Institutional Review Board
40 Worth Street, Fifth Floor
New York, New York 10013-2988
Tel: (646) 619-6400; Fax: (646) 619-6777
www.healthsolutions.org
IRBAdministrator@healthsolutions.org

REQUEST FOR EXEMPT STATUS

General Submission Instructions

The submission for request of exempt status should consist of 4 parts:

1. The completed application form.

2. The document(s) used to obtain informed consent.

3. Any questionnaires, notices, posters, and flyers associated with this research study; these should be submitted in English as well as all additional languages in which the research will be conducted.

4. The full proposal submitted to the funder, if there is one.

The application form can be submitted as a hard copy or as a computer file. Acceptable computer files are: any Microsoft Word version and Adobe Acrobat PDF file. Please contact Dayana Bermudez, IRB Administrator (646) 619-6701 for additional information if you would like to submit a computer file. Public Health Solutions will supply you with the application form in a Word file via email.

It is the responsibility of the Principal Investigator to submit the application in a format that can be accessed by Public Health Solutions, and the Administrator of the Institutional Review Board reserves the right to request a specific format if necessary to facilitate the administrative process.

If you are submitting protocols to multiple Review Boards you can submit another institution's form in place of Public Health Solutions' to address questions that overlap on both forms. For those questions on the Public Health Solutions form that are NOT addressed on the other form, you must submit Public Health Solutions' form with those additional questions answered.

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A submission is not considered complete unless all of the items on the Public Health Solutions form are answered, either on the other institution's form or Public Health Solutions'.

Computer File Submission Instructions

1. Request electronic file of the Request for Exempt Status from Dayana Bermudez (646) 619-6701 or via email at dbermudez@healthsolutions.org.

2. Print out a hard copy of the application form for reference before you begin.

3. Keep a copy of the original file on another disk or a hard drive as a back-up. This will be useful if an unrecoverable error is made to the working file.

4. The form has blank spaces for typed responses; use the amount of space as a guide to how long the corresponding response should be. Please do not add any additional lines to a response space. **The only exception will be when you need to report co-investigators or funding sources beyond the number currently on the form**. In that case, please copy and paste as many additional co-investigator or funding source response items as necessary.

5. Questions where the respondent must choose yes or no are automatic fill boxes. Please click on the appropriate box and mark "Checked".

6. A copy of the application and all relevant files should be sent via email to the IRB administrator at IRBAdministrator@healthsolutions.org.

7. Please submit a hard copy of your application form with the completed computer file. Please address all correspondence to

   Dayana Bermudez
   Public Health Solutions
   40 Worth Street, Fifth Floor
   NY, NY 10013

Hand deliveries can be left with the Public Health Solutions receptionist at the above address.

Submissions should be complete when they arrive at Public Health Solutions. This includes the electronic files and hard copy of the application form, a hard copy of the document(s) used to obtain informed consent, and any questionnaires, notices, posters, and flyers associated with this research study.

45 CFR 46.101(b) Categories of Exempt Human Subjects Research

The following are the six exempt categories as listed in 45 CFR 46.101(b):

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless:
    a. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to them.
    b. Any disclosure of the human participant's responses outside the research could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if:
    a. The participants are elected or appointed public officials or candidates for public office.
    b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the researcher in such a manner that participants cannot be identified, directly or through identifiers linked to them.
5. Research and demonstration projects conducted by or subject to the approval of Federal department or agency heads and designed to study, evaluate, or otherwise examine public health benefit or service programs.
6. Taste and food-quality evaluation and consumer acceptance studies.

These exemptions do not apply to research involving prisoners, fetuses, pregnant women, or newborns. Further, the exemption in item 2 above does not apply to children, except in research involving observations of public behavior when the researcher(s) do not participate in the activities being observed. Interviews, surveys, and interactive observations are not exempt, while educational tests and noninteractive observations are exempt.