, rural and remote settings. The application of information and communication technologies to mental health and psychiatric service delivery in these locations is particularly relevant because geographic distribution of psychiatrists in Canada is one of the most uneven of all medical specialties.

It may be possible to use telecommunications technology (telehealth) to provide mental health care as outlined in the guidelines prepared by the Ontario Ministry of Health and Long-Term Care for the Family Health Teams. There are however barriers to implementing telehealth such as policy, regulatory and system barriers.

Research Purpose and Approach

There is a need to conduct research to collect and analyze professional and documentary data relevant to the interface of telehealth, primary care and mental health care. Therefore, the purpose of this research project is to examine and describe the actual and potential use of telehealth in primary care to provide mental health services for Ontarians. The approach will be to conduct:

1. A focused literature search and review
2. Key informant interviews
3. Focus group discussions

Research Questions

1. What are the successes/failures in existing tele-mental health service delivery?
2. What are the barriers/facilitators, strategies/ideas, organization policies identified by key informants of utilizing tele-mental health services in primary care reform?
3. What are recommendations regarding the use of tele-mental health services in primary care reform?

Research Objectives

1. Summarize the relative literature
2. Identify barriers/facilitators, strategies/ideas from available literature and key informants
3. Suggest implications for policy and decision-makers

B. RESEARCH METHOD: Describe

- 1) Procedures for selecting the subjects (random sample, convenience sample, and so on). Specify the sampling frame if a survey is to be used. For experimental designs, give details regarding the assignment of members to groups.
 - 2) Characteristics of the subjects; i.e. age, gender, institutional affiliations, and so on.
 - 3) How subjects will be recruited, if applicable.. **Note: Recruitment must be done in a way that ensures that a potential subject's private information (phone number, e-mail address) is not available publicly.**
 - 4) Method for collecting data.
 - 5) **Attachments required: 1) Recruiting material (poster, flyer); 2) questionnaires or list of topics for structured interview; 3) Details on other research instruments to be used.**
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This is an exploratory study and will be conducted over the next four months. The design will utilize document review, individual interviews and focus groups to examine the use of tele-mental health in primary care. The role of the researchers is to engage stakeholders in the process of examining the pros and cons of telehealth in primary care for mental health services.

- I. ***Document Search and Review:*** This aspect of the study will not involve direct contact with human subjects. Data available and accessible in the public domain through Internet access and published documents will be utilized to generate information specific to the focus of the study. Bibliographic databases will be searched from 1990 to 2005 for relevant publications. The primary databases will be the Telemedicine Information Exchange, Medline/Pubmed and PsycINFO. Other databases to be searched will include the Cochrane Database of Systematic Reviews, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Social Science Abstracts.. Databases will be searched for the following keyword groups: (1) telehealth or telemedicine or e-health (or related keywords such as tele-mental health or telepsychiatry or e-mental health); (2) mental health or psychiatry; and (3) primary care reform, shared care, or similar keywords. The keyword groups will be refined or expanded as needed, and used in combination to identify potentially relevant publications. The World Wide Web will also be explored for relevant research reports using search engines such as Google (www.google.ca) and Vivísimo (<http://vivisimo.com>). Information derived from the literature review and policy/program analysis will be examined critically to identify major themes pertinent to the research objectives.
- II. ***Key Informant Interviews:*** Semi-structured interviews will be conducted by members of the Research Team. All interviews will be recorded electronically (with the participant's consent) to preclude recall bias and allow the interviewer to focus on the participant. The anticipated length of each interview is flexible and anticipated to take less than one hour. Interviews will be conducted by telephone or in-person.
 1. ***Sample Size:*** The Research Team will interview 4-6 experts in each of the three knowledge areas (12-18 in total). The Research team will employ "snowball" sampling by asking potential participants if they are interested in participating and asking them to suggest other potential participants. The Research Team will ask the Ministry of Health and Long-Term Care (MoHLTC) and the Ontario Mental Health Foundation (OMHF) to suggest potential participants.
 2. ***Characteristics of Participants:*** Participants may include MoHLTC and OMHF officials as well as senior managers and administrators in primary care or mental health organizations. Participants may include clinicians, other health care professionals and

researchers with experiential knowledge in primary care reform, mental health or telehealth. Gender, age and other demographic characteristics are not known in advance.

3. Recruitment: Potential participants will be contacted by members of the Research Team who will describe the project and the participants requirements and rights using the cover letter and consent form (Appendices A and B). Interested participants will receive a copy of the cover letter, consent form, Interview Guide (Appendix C) and Focus Group Guide (Appendix D). Participants will be asked to mail/e-mail their consent. Subsequent contact by telephone or email will set up the time, date and place for the telephone or in-person interview or focus group discussion. Participants will receive this information at least 5 days in advance of the interview or focus group discussion.
4. Data Collection and Analysis: Electronically recorded sessions will be transcribed by a research assistant and analyzed by standard content analysis by a member of the Research Team. Initial coding will identify basic issues and ideas, grouped into categories and with categories grouped into themes. Results from the key informant interviews will be combined with findings from the literature review to develop a series of main issues with suggested solutions and possible policy recommendations for discussion during the focus groups.
5. Attachments: Appendix A – Cover Letter
Appendix B – Consent Form
Appendix C – Interview Guide

III. ***Focus Group Discussions***: The Research Team anticipates a 3-hour facilitated session, starting with a 45-minute presentation of main issues, suggested solutions and possible policy recommendations. This would be followed by a facilitated discussion for about 2 hours with a 15-minute wrap-up. The 3-hour session will include a 15-minute nutrition break. Each focus group will be electronically recorded (with the consent of all participants). All participants will receive a verbal message at the beginning of the session and written explanation in the consent form about the measures that will be used to protect the privacy of individual participants. Data derived from earlier focus groups and interviews will be used to develop discussion questions for subsequent focus groups.

1. Sample Size: Two focus groups comprised of a minimum of 5-6 experts in each group will be used towards the end of the study to discuss the findings, implications and policy recommendations. It is likely that one focus group will be convened in Northern Ontario (e.g., Sudbury) while the other will be convened in Southern Ontario (e.g., Toronto).
2. Characteristics of Participants: [Same as for Interviews.]
3. Recruitment: [Same as for Interviews.]
4. Data Collection and Analysis: The electronically recorded sessions will be transcribed by a research assistant and analyzed by standard content analysis by a member of the Research Team. Initial coding will identify basic issues and ideas; these ideas and issues will be grouped into categories and combined into themes. Depending on the timing, categories and themes identified in the initial focus groups may be revised through analyses of succeeding group interviews. Differences will be resolved by consensus.
5. Attachments: Appendix A – Cover Letter
Appendix B – Consent Form
Appendix D – Focus Group Guide

C. POTENTIAL RISKS: Describe:

- 1) Potential physiological and/or psychological risks to subjects **or to third parties**. **Third parties** are those who are affected by research but do not fall within the traditional definition of "research subjects". (See *Laurentian University Policy on Integrity in Research and Scholarship, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*).
 - 2) Steps that you intend to take to either reduce the risks or to take action once the risks become obvious to you during the research implementation.
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All participants will be exposed to minimal risk as it is anticipated that the questions asked in the interviews and focus groups, as well as participant interaction in the focus groups would be similar to that encountered by the participant in their normal work environment.

Interviews

Each prospective participant will be assured that there is no known physiological risks. Psychological risks, if any, are believed to be minimal. Each participant will be informed that he/she can withdraw from the study at any time, or refuse to answer any question. Each participant will be asked for his/her permission to electronically record the interview. Participants' anonymity and confidentiality will be protected.

Focus Groups

No adverse effects for participants involved in focus groups are anticipated. The focus groups will be comprised of participants with similar occupational categories.

Each participant will be asked for his/her permission to electronically record the discussion. Participants will be informed of their right to withdraw from the focus group at any time without explanation. Participants will be informed that code numbers will be used and their names or any identifying information will not be included on electronically recorded data or transcripts.

Participants will be willing to talk and share in a face-to-face group format and agree to consent to confidentiality measures protecting participants' rights. The processes involved in the recruitment for focus groups will ensure the privacy rights of participants are respected. Anonymity associated with face-to-face contact in focus group method is not possible. To address this issue focus group facilitators will provide verbal and written explanation at the beginning of the focus group describing the measures utilized to protect the privacy of the individual participant. For example, participants will be informed that it is expected that what is said in the room, stays in the room.

D. POTENTIAL BENEFITS:

Describe in detail the benefits for the individual subjects and/or for society.

Participants may not be able to benefit directly from participating in the study. Research participants, however, may find the discussion and shared knowledge to be useful in their work and may find it fulfilling to contribute to the study. Feedback provided by participants will assist decision makers in identifying the potential for tele-mental health services in primary care reform.

E. INFORMED CONSENT:

In cases where there is any risk to the subjects or need for confidentiality, written consent forms are required. If you feel that use of a written consent is impossible, state why. When written consent forms are not used, a letter should describe the research and identify and provide contact information on the researcher(s). A copy of the consent letter (or information on the study and contact information for the investigators) should be given to the subjects. See Appendix 1 for pro forma consent form.

The following eight points need to be addressed in the Consent Form or Information Letter:

1. **Purpose** of the research
 2. **Benefits** envisaged from the research
 3. Any **inconveniences and/or risk of harm** to participants (see also #7)
 4. **Tasks** to be performed when participating
 5. Rights of the subject to **withdraw** at any time without penalty
 6. Right of the subject to have his/her personal information held **confidential**
 7. Potential **psychological or physiological risks** and how they will be managed by the researcher.
 8. The name(s) of the person(s)/group(s)/institutions eliciting or receiving the consent. (For Student projects, the name and University telephone number of the student's supervisor should be used.)
1. **See Appendix 2 for additions that may be required in some cases.**

If the Subjects are a captive population (i.e. students, employees, patients, prisoners) be sure to state that their future will not in any way be affected by participating or not participating in the study.

Deception should never be permitted when there is risk of harm to the subject or when it is not possible to advise subjects subsequently as to the reasons why the deception was necessary. If deception is needed, describe why it is needed and how it will be dealt with.

***Attach your consent form and detail below your plan for obtaining informed consent.**

The participant will be forwarded a letter that explains the study (Appendix A) and sent a copy of the consent form (Appendix B) and interview guide (Appendix C) and/or the focus group guide (Appendix D). Within two weeks of the letter, a member of the Research Team will contact the potential participant to answer any questions that he/she may have and ask if he/she is willing to participate. Those who agree to participate will be asked to sign a written consent form (Appendix B). Signed consent forms will be mailed or e-mailed to the Centre for Rural and Northern Health Research.

Consent will be reviewed prior to the interview and the focus group session in order to remind the participant of the purpose and meaning of the research. The participant will be able to keep copies of the explanation of the study for reference. Participants are invited to ask questions about their involvement and the study at any time.

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- F. ANONYMITY AND CONFIDENTIALITY OF DATA:** Describe how anonymity and confidentiality will be maintained, if it is necessary to do so for the protection of subjects from harm or embarrassment.
NOTE: Anonymity and confidentiality can be maintained without destroying data.
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All participants will be assigned a code name. In the transcription only these code names will be used as other identifying information will be removed. The electronic records and transcripts will be stored separately from identifying information in a locked cabinet at CRaNHR and then destroyed seven years after the completion of the study. Consent forms and data will be stored in separate and secure cabinets, accessible only to members of the Research Team.

Anonymity associated with face-to-face contact in focus group discussions is not possible. To address this issue, focus group facilitators will provide verbal and written explanation at the beginning of the focus group describing the measures utilized to protect the privacy of the individual participant. Participants will be encouraged to respect the privacy and confidentiality of other participants.

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- G. HOW THE SUBJECTS WILL BE INFORMED OF THE RESULTS OF THE STUDY:**
Describe how subjects will be informed of the study's results.
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Participants may request a summary of the final report to be forwarded to them at the end of the study. Request may be made verbally or in writing (preferred) to any member of the research team who will then forward the request to the Principal Investigator, Dr. Raymond Pong.

The results will be used for research purposes only and may be published in academic journals, at professional presentations, reported in trade journals, or summarized in organizations' newsletters (e.g., CRaNHR's 4-page summary series called ^{Research in} Focus _{on Research}).

Ongoing Review of the Proposal:

The Tri-Council Guidelines mandate that all research conducted with human subjects should be subject to ongoing review. Indicate the level of ongoing review which you consider the proposal requires. (Periodic reporting is adequate for research involving minimal risk, but more thorough review may be required where there is a higher level of risk.) Indicate dates on which reports may be expected by the REB. Continuing approval requires the timely submission of reports.

In all cases, any unexpected incidents which place participants at risk must be reported to the REB immediately.

A report to the REB will be prepared upon completion of the study in February 2006. If any adverse event occurs, then there will be an immediate report to the REB on the event and its resolution.

List of Appendices

- Appendix 1a: Cover Letter (Information for Prospective Participants)
- Appendix 1b: Research Consent Form
- Appendix 1c: Interview Guide and Questions
- Appendix 1d: Focus Group Guide and Questions

Appendix 1a: **Information for Prospective Participants**

Study Title: Using Telehealth to Augment Delivery of Mental Health Services by Family Health Teams: Potential Barriers and Possible Solutions

Principal Investigator: Dr. Raymond Pong Co-Investigators: Dr. Katherine Boydell
Dr. Phyllis Montgomery
John C. Hogenbirk

This study comes out of a need to identify which mental health care services could be provided by Family Health Teams by means of telecommunications technology. The researchers wish to engage key informants to help review successes/failures in tele-mental health service delivery – focusing on those that have the highest relevance to Ontario and primary care. In addition, the study will seek the opinion of experts as to potential solutions to barriers such as those related to readiness, integration, policies (e.g., remuneration, licensure, credentialing), client and provider willingness-to-use, etc. By assessing the views and perceptions of key informants, the study hopes to identify knowledge gaps and synthesize the findings and their implications for policy and decision-makers.

The Centre for Northern and Rural Health Research (CRaNHR) has received funding from the Ontario Mental Health Foundation to conduct this study. This study is being supported by the Mental Health and Rehabilitation Policy Unit of the Ministry of Health and Long-Term Care. The Research Team will conduct individual interviews, focus groups and document review to achieve research objectives. This study received approval from Laurentian University Research Ethics Board.

The Research Team would like to invite you to participate in the study. Your participation in the study is entirely voluntary. You may withdraw from the study at any time. No potential risks to participating in the study are anticipated. Participation in the study may not yield immediate benefits but will assist stakeholders in identifying the role of tele-mental health in primary care reform. It is anticipated that results from the study will be utilized to make policy recommendation and changes for collaborative networks.

Confidentiality and anonymity will be protected. Code numbers will be used in data collection and personal identifiers will not be recorded on the transcripts. Data will be kept in a locked cabinet, which will only be accessible to members of the research team. Participant names will not be used in the report. Data will be pooled and reported as group data. At the conclusion of the study a summary of the study results will be available to study participants upon request.

You are invited to participate in either an individual interview or a focus group session. Please note that if you decide not to participate in an individual interview, you may still be eligible to be a member of the focus group or vice versa. Before an interview or a focus group session, you will be asked send notice of consent via email or to mail the signed consent form (attached).

Individual interviews will be conducted by members of the Research Team and are expected to last 20-30 minutes. The purpose of the interview is to obtain your perspective on which mental health care services could be provided by Family Health Teams by means of telecommunications technology.

Focus group sessions will be facilitated by 2 or 3 members of the Research Team and are expected to last 3 hours. Travel to focus group sites (Sudbury or Toronto) will be reimbursed as per Laurentian University's Reimbursement Policy.

The interview and focus group discussions will be recorded electronically with your consent. Information from the interview and focus groups will be identified only by a code name. The recording will be used

for research purposes only. At the completion of the study, the electronic recording and transcripts will be stored for seven years at CRaNHR in a secure, locked room, and then destroyed or erased.

Please take a few minutes to review the enclosed information pertaining to this research study and to consider participation in this project. A member of the research team will be calling you to answer any question you may have about the study and to ask if you would be willing to participate in either an individual interview or a focus group session.

If you have any further questions about this study or to request a copy of the results, please feel free to contact, Dr. Ray Pong, Principal Investigator, at 705-675-1151, extension 4357. If you have questions or concerns about the conduct of this study you can contact Gaby Miller, Research Officer at Laurentian University, 705-675-1151, extension 3213.

Thank you for your consideration.

Sincerely,

Dr. Raymond Pong
Research Director
Centre for Rural and Northern Health Research
Laurentian University
935 Ramsey Lake Road
Sudbury, Ontario
P3E 2C6

705-675-1151, extension 4357
rpong@laurentian.ca

Encl.

(October 2005)

Appendix 1b: **Research Consent Form**

Study Title: Using Telehealth to Augment Delivery of Mental Health Services by Family Health Teams: Potential Barriers and Possible Solutions

Principal Investigator: Dr. Raymond Pong Co-Investigators: Dr. Katherine Boydell
Dr. Phyllis Montgomery
John C. Hogenbirk

As a key informant regarding telehealth/tele-mental health/primary care reform/mental health care, I acknowledge that the research described above has been explained to me and that all questions that I have asked have been answered to my satisfaction. I know that I can ask other questions at any time during the interview. I have been informed of my right not to participate in this study and of my right to withdraw at any time without penalty. The potential harms and inconveniences have been explained to me, and I also understand that while this study may not be of direct benefit to me, my participation in the study will be of long term benefit to the field of primary mental health care.

All data including the recordings will be given a code number and will be stored in a locked file cabinet at the Centre for Rural and Northern Health Research, Laurentian University. Only members of the research team will have access to the data. All data (databases, transcripts and recordings) will be destroyed seven years after the completion of the project.

By signing this form I have not given up any of my legal rights that I would otherwise have as a research participant. If I wish to speak with a research resource person who will answer any questions about my rights in this research project or to request a copy of the findings, I will contact Dr. Ray Pong, the Principal Investigator at 705-675-1151, extension 4357. I can contact Gaby Miller, Research Officer at Laurentian University, 705-675-1151, extension 3213, if I have questions or concerns about the conduct of this study.

I will receive a signed copy of this consent form via mail within two weeks.

Having read, understood and had full explanation of this consent form and the research study, I voluntarily consent to participate in this research study and to have my interview/focus group discussion recorded electronically.

Name of Participant (please print)	Signature of Participant	Date
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I confirm that I have explained the nature and effect of this study to the person who signed the above consent form.

Name of Person soliciting consent (please print)	Signature of person soliciting consent	Date
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Mail to: John C Hogenbirk
Centre for Rural and Northern Health Research
Laurentian University
935 Ramsey Lake Road
Sudbury, Ontario P3E 2C6

Thank you for participating in this research project

Text for consent via email.

Please cut and paste the following **bolded** text into an e-mail message and send it to:
John Hogenbirk
Senior researcher
Centre for Rural and Northern Health Research
jhogenbirk@laurentian.ca

Thank you for participating in this research project

In sending this email, I assert that I have read, understood and had full explanation of this consent form and the research study, I voluntarily consent to participate in this research study and to have my interview/focus group discussion recorded electronically.

Sincerely,

[your name]
[your contact information]

Upon receipt of the e-mail, the principal investigator or one of the co-investigators will send the following reply:

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Thank you for agreeing to participate in this study and to have the interview or focus group recorded electronically.

In sending this email reply, I assert that I have explained the nature and effect of this study to your satisfaction.

A member of the research team will be contacting you shortly to arrange the time and date of the interview or focus group.

Sincerely,

[name of research team member]
[contact information]

October 2005

Appendix 1c: **Interview Guide**

A. Basic Information (asked at start of interview)

1. What is your job title?
2. What are your roles and responsibilities in your current organization?
3. Briefly, what is your experience with:
 - (a) Primary care reform? How many years?
 - (b) Mental health care? How many years?
 - (c) Telehealth? How many years?

B. Telemental Health and Primary Care Reform

1. What are some of the ways in which mental health care services can be integrated into primary care reform?
2. Which of these services could be provided by telehealth (as telemental health)?
3. What are the limitations or things to watch out for with regard to these mental/telemental health services?
4. What are the possible solutions to these limitations?
5. What are some of the barriers to the adoption of mental/telemental services in primary care reform?
6. What are some of the potential ways around these barriers?
7. Which issues about mental or telemental health would you highlight for these practitioners engaged in primary care reform projects?
8. Any other comment?

Thank you for your time

November 2005

Appendix 1d: **Focus Group Guide**

A **Basic Information** (to be completed by participants prior to focus group discussion)

1. What is your job title? _____
2. What are your roles and responsibilities in your current organization?

3. Briefly, what is your experience with:
 - (a) Primary care reform? _____
How many years? _____
 - (b) Mental health care? _____
How many years? _____
 - (c) Telehealth? _____
How many years? _____

B Recommendations for Discussion

- I. The Research Team would like your feedback on the issues, possible solutions and policy recommendations.
 1. Needs assessments followed by pilots or trials could be used to determine which services should be provided by telecommunications and information technologies for a given Family Health Team.
 2. Adequate financial support is needed to set-up and maintain the telehealth equipment and network, as well as to pay for professional and technical support personnel.
 3. Tele-mental health services need technically reliable equipment that is easy to use, consistent in technical quality, and is adequately and consistently supported. Expert advice and support should be available within a pre-determined time period for each specialty or subspecialty.
 4. Both the Family Health Teams and the experts should know what to expect in terms of when and who is available to give advice, support or backup.
 5. Each physical location needs to have a backup plan for emergencies related to patient condition/behaviour and technical malfunctions.
 6. Family Health Teams may wish to take advantage of the expertise of existing telehealth networks in Ontario to make use of:
 - a. existing policies (e.g., informed consent, duty of care, liability, on-site backup, privacy, security, confidentiality, staffing levels, training, education, professional responsibilities).
 - b. existing support services (e.g., technical, logistical, administrative)
 7. Health care providers may wish to refer to their professional associations and colleges to read up on any policy or guideline or legal requirement that deal with tele-mental health.

- II.** Are there any other major issues that the Research Team did not mention?
 - (a) What might be the solution to these issues?
 - (b) Which issues require the most immediate action?
 - (c) Which issues require long-term planning?
- III..** Are there any other issues or concerns that need to be considered?
 - (a) What are the possible solutions, policy recommendations with respect to these issues?
- IV.** Any other comment?

March 03, 2006