Screening Questions to Determine if an Exemption Request Application is Appropriate

This list of questions will help you to determine if your research project falls under one of the categories that are exempt from Federal Regulations and therefore not subject to IRB review. Please see page 14 of the Applicant Manual for the list of exempt categories to which the screening questions refer. All of the activities that you will employ must fall into one or more of the exempt categories in order for the project to be exempt. Please contact the IRB at x7666 if you are unsure.

If you are only using existing data, and will have no contact with subjects, please skip to # 9.

1. Does this research involve the use of any drug, device or invasive procedure, place participants at risk for bodily injury or involve them in risky behavior?  
   □ YES - submit the standard IRB application.  □ NO - continue.

2. Does your research target pregnant women or fetuses (and put the pregnancy or fetus at risk), prisoners, including individuals on probation or otherwise involved in the criminal justice system, or individuals with impaired decision-making capacity?  
   □ YES - submit the standard IRB application.  □ NO - continue.

3. Is the research conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)  
   □ YES - answer 3a.  □ NO - go to #4.

   3a. Does the research involve only normal education practices (such as research on regular or special education instructional strategies, research on effectiveness of or comparison among instructional techniques, curricula, or classroom management methods) and involve no extraordinary educational or non-educational activity?  
      □ YES - submit a Request for Exemption under Exemption Category 1. (NOTE – if your project involves surveys or interviews of minors under 18, conducted solely for the research, it cannot be exempt.)  
      □ NO - continue.

4. Does your research involve only the administration of standard educational tests (cognitive, diagnostic, aptitude, achievement)?  
   □ YES - submit a Request for Exemption under Exemption Category 2.  
   □ NO - continue.

Research conducted in schools, even if exempted by the IRB under category 1 or 2, must follow any guidelines/restrictions imposed by the school(s) or district(s). You must submit evidence of approval from any school in which the research will take place. This approval should also state whether or not the school requires or waives parental consent for the research. (Note that the UA IRB may require parental consent even if the school doesn’t.)

5. Does the research involve observation of public behavior in which the investigator does not participate in the activity being observed?  
   □ YES - submit a Request for Exemption under Exemption Category 2.  
   □ NO - continue.

6. Does your research involve the collection of data through surveys, questionnaires, interviews or focus groups, or observation of public behavior in which the investigator interacts with the subjects being observed, or?  
   □ YES - answer 6a.  □ NO - go to #7.

   6a. Are any of your subjects under the age of 18?  
      □ YES - submit the standard IRB application.  □ NO - answer 6b.

   6b. Could the data collected reveal damaging or sensitive financial or personal information, or expose criminal activity about your subjects, or persons they know?
NO - submit a Request for Exemption under Exemption Category 2.
YES - you must also answer YES to 6c, 6d or 6e to qualify for an exemption.

6c. Are data collected anonymously so that no link ever exists between the research records and the participant’s identity?
  □ YES - submit a Request for Exemption under Exemption Category 2. □ No - continue.

6d. Are your subjects elected officials or candidates for public office?
  □ YES - submit a Request for Exemption under Exemption Category 3. □ No - continue.

6e. Does any Federal statute require without exception that the confidentiality of the personally identifiable data will be maintained throughout the research and thereafter?
  □ YES - submit a Request for Exemption under Exemption Category 3. □ No - continue.

If you did not answer “YES” to 6c, 6d OR 6e, you must submit the standard IRB application.

7. Is the research conducted or approved by a Federal Department or Agency head and involve only the study, evaluation, or examination of a public benefit or service program?
  □ YES - submit a Request for Exemption under Exemption Category 5. (NOTE: This exemption is for Federally-supported projects and is most appropriately invoked with authorization or concurrence by the funding agency.)
  □ NO - go to #8.

8. Is this a study of food preferences or quality assessment to determine consumer acceptance of wholesome foods containing either no additives or additives at levels found to be safe by the Food and Drug Administration or approved for consumption by the Environmental Protection Agency or the U.S. Department of Agriculture?
  □ YES - submit a Request for Exemption under Exemption Category 6.
  □ NO - submit a standard IRB application.

Questions 9-10 are for studies involving only access to secondary data and no direct interaction or involvement with subjects.

9. Does your research involve access to private data from archives, databases, private records or biological specimens?
  □ YES - go to #10.

10. Are the subjects who provided the data individually identifiable?
  □ NO - your research does not meet the federal definition of “research on human subjects”. Please submit the IRB Registration Form.
  □ YES - answer 10a.

10a. Will all data, documents, records, or specimens be in existence before your research project begins?
  □ YES - answer 10b. □ NO - submit the standard IRB application.

10b. Is the archive, database or record collection publicly available?
  □ YES - submit a Request for Exemption under Exemption Category 4.
  □ NO - answer 10c.

10c. Will any identifying information that may link your project data to individuals in the database/archive be included in your research records? For example, will you create a link list for follow-up purposes or to compare data from multiple sources?
  □ NO - submit a Request for Exemption under Exemption Category 4.
  □ YES - submit the standard IRB application.