



DATE: -----/-----/-----
(yyyy/mm/dd)

FORM C - HUMAN SUBJECTS REVIEW SUMMARY

PURPOSE: This form is to be completed and submitted when human subjects are involved in your study.

INSTRUCTIONS: Prepare a brief summary (~2 pages) of the project goals and the involvement of human subjects, using the headings listed below.

1) **Study goals / objectives**

2) **Description of subjects**

Please describe study inclusion and exclusion criteria for subjects (e.g. age, sex, hospital service, inpatients or outpatients, clinical status, and participation in other concurrent studies).

3) **Method of recruitment**

Where and how will subjects be recruited? Append copies of any advertisements or other materials that will be used to recruit subjects. Please note that all information posted on hospital grounds must be bilingual (see Form A, section E)

4) **Type of involvement**

Duration of subjects' involvement, frequency of measures, length of interviews, etc.;

5) **Interventions**

Describe any treatments, evaluations, or other interventions that subjects will receive as part of the study, that they would not receive as part of their routine clinical care.

6) **Consent Procedures**

- (a) What type of consent will be obtained (written or oral). If consent form does not include all the elements of the Consent Form Checklist, provide justification. If you are requesting a waiver, please provide written justification.
- (b) How, where and by whom will permission be recorded/obtained?
- (c) If subjects are children, or mentally incompetent adults, provide a description of how and by whom permission will be granted.

7) **Risks**

- (a) Any physical, psychosocial, social, legal, economic, or other immediate or long range risks;
- (b) Rationale for the necessity of such risks, alternatives that were or will be considered and why alternatives may not be feasible.

8) **Benefits**

- (a) All the potential benefits to subjects who agree to participate in the study;
- (b) Why you feel the value of the information to be gained outweighs the risks.

9) **Quality of Data**

- (a) Who will be responsible for collecting and recording research data? Describe how the quality of the research data will be ensured.
- (b) If any treatments or interventions are involved in your study, who will be responsible for ensuring the quality of treatment, and how will the quality of treatment be ensured. Describe how the quality of treatment is ensured.
- (c) Describe how the research database will be maintained.

10) **Monitoring**

What type of monitoring do you propose for this study (e.g. correct completion of consent forms, document conservation)?