How to Select the Appropriate IRB Submission Form

Investigators must complete one of the following two forms when submitting an initial protocol application form for review: 1) the Request for Exemption form, or 2) the Application for Expedited or Convened Review form. Investigators must complete the Change of Status/Annual Continuing Review/Final Report form (Part H) to revise an Exempt protocol. Investigators must complete the Change of Status/Annual Continuing Review/Final Report form (Part H) to revise, renew, or close-out an Expedited or Convened Review protocol. To determine which form is most appropriate, please utilize the IRB Mentoring Program or use the guidelines below.

1) The Request for Exemption form is used when the research to be reviewed by the IRB falls into one of the special categories of research that the federal government has qualified as exempt from the federal regulations governing human subjects research. [NOTE: It is important to understand that the form is used to *request* an exemption from the IRB (i.e., the Board will have final authority to determine whether an exemption is granted) and that protocols granted exemption from the federal regulations are still reviewed by the IRB and subject to any changes that are required by the Board.] Assuming the project does *not* involve fetuses, pregnant women, prisoners, or the cognitively impaired, the following special categories of research may qualify for exemption; thus, researchers who propose such projects should complete the Request for Exemption form:

    a) Research on regular and special education instructional strategies, or research on the effectiveness or the comparison of instructional techniques, curricula, or classroom management methods;
    b) Research involving educational tests, survey procedures, interview procedures, or observation of public behavior, *unless* the data collected could identify specific participants *and* either place those participants at risk of civil or criminal liability or be damaging to their financial standing, employability, or reputation;
    c) Research involving the collection or study of existing data, documents, records, or existing pathological or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, either directly or through identifiers linked to the subjects;
    d) Research and demonstration projects designed to study, evaluate, or otherwise examine public benefit or service programs (i.e., those administered by federal Departments or Agencies), procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs; OR
    e) Research on taste and food quality evaluation and consumer acceptance studies, as long as either wholesome foods without additives are consumed or the food additives/ingredients consumed have been deemed to be safe by the FDA, USDA, and/or EPA.

2) If the research to be reviewed by the IRB does not fall into the above categories, or if it involves fetuses, pregnant women, prisoners, or the cognitively impaired, all relevant parts of the Application for Expedited or Convened Review form should be completed and submitted. If this form is used and the research involves minimal risk to the proposed participants, the researcher may request that the protocol be submitted for expedited review. [NOTE: See page 2 of the form to determine whether your research may be considered for expedited review, and please note that based on the information provided the IRB will determine whether to grant the researcher's request for expedited review.] If the project involves more than minimal risk to participants and/or if it involves pregnant women, prisoners, or the cognitively impaired, the research may be reviewed by the convened board. We encourage you to contact the IRB Chair before completing your protocol.

3) The Change of Status/Annual Continuing Review/ Final Report Form (Part H) should be used when:

    a) an Exempt, Expedited or Convened Review protocol has been approved by the IRB and the researcher(s) subsequently would like to change part of the approved procedure or materials to be used;
    b) an annual continuing review is due to the IRB for an Expedited or Convened Board protocol [NOTE: An annual continuing review must be submitted before the date for continuing review that is listed on the IRB approval notification form.]; OR
    c) an approved Expedited or Convened Board protocol is completed or closed for any reason.