



Brandeis University

Brandeis Committee for Protection of Human Subjects

RESEARCH REVIEW FORM

Project Title: _____

Principal Investigator: _____ Academic Title: _____ Department: _____

Work Phone: _____ Home Phone: _____ E-mail: _____

Mailing Address/Code (Campus or Home) _____

Co-Investigator: _____ Faculty Advisor (students only): _____

Projected Dates of Data Collection and Analysis: Begin Recruitment Date: _____ End Analysis Date: _____

Review Type: Exempt _____ Expedited _____ Full Review _____

Funding Status: Not Funded _____ Funded _____ Pending _____ Funding Source: _____ Brandeis #: 4- _____

1. Existing Data: Will study involve use of existing data, documents, records, pathological specimens, or diagnostic specimens? If yes, include authorization to access the data if not publicly available.

2. Subjects to be Recruited (check all that apply)		3. Data will include (check all variables included)			
a. Adults (18+ years)	<input type="checkbox"/>	a. names of people	<input type="checkbox"/>	h. income	<input type="checkbox"/>
b. Children and Minors (under 18)	<input type="checkbox"/>	b. addresses	<input type="checkbox"/>	i. social security number	<input type="checkbox"/>
c. Cognitively Impaired Persons	<input type="checkbox"/>	c. phone numbers	<input type="checkbox"/>	j. job title	<input type="checkbox"/>
d. Prisoners	<input type="checkbox"/>	d. age	<input type="checkbox"/>	k. names of employers	<input type="checkbox"/>
e. Elderly/Aged Persons	<input type="checkbox"/>	e. gender	<input type="checkbox"/>	l. types of employers	<input type="checkbox"/>
f. Minorities	<input type="checkbox"/>	f. ethnicity	<input type="checkbox"/>	m. other unique information:	<input type="checkbox"/>
g. Students (describe) _____	<input type="checkbox"/>	g. marital status	<input type="checkbox"/>	_____	
h. Others (describe) _____	<input type="checkbox"/>			_____	
i. Using existing data, no subjects will be recruited	<input type="checkbox"/>	4. Are codes used to link data to subject?			

5. Is Compensation Offered? _____ 6. Number of Subjects: _____ 7. Method of Recruiting: _____

8. Will Subject be involved in: a. an Intervention or Manipulation? _____ b. Deception? _____

9. Potential Risk Exposure: Physical Psychological Economic Legal Social

10. Instruments*	11. Recorded by	12. Administered . . .	13. Findings used for . . .
a. standardized tests <input type="checkbox"/>	a. written notes <input type="checkbox"/>	a. in person (group) <input type="checkbox"/>	a. publication <input type="checkbox"/>
b. questionnaire <input type="checkbox"/>	b. audio tape <input type="checkbox"/>	b. in person (individual) <input type="checkbox"/>	b. evaluation <input type="checkbox"/>
c. interview <input type="checkbox"/>	c. video tape/film <input type="checkbox"/>	c. telephone <input type="checkbox"/>	c. needs assessment <input type="checkbox"/>
d. other (specify) _____ <input type="checkbox"/>	d. photograph <input type="checkbox"/>	d. electronic mail <input type="checkbox"/>	d. thesis/dissertation <input type="checkbox"/>
		e. online survey <input type="checkbox"/>	e. class assignment only <input type="checkbox"/>
		e. standard mail <input type="checkbox"/>	e. other <input type="checkbox"/>

*Provide copy of instrument(s).

Principal Investigator:

Name	Title
Signature	Date

Faculty Sponsor for Student-Initiated Research: The signature below verifies the attached protocol meets with department approval and is in compliance with procedures/regulations designed to protect human subjects.

Name	Title
Signature	Date

BCPHS REVIEW: E X C R MR A CA D BCPHS Authorization: _____ Date: _____

Brandeis Committee for Protection of Human Subjects

Application Guidelines

The Principal Investigator is responsible for providing the following:

One signed, hard-copy original of the application (delivered to the Office of Research Administration, Bernstein-Marcus Rm. 121, or mailed to Brandeis Committee for Protection of Human Subjects, MS #116), **and**

One full copy of the application via e-mail (to irb@brandeis.edu).

Please note that a submission will not be deemed ready for review until both the e-mailed and hard-copy materials have been received by the IRB Administrator.

Applications must include the following:

1. FORMS:

Research Review Form

Note: There is a separate Research Review Form for research involving existing data.

Principal Investigator's Assurance

Faculty Sponsor Assurance (for student-initiated research only).

Statement of Protected Health Information Use (for projects involving health/mental health information).

2. PROTOCOL:

Title of the study.

Purpose of the study (including the expected benefits obtained by doing the study).

Sponsor of the study (for externally-funded projects).

Principal Investigator's professional qualifications to do the research (including necessary support services and facilities).

Results of previous related research.

Subject characteristics.

Subject inclusion/exclusion criteria, e.g. on the basis of ethnicity, gender, etc.

Justification for use of any special/vulnerable subject populations (for example, the decisionally impaired, children)

Recruitment procedures and materials (e.g., brochures, flyers, etc.)

Study design (including as needed, a discussion of the appropriateness of research methods).

Description of procedures to be performed.

Anticipated risks and benefits to participation in study.

Provisions for managing adverse reactions, such as physical and/or psychological harm to subjects or others.

Plans for obtaining informed consent, including circumstances surrounding consent procedure (e.g. setting, subject autonomy concerns, special considerations for vulnerable and/or non-English-speaking populations).

Procedures to be followed for documentation of informed consent, including any procedures for obtaining parental consent and child assent when subjects are minors, and using witnesses or translators.

Plans for document storage (e.g., signed consent forms, field notes, audiotapes, surveys, etc.).

Provisions for protection of subjects' privacy.

Compensation to subjects for their participation in the study.

Anticipated costs to subjects for their participation in the study.

3. SUPPORTING DOCUMENTS:

[Principal Investigator's Assurance](#)

[Faculty Sponsor Assurance](#) (student-initiated research only).

Statement of Protected Health Information Use (for projects involving health/mental health information).

The proposed informed consent documents (including parental permission forms and child assent scripts where applicable), following guidelines stipulated in 45 CFR 46 (see [Informed Consent Guidelines and Checklist](#)).

Recruitment materials (flyers, brochures, etc.)

Copies of surveys, questionnaires, interview guides, tests, or other instruments to be utilized in the research.

4. GRANT PROPOSAL (for externally-funded projects only)

5. FOLLOW-UP DOCUMENTATION

Modification Request Forms for any modifications, amendments, or addenda to approved protocol and/or attachments. These must be approved by the Committee prior to implementation.

Reports of unexpected adverse events.

Continuing Review Requests/Progress Reports, as frequently as required by Committee, but no less than annually.

Important: Final report, indicating date of completion and plans for data storage and/or destruction.

Before submitting protocol, please make sure that:

- The protocol is paginated and collated.
- Spelling is correct and grammar is accurate.
- All sections are complete to the detail requested.
- The consent and/or parental permission is written in the 2nd person, targeting a 6th-8th grade reading level, and includes all of the required informed consent elements with headings.
- Appropriate departmental signatures are documented.
- You've kept a copy of the application materials for your records.