

GUIDELINES FOR WRITING A SOCIAL/BEHAVIORAL SCIENCE RESEARCH PROTOCOL

Official Format for Social and Behavioral Science Research Protocols at
Dana-Farber/Partners Cancer Care and Dana-Farber/Harvard Cancer Center

Office for Human Research Studies

Dana-Farber Cancer Institute
20 Overland Street, 2nd Floor
Boston, MA 02215
Tel. 617-632-3029
Fax 617-632-2686

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**Social/Behavioral Science Research Protocols Include But Are Not Limited To
Psychosocial, Epidemiological, Genetic, and Behavioral Intervention Studies**

GENERAL INSTRUCTIONS

Instructions in this document are intended to guide investigators in preparing Social/Behavioral Science protocols.

NOTE

Protocols written and submitted in a grant format will not be accepted for review.

Any questions about the instructions or the protocol submission and review process should be addressed to the **Office for Human Research Studies** at Dana-Farber Cancer Institute (DFCI), tel. (617) 632-3029.

The OHRS mailing address is: Office for Human Research Studies, Dana-Farber Cancer Institute, 20 Overland Street, 2nd Floor, Boston, MA 02215.

Materials for New Protocols

The following materials will be needed when preparing a new protocol document for submission to the OHRS.

1. **PROTOCOL APPLICATION FORMS** – Forms must be completed and submitted with the protocol. All forms are available online through the OHRS web site at: <http://www.dfcc.harvard.edu/ohrs/>
2. **PROTOCOL DOCUMENT**
3. **DF/HCC AND AFFILIATED NETWORK CONSENT FORMS.** Please remember that consent forms must be submitted on a disk. The appropriate templates and instructions are available through the OHRS web site at: <http://www.dfcc.harvard.edu/clinical-research-support/office-for-human-research-studies-ohrs/consent-documents/>
4. **OTHER RELEVANT DOCUMENTS:** All accompanying materials to be used for the study such as pilot study materials, focus group materials, recruitment letters, surveys/questionnaires, flyers, and telephone/interview scripts should be submitted as hard copies.

Protocol Page Setup

1. Font: Times New Roman, 12 pt.
 2. On each page, include the short title and the date the protocol was last changed, and the page number.
 3. Margins: Left/Right – Minimum 0.5 inches
Top/Bottom – Minimum 0.4 inches for the header and footer
 4. Pagination: bottom of page, centered.
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Protocol Design

GENERAL GUIDELINES/CHECKLIST

Social/Behavioral Science protocols and sections from greater than minimal risk protocols containing Social/Behavioral Science components should adhere to the guidelines specified below. These guidelines may be used by investigators as a checklist to ensure that all necessary aspects of a study are included in the written protocol. In addition, these specifications are followed by the committee members during the review process.

Methodology

- 1. The Social/Behavioral Science component should be listed as one of the primary, secondary, or exploratory goals.
- 2. Selection of instruments should be justified both from scientific and psychometric perspectives. A description of the instrument validation, and experience in previous studies should be included.
- 3. Timing of the instrument administration should be discussed.
- 4. The analytic plan should be clearly outlined and it should contain the following information:
 - Primary and secondary endpoints
 - Scoring of instruments/interviews
 - Sample size/power considerations
 - Analysis plan
 - Handling of missing data.

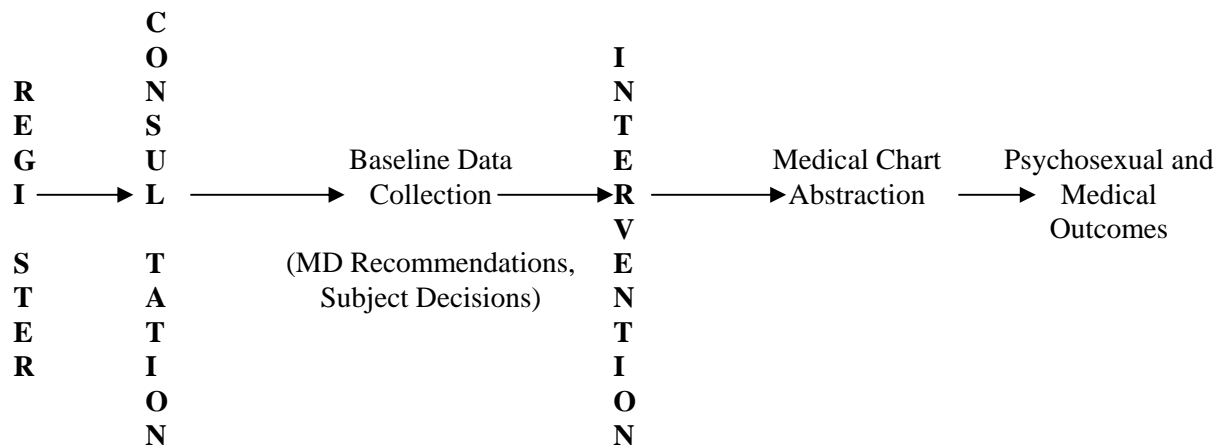
Logistics

- 5. All survey instruments, interview scripts, and any planned correspondence with subjects or their physicians should be attached.
- 6. The protocol has to include information on how Social/Behavioral Science data will be handled and disseminated (e.g. confidentiality issues, information sharing with treating physicians, information inclusion in medical charts). This information should also be included in the Consent Form.
- 7. The protocol should address how detection of serious concerns discovered during quality of life testing would be handled (e.g. access to support staff, availability of counseling).
- 8. The Consent Form has to adequately address Social/Behavioral Science testing.

SECTION 1: Protocol Schema

The schema is a diagram that gives an overall picture of the study design and treatment. It will be placed on the front of the protocol as a quick reference guide. The schema should include the major decision points and all possible outcomes. Examples of a non-randomized study schema and a randomized study schema are given below. The Quality Assurance Office for Clinical Trials (QACT) should be contacted if there are questions regarding the policy and procedures for registering and randomizing subjects.

Example 1



SECTION 2: BODY OF PROTOCOL

This part of the outline is formatted to correspond directly with the major numbered sections of a proposed protocol. The sections in this document provide information and instruction for the writing of the corresponding sections in the protocol document. Format the protocol using the major section numbers (1.0, 2.0, etc.). Subheadings (1.1, 2.1.2, etc.) may be used where appropriate.

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Example:
TABLE OF CONTENTS

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1.0 INTRODUCTION

The Introduction must be succinct; it is not a manuscript.

1.1 Overview

The first paragraph should summarize the proposed study. It should describe the study purpose and give answers to the following questions: 1) Does the study seek to test a pilot hypothesis for a future project? 2) Does the study seek to validate an instrument? 3) Will any future interventions be designed based on the findings? If applicable, this paragraph should also mention the funding information.

1.2 Background and Rationale

This section should give the background and rationale for initiating the study. Findings from a literature search must be outlined including appropriate detailed references to earlier studies and data. Results from any pilot studies conducted, if applicable, should be included. If necessary, additional references to supporting data or additional information may be included in an appendix.

2.0 OBJECTIVES

The Objectives section should give a concise statement of the research hypotheses. This section should also state whether the protocol is a feasibility or descriptive study.

Example:

To test an instrument ...

To describe ...

The study design must allow the investigator to answer the research objectives and the statistical section will have to clearly outline how the data will be evaluated in relation to each of these objectives.

3.0 RESEARCH SUBJECT SELECTION

This section should give a detailed description of research subject population being evaluated by the protocol. Consideration should be given to the following factors: 1) subject disease group and response to treatment; 2) participation in treatment protocols; and 3) prior therapy received and determination of a risk group. Any gender, employment, geographical, language, or other requirements must be also clearly stated and justified.

NOTE

A participant's eligibility cannot be affected by his/her refusal to answer individual questions on any instrument. The participant's ability to obtain treatment must likewise not be affected by refusal to participate in the Social/Behavioral Science portion of the study. However, the ability to participate in the treatment segments of protocols with Social/Behavioral Science components may be affected by the refusal to take part in the Social/Behavioral Science portion if: 1) it is a commercially sponsored study which mandates Social/Behavioral Science data collection, and/or 2) Social/Behavioral Science is the primary endpoint of the trial. Subjects have to be fully apprised about these facts and about any other conditions which may affect their ability to receive treatment.

4.0 RESEARCH SUBJECT ENTRY

This section should describe procedures for subject recruitment, registration and/or randomization. The means of obtaining consent, implied consent issues, use of opt-in/out cards, etc. should be fully described. If the investigator wishes to request a waiver of consent this must be specifically explained and rationale provided for the request. This section may also include a statement regarding a requirement to contact the Principal Investigator or designee prior to entering a subject on a study.

The name and telephone number of research study person who will be responsible for contacting the Quality Assurance Office for Clinical Trials (QACT) if applicable, should be specified.

It should also be stated whether subjects are to be registered through the Quality Assurance Office for Clinical Trials, and if so, how that will be accomplished.

Example:

To randomize and/or register a research subject to this protocol, contact the Quality Assurance Office for Clinical Trials, 20 Overland Street, 2nd Floor, at tel. 617-632-3761, FAX 617-632-2295.

When registering subjects through the QACT, the Center will ask for the following information:

- Name and telephone number of a person contacting the QACT;
- Protocol name and number;
- Date subject begins the study;

- Subject name;
- Subject date of birth;
- Service;
- Subject ID number;
- Primary physician;
- Primary treatment institution;
- Confirmation of eligibility (Eligibility Checklist, if applicable);
- Stratification or classification factors, if applicable.

NOTE

Eligibility Checklists are developed in the Quality Assurance Office for Clinical Trials and are required for all in-house protocols. The QACT should be contacted if there are any questions regarding the policy and procedures for registering and randomizing research subjects.

5.0 STUDY DESIGN AND METHODS

This section should give a detailed description of the study process.

5.1 Design/Study Type

This segment should describe the type of design being used in the protocol, e.g. randomized, cohort, case-control, etc.

5.2 Selection of Instruments

This section should provide specific information about the instruments used in the study. Consideration should be given to the following factors: 1) rationale for selecting particular instruments; 2) psychometric properties of the instruments; 3) prior pre-testing of instruments; 4) use of selected instruments in earlier studies; 5) estimated time required for completing each instrument in selected subject population; and 6) estimated duration on study for each subject.

5.3 Description of Intervention

The nature of any behavioral intervention used in the study should be described in detail including the procedures employed in the development and pilot testing of the intervention.

5.4 Data Collection

This section should specify the data which will be collected. The following tabular form may be used. If differences exist in the required data for different groups of subjects participating in the study, this should be clearly addressed in one table or if necessary - multiple tables may be used.

Example

Data	At Entry	At One Month	At One Year	At Two Years
Age	X			
Gender	X			
Disease Status	X	X	X	X
Instrument 1	X	X	X	X
Instrument 2		X	X	X

5.5 Description of Study Process

This section has to provide a detailed description of procedures to be followed in conducting the study. Consideration should be given to the segments listed below.

5.51 Instrument Administration

Clear directions explaining how the instruments will be administered (e.g. self-administered, interview-administered, etc.) have to be given. Specific information regarding the setting and supervision of the testing, mode, use of surrogates, timing, and procedures to minimize missing data has to be provided. In addition, this section should give details about the timing of the instruments such as prior notice, lead time, time to completion, etc.

5.52 Intervention Administration

This section has to address how the intervention will be executed. Information regarding frequency of intervention, setting, and disciplines of individuals administering the intervention have to be explained.

5.53 Special Concerns

Description of any anticipated complications and their proposed management and resolution strategies has to be provided.

5.54 Compensation

The issue of compensation has to be addressed in this segment. Compensation information should also be included in the Consent Form.

5.6 Adverse Reactions and Their Management

This section should include the following segments:

5.61 Reporting Adverse or Unanticipated Events

This segment must define which adverse events are reportable and must contain a plan for notifying the Institutional Review Board (IRB).

5.62 Anticipated Reactions

Description of reactions that may be expected as a consequence of participating in a study, such as distress or anger, should be stated.

5.63 Reaction Management

Instructions for reaction management and control of induced stress have to be provided. Information about available help resources, as well as names and telephone numbers of people such as psychologists and social workers who are not associated with the study, but who can be contacted in case of subject distress have to be listed. All necessary arrangements regarding the use of the above mentioned resources have to be made prior to study implementation and information about these arrangements should be stated in the protocol.

NOTE

A Social/Behavioral Science component written as part of a greater than minimal risk protocol must address the issues listed in the General Guidelines/Checklist section, page 4, of the Instructions for Writing a Social/Behavioral Science Research Protocol.

6.0 STATISTICAL ANALYSIS

The statistical analysis section should summarize the study design and rationale. It should provide evidence that the proposed design will allow investigators to achieve the principal objectives of the study and should describe the analytic plan for each objective. It should explicitly discuss how data from each of the Social/Behavioral Science instruments will be analyzed. The considerations should include discussions of the following segments, if applicable:

6.1 Primary and secondary endpoints.

6.2 Sample size and statistical power or precision associated with the sample size. 6.3 The length of time required to accrue an adequate number of subjects to the study should be indicated.

6.3 Stratification factors and intervention allocation plan for randomized studies.

- 6.5 Stratification factors and their impact on design.
- 6.6 Early stopping rules, if appropriate.
- 6.7 Definition of and allowance in design for unevaluable/ineligible participants.
- 6.8 Analysis plan.
- 6.9 Handling of missing data in the analysis.

NOTE

The Statistical Analysis section should be developed in consultation with the Department of Biostatistical Science.

7.0 REFERENCES

Each study has to contain a list of references. References should be numbered according to the order of their appearance in the text and cited in the text by the number in parenthesis. It is recommended that the reference format follow the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” (<http://www.acponline.org/journals/annals/01jan97/unifreqr.htm>)

8.0 APPENDICES

Copies of all instruments to be used, letters to potential participants or their physicians, as well as any other study materials to be seen by the participants must be submitted with the protocol.