

## Organizing your NEW Human Subject Project

### **ALL INVESTIGATORS:**

All instructions and forms to complete your package for submission can be found in the IRBNet library once you have registered in IRBNet. When organizing your human subject research protocol and prior to submitting it for approval determination, you should look at the questions below and consider what you will need to address in preparing your submission package.

If your study involves survey or evaluation procedures, you may submit a “Request for Exemption Form”. This form is located on our web site. Exemption does not mean that you do not need to submit a study for review; our office requests information about your study to have on file for informational purposes.

If you have any questions, feel free to contact our office for assistance. Please see “Which forms do I complete?” page 2 for a list of the required and/or additional forms that you may need to complete and submit with your application.

### **STUDENT INVESTIGATORS:**

If you are a student organizing a project, you should be prepared to review this list of questions with your faculty research advisor (this may be someone different from your academic advisor) who will assist with the development of your research protocol and who will also be responsible for signing your IRBNet package prior to submitting the package for processing.

### **Human Subject research:**

1. Is this a systematic investigation designed to develop or contribute to generalizable knowledge?
2. Will you obtain information about living individuals?
3. Will you interact or intervene with these people?
4. Is this a graduate level research project?
5. Do you plan to
  - Publish or present the results, (e.g. senior design or enterprise, thesis, dissertation, public forum)?
  - Will your professor plan to use your data in a future publication or presentations?
6. Will you audio or video tape or digitally record research participant responses?
7. Does research involve members of a protected population, e.g. children, prisoners, economically or educationally disadvantaged individuals (homeless, participants whose native language is not English, etc.), pregnant women?
8. Will data be collected and stored in a manner such that participants may be individually identified directly or indirectly?
9. Is this research supported by grants or external funds?
10. Are you supported as a student by grants or external funds?
  - If so, are these federal funds?
11. Is there any potential that questions, discussions or interventions may cause discomfort (mental or physical), anxiety, or tension in participants?

## Which form(s) do I complete?

- **Request for Exemption Form** - If an exempt status is requested, do not submit through IRBNet. This form can be found on our web site and should be used when an exempt status is requested.
  
- **New Study Application Coversheet (required)**
  1. Once you have logged into IRBNet, you will need to complete the wizard document “New Study Application Coversheet” which is found on the Designer tab. Click on “Add New Document” to locate this form. This is a “*smartform*” which will automatically generate and upload to your package upon completion.
    1. This form must be completed and attached to your package with the initial request for review of your study or your request will be returned, unprocessed.
  2. See “*Required Elements Guide*” in the IRBNet library.
    1. If you are using data collection instruments, you will need to attach copies of them. Instruments which cannot be attached must be explained in detail in the protocol, (i.e., for an online survey monkey you need to either provide a copy of the survey, the link to the survey, or a document with the types of questions being asked).
  3. If this research will be conducted elsewhere (i.e., at another school, at a place of business), attach scanned signed permission letters from the institution / company.
  4. Attach letter(s), flyer(s), ad(s), or example email(s) being sent, etc. used for recruitment.
  5. If you will access information such as health-related data (HIPAA) or identifiable information from students’ educational records (FERPA), you will need to obtain written approval from the institution indicating your permission to obtain this type of data from their office, and include this letter of permission in your package.
  
- **Consent / Assent forms (required)**
  1. Submit these forms as applicable. The IRBNet library has templates to use for various situations (e.g., parent/guardian consent, child assent, adult consent, anonymous surveys, etc.)
  2. The type of consent form and/or assent form required will depend on your participants. Use the following information to determine what to submit to the IRB. Note: the consent form should be written at the level of the average newspaper reader, and you need to provide this both in English and translated if it will be presented in a native language. Explain the credentials of the translator if another language is being submitted. The consent form should be written in ‘first person’ language, (i.e., you will be..., if you have questions...)
    1. Normal volunteers (ages 18 and older)
      - a. Standard adult consent form
      - b. If you are conducting an anonymous returned survey – submit a consent for anonymous survey (see templates in the IRBNet library),
      - c. If you are conducting a telephone / informal interview – submit a consent form for interview. Consider requesting a waiver of written consent if the only thing connecting the participant to the study is the consent form, see “*Request for Waiver of Written Consent Form*” in the IRBNet library.
    2. Minors
      - a. Under age 18 – submit both a child assent form AND parental consent form (see templates in the IRBNet library). The assent must be written at an appropriate age level of the participant. See the template in the IRBNet library.
    3. **Request for waiver of written consent**

- a. During the initial review, the IRB requires the investigator to explain and provide the rationale for each condition if a waiver or alteration of informed consent is requested. For modifications to an approved project, the investigator will also be asked for an explanation if requesting a waiver or alteration of informed consent. All the conditions have to be met for the Institutional Review Board (IRB) to grant a waiver or alteration of informed consent.
  - b. You must meet specific requirements when requesting a waiver of consent, you will still need to provide informed consent language which will either be read or copied and given to participants.
    - i. **DHHS – 45 CFR 116:** “An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that”:
      1. the research involves no more than minimal risk to the subjects;
      2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
      3. the research could not practicably be carried out without the waiver or alteration; and
      4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- **Recruitment materials, permission letters, data collection instruments**
    1. These materials are created by you and are not found in the IRBNet library. All applicable documents such as sample emails, questionnaires, surveys, etc., must be uploaded to your study package and must be submitted at the time of initial submission.

**Which form(s) should you use for existing approved studies?**

- **To request CHANGES to a protocol or personnel during approval or at renewal**
  1. Complete the “**Update / Modification / Completion Form**” whenever it is necessary to make changes to the protocol or personnel to an open approved study or one that is about to expire.
- **To request RENEWAL at expiration with NO CHANGES**
  1. Complete the “**Update / Modification / Completion Form**”
- **To request CLOSURE of a project at any time**
  1. Complete the “**Update / Modification / Completion Form**”
- **Unexpected Problems / Serious Adverse Event reporting**
  1. Use the “**Unanticipated Problem / Serious Adverse Event Report Form**” to report any unexpected, unanticipated or adverse events that occur during the course of the study.