# Investigator Manual

**Wheeling University**

**Revision Date: 9/01/2009**

## Investigator Responsibilities

Investigators are obligated to fulfill the following responsibilities when conducting research with human participants at, on behalf of, or in collaboration with Wheeling University.

- Investigators are responsible for protecting the rights and welfare of human participants involved in research and for complying with all applicable Federal regulations.

- Investigators are responsible for submitting a complete application and supporting documents to the IRB Committee including but not limited to (1) an application; (2) the informed consent form; (3) recruitment materials; (4) instruments (e.g., surveys, interview questions, questionnaires); and (5) any other supporting documents.

- Investigators are responsible for obtaining informed consent from all human participants according to the procedure approved by the IRB, unless the IRB has specifically waived this requirement. All signed consent forms must be retained in a manner approved by the IRB.

- Investigators will promptly report proposed changes in previously approved research to the IRB. The proposed changes will not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the participants.

- Investigators will promptly report to the IRB any injuries or other unanticipated problems involving risks to participants or others.

## Education and Training

All investigators and research staff involved with human participant research must complete the WU IRB training at the following URL: http://phrp.nihtraining.com/users/login.php Print your completion certificate and file. Copies must be submitted with your application. Certification training is a one-time requirement at WU.

For researchers conducting a study subject to HIPAA regulations, completion of training specific to how this regulation affects research is required before study approval is granted at WU. Training sites can be located on the IRB website.

## Levels of Review

Research studies are reviewed at a full board meeting, unless the study can be classified as minimal risk and qualifies for exempt status or expedited review. The type of review depends on the risks posed to potential participants.
According to the federal regulations, minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Risk includes not only physical risk, but also psychological, emotional, legal, social, and financial. The definition of minimal risk serves as the starting point for the determination of the category of review.

## *Exempt Research*

Research involving human subjects in whom the investigator obtains data through intervention or interaction with the subject and the research involves:

- No more than minimal risk to the subject.
- No manipulation of the subject or the subject's environment.

There are five types of exempt research. Any individual research study may involve one or more types of exemption considerations. Some types or subtypes of exempt research allow exemptions if subjects are minors. Some types do not. The researcher who wishes to submit research as exempt from IRB review should study each type and evaluate the research for each type that applies.

**Type 1:** Research conducted in established or commonly accepted educational settings, involving normal educational practices such as (i) research on regular and special education instructional strategies or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This research **may** involve minors. With the adoption of the Internet for formal and informal learning, there is an expansion of what is considered a commonly accepted educational setting. Researchers should include a supplemental statement to warrant any claims when using learning environments that are now commonly accepted, but non-traditional. Include the statement within your abstract.

**Type 2:** Research that involves only the recording and analyzing of public or usual behavior. Type 2 Research design and instruments include:

- *Educational tests.* Educational tests include cognitive, diagnostic, aptitude, or achievement tests. This research **MAY** involve minors.
- *Survey procedure.* This research may **NOT** involve minors. WU IRB does not consider the collection of demographics (e.g., age, gender, and race) that accompany data collection with educational tests or within established or commonly accepted educational settings to be a survey procedure.
- *Interviews.* This research is **NOT** exempt if minors are subjects.
- *Observation of public behavior.* This is **NOT** exempt if minors are subjects and the investigators participate in the activity being observed. In this case, "participation" means obtaining data through intervention or interaction with the subject.
- *Other* (specify and explain). Exempt Type 2 research may involve other designs and instruments. These must be considered on an individual basis. Please contact the IRB chair if you require guidance for Type 2 research instruments and designs not listed within this section. If you will be using instrumentation or methodologies to analyze public behavior, and they were not included within the four listed above, you will have to explain what they are and how they fall within Type 2 exemption. You will make a note on the form that you included this information within your abstract.

**Type 3:** Research that involves only the collection or study of **existing** data, documents, or pathological specimens. This type of research **MAY** involve minors. There are two categories of Type 3 research:

- Data is publicly available. One example might be schools' report cards or demographic data, available through school, state, or federal education websites.
- Data is not publicly available, but it is recorded in such a manner that subjects cannot be identified.

**Type 4:** Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- Public benefit or service programs.
- Procedures for obtaining benefits or services under those programs.
- Possible changes in or alternatives to these programs or procedures
- Possible changes in methods or levels of payment for benefits or services under those programs.

This research **MAY** involve minors.

**Type 5.** Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed. This research **MAY** involve minors.

## *Applicant procedure*

1. *Terminology.* Check the IRB glossary if you encounter any IRB terminology that is unfamiliar.
2. *IRB Training.* Every WU IRB application must document that the primary Investigator and each project researcher has completed a WU-approved IRB training course. Training is available for free online at http://phrp.nihtraining.com/users/login.php. Researchers who complete training should print their training completion certificates and file them. IRB application materials must contain a copy of the WU-approved IRB training completion certificate for ***each*** project researcher listed on page 1 of your IRB application.
3. *Eligibility.* Review exempt research types 1-5 and determine that the research is exempt. Some types of research are not exempt if the subjects are minors. If your research involves minors, confirm that your research meets the criteria for each type of research that pertains to your study. For example, *Type 2. Survey Research* is not exempt when the subjects are minors.
4. *Plan Your Research.*
   - How will you obtain informed consent?
   - How will you insure anonymity of your participants?
   - How will you secure, store, and later destroy your data?
   - What are your independent variables?
   - What are your dependent variables?
   - Write out your research protocols (procedures).
   - Write your informed consent document/s. If you are working with a collaborating, external institution or organization, you must prepare a consent form to be signed by an individual with signature authority representing the external entity. Use the list of twelve required elements from Section D of the application to help you draft your informed consent form. You will need to address each item on the list. Sometimes, a required element will not pertain to your study. For example, required element #7: "Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject" doesn't apply to a survey study of adult's use of the Internet and email. Make note of required elements that do not apply to your study. You will mark these with a N/A on the application form.

- Write, develop, and/or prepare descriptions of any instrumentation. There are many types of instruments used in human subjects research. Some studies use surveys, tests, interview protocols, or observation protocols. Others use equipment, such as a pedometer or thermometer or EKG.

5. *Documentation Abstract.* Complete section D making sure to address the following 7 items:
    1. Research purposes and goals, as well as benefits and risks.
    2. Research instruments and methods.
    3. Specific methods and procedures of collecting, distributing, reporting, and recording information in ways that protect against potential risks to subjects.
    4. Specific methods and documents for obtaining informed consent of research subjects and cooperating institutions (where applicable).
    5. Specific methods and justifications for selection of subject population(s).
    6. Exact copies of consent forms for subjects as well as consent from cooperating institution. (Conditions for informed consent are described in the rib Consent Form Checklist.)
    7. Exact copies of instruments.

    Make sure your abstract provides enough information for the IRB chair to determine if your research design meets the criteria for exempt review. You will submit two copies of your abstract with your application form. Include any supplemental information as part of the abstract. For example, you could provide supplemental information for (a) Type 1. A warrant for a claim that an educational environment is commonly accepted or (b) Type 2. Description of research designs and instruments that were not specified on the IRB form.
6. Complete the application form
    - Please **type or word process** your responses to your application form. Electronic templates are available online at the WU IRB Website/Forms or paper copies are available from the IRB Administrative Assistant. Designate a project Principal Investigator. Enter the principal investigator's contact information on application form page 1. Make sure the contact email address is a working address, and one that the Principal Investigator checks regularly.
    - Designate a project Principal Investigator. Enter the principal investigator's contact information on application form page 1. Make sure the contact email address is a working address, and one that the Principal Investigator checks regularly.
    - List the first and last names of all other researchers on your team (see glossary for definition of "researchers".
    - All student applicants must specify a WU research sponsor and the sponsor's email address.
    - Researchers not enrolled in or employed by Wheeling University must specify a WU research sponsor and the sponsor's email address.

- Take time to carefully review the items listed within the checklist in "Section E. Informed Consent Documents." If a require element does not apply to your study, mark it with a N/A on the application form.
- Include a copy of your WU-approved IRB training completion certificate/s with your supplementary materials.
- Obtain the proper signatures. Make sure that your research sponsor carefully reviews your application. Your application approval will be delayed if the IRB chair reviews your materials and finds they require modifications.
- Submit two (2) copies of: the completed application form, a brief abstract of the research design (purposes, goals, benefits, risks, subject population, and supplemental information), informed consent document, and exact copies of instruments to IRB, c/o Ms. Jackie Davis, IRB Administrative Assistant, Donahue Hall Room 102.

## *Research Sponsor's Responsibilities:*

Application approval will be delayed if the IRB reviews application materials and requires modifications. Please carefully review application materials for accuracy and completeness. Use the checklist to pre-screen for frequently encountered application errors.

### √- *Research Sponsor Checklist*

Make sure frequent application errors do not appear within applications signed by you by checking that the following are correct.

| | |
|---|---|
| | Contact information is legible, accurate, and complete. |
| | Research sponsor's name and email address appear on page 1. |
| | Research type and subtypes are clearly indicated. |
| | If research concerns minors, restrictions are followed. |
| | The informed consent form contains all applicable required elements. |
| | Non-applicable required consent form elements are clearly indicated with an N/A on the application within "Section D." |
| | If the researchers are working with a collaborating, external institution or organization, the application must contain a consent form signed by an individual with signature authority or provisions to obtain such signatures. No WJU study that involves external institutions is approved by the IRB until the IRB receives an informed consent from signed by an institutional representative with signature authority or an acceptable alternative practice is proposed. |
| | Includes copy of WU-approved IRB training certificate for every researcher. |

## *Review procedure*

- The IRB Chair will review the application for completeness. Incomplete or improperly prepared applications will be returned to the Principal Investigator without review.
- The review time for exempt studies is approximately 3-7 days.
- The IRB Chair will review the application abstract to determine if the research design meets the criteria for exempt review. Research that does not qualify will be returned with a suggestion that it be revised for submission as an expedited or formal review.
- The IRB Chair will review all supplementary materials.
- The informed consent documents will be compared with the required elements.
- Once the review has been completed, an email may be sent to the investigator with requests for additional clarification or materials prior to final determination. This email will indicate that if a response is not received within **30 days**, the application will be withdrawn from consideration for approval. If the investigator wishes to pursue the study at a future date, s/he must submit another application.

## *Expedited Research*

Federal regulations recognize certain kinds of research that may be reviewed by an IRB through an expedited review procedure. Expedited review means that the research need not wait for a full board meeting, but instead the IRB Chair or his/her designee is responsible for the review and approval.

The IRB Chair or his/her designee is the sole authority for determining whether the research meets the expedited criteria, based on review and approval of the investigator's application to the IRB. The IRB Chair or his/her designee retains the discretionary right to require full board review, even when the study appears to meet the criteria for expedited review.

Expedited review is limited to research involving no more than minimal risk, which involves human participants in one or more of the following nine categories. The activities listed are not deemed to be of minimal risk simply because they are included on the list. Inclusion on the list merely means that the activity is eligible for expedited review when the specific circumstances of the proposed research involve no more than minimal risk to human participants. If the research study as a whole involves more than minimal risk, it must be reviewed by the full board, even if the activities are limited to those listed.

1. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:

> (a) from healthy, non-pregnant adults, who weigh at least 110 pounds. For these participants, amounts drawn may not exceed 550 ml in an 8 weeks period and no more than 2 times per week; or
>
> (b) from other adults and children, considering age, weight, and health, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and no more than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

- hair and nail clippings, in a non-disfiguring manner;
- deciduous teeth at the time of exfoliation;
- permanent teeth if patient care indicates a need for extraction;
- collection of excreta and external secretions (including sweat);
- uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or applying a dilute citric solution to the tongue;
- placenta removed at delivery;
- amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- collection of both supra- and subgingival dental plaque and calculus, provided the collection procedure is accomplished in accordance with accepted prophylactic techniques;
- mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed they must be cleared/approved for marketing. Examples:

- physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy;
- weighing or testing sensory acuity;
- magnetic resonance imaging;
- electrocardiography, electroencelphalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, ultrasound, infrared imaging, doppler blood flow, and echocardiography;
- moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

5. Research involving materials (data, documents, records or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

8. Continuing review of research previously approved by the convened IRB where

(a) the research is permanently closed to the enrollment of new participants, all participants have completed all research-related interventions, and the research remains active only for long-term follow-up of participants;

(b) where no participants have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

## *Applicant's procedure*

1. *Terminology.* Check the glossary if you encounter any IRB terminology that is unfamiliar.
2. *IRB Training.* **Every** WU researcher must complete IRB training at the URL http://phrp.nihtraining.com/users/login.php. Print your completion certificate and file. Copies must be submitted with your application.
3. *Eligibility.* Review exempt and formal research types to determine whether your research qualifies for either of those types of review.
4. *Plan Your Research.*
   - How will you obtain informed consent?
   - How will you secure, store, and later destroy your data?
   - What are your independent and dependent variables?
   - Write out your research protocols (procedures).
   - Write your informed consent document/s.
   - Write, develop, and/or prepare descriptions of any instrumentation.
5. *Justification for risks.* Describe your research design, paying particular attention to the risks to the subjects. Your document should contain:
   - Purposes, goals, hypotheses, key variables.
   - Procedures, instruments and methods.
   - Benefits to subjects and to the field of study
   - Risks to the subjects. Including (but not limited to) possible research-related injury; loss of anonymity, privacy, confidentiality; criminal or civil liability; financial or academic standing; reputation, employability
   - Specific methods for selection of the subject population.
   - Exact copies of the instruments to be used.
6. Complete the application form

- Please **type or word process** your responses to your application form. Electronic templates are available online at the WU IRB Website/Forms or paper copies are available from the IRB Administrative Assistant. Designate a project Principal Investigator. Enter the principal investigator's contact information on application form page 1. Make sure the contact email address is a working address, and one that the Principal Investigator checks regularly.
- Designate a project Principal Investigator. Enter the principal investigator's contact information on application form page 1. Make sure the contact email address is a working address, and one that the Principal Investigator checks regularly.
    - List the names of all other researcher on your team (see glossary for definition of "researchers".
- All student applicants must specify a WU research sponsor and the sponsor's email address.
- Researchers not enrolled in or employed by Wheeling University must specify a WU research sponsor and the sponsor's email address.
- Take time to carefully review the items listed within the checklist in "Part D. Informed Consent Documents." If a require element does not apply to your study, mark it with N/A on the application form.
- Include a copy of your IRB training completion certificate with your supplementary materials.
- Obtain the proper signatures. Make sure that your research sponsor carefully reviews your application. Your application approval will be delayed if the IRB chair reviews your materials and requires modifications.
- Submit two (2) copies of: the completed application form, a brief abstract of the research design (purposes, goals, benefits, risks, subject population), informed consent document, and exact copies of instruments to IRB, c/o Ms. Jackie Davis, IRB Administrative Assistant, Donahue Hall Room 102.

## *Research Sponsor's Responsibilities:*

Application approval will be delayed if the IRB reviews application materials and requires modifications. Please carefully review application materials for accuracy and completeness. Use the checklist to pre-screen for frequently encountered application errors.

| √ - *Research Sponsor Checklist* | |
|---|---|
| **Make sure that:** | |
| | Contact information is legible, accurate, and complete. |
| | Research sponsor's name and email address appear on page 1. |
| | Research type and subtypes are clearly indicated. |
| | If research concerns minors, restrictions are followed. |
| | The informed consent form contains all applicable required elements. |
| | Non-applicable required are clearly indicated with an N/A on the application |

| | |
|---|---|
| | within "Section D." |
| | If the researchers are working with a collaborating, external institution or organization, the application must contain a consent form signed by an individual with signature authority or provisions to obtain such signatures. No WJU study that involves external institutions is approved by the IRB until the IRB receives an informed consent from signed by an institutional representative with signature authority or an acceptable alternative practice is proposed. |
| | Materials include copy of IRB training certificate for every researcher. |

## *Board procedure:*

- The IRB secretary will receive the application.
- An official Expedited Review identification number will be assigned.
- The date the application is received will be documented
- The IRB Chair will review the proposal (see below). A decision regarding approval/request for additional information will be forwarded to the researcher and research sponsor by an IRB Chair or IRB designee.
- In the case of an incomplete or improperly prepared proposal, or of requested revisions, a response from the investigator is expected with **30 days** from the date the notice is sent by the IRB Chair. In extreme circumstances, additional time may be granted at the discretion of the IRB.

## *Review procedure:*

- The IRB Chair will review the application for completeness. Incomplete or improperly prepared applications will be returned to the principal investigator.
- The review time for expedited studies is approximately 5-10 days.
- The IRB Chair or IRB designee will review all materials.
- The informed consent documents will be compared with the required elements. The IRB Chair will make a decision on whether or not the research application is accepted as is, accepted pending suitable revisions, or not accepted.

## *Formal Review*

All research involving human subjects which does not meet the requirements for either exempt or expedited review must pass through the formal review process by the IRB.

In particular, any research involving more than minimal risk to the subject, manipulation of the subject's environment, or identification of the subject requires Formal Review. Furthermore, most research involving minors requires Formal Review.

## *Applicant's procedure:*

1. *Terminology.* Check the glossary if you encounter any IRB terminology that is unfamiliar.

2. *IRB Training.* **Every** WU researcher must complete IRB training at the URL http://phrp.nihtraining.com/users/login.php. Print your completion certificate and file. Copies must be submitted with your application.
3. *Eligibility.* Review exempt and formal research types to determine whether your research qualifies for either of those types of review.
4. *Plan Your Research.*

- How will you obtain informed consent?
- How will you secure, store, and later destroy your data[1]?
- What are your independent and dependent variables?
- Write out your research protocols (procedures).
- Write your informed consent document/s.
- Write, develop, and/or prepare descriptions of any instrumentation.

5. *Justification for risks.* Describe your research design, paying particular attention to the risks to the subjects. Your document should contain:

- Purposes, goals, hypotheses, key variables.
- Procedures, instruments and methods.
- Benefits to subjects and to the field of study
- Risks to the subjects. Including (but not limited to) possible research-related injury; loss of anonymity, privacy, confidentiality; criminal or civil liability; financial or academic standing; reputation, employability. Also address how you will limit any risks which may exist.
- Specific methods for selection of the subject population.
- Exact copies of the instruments to be used.

6. *Complete the application form.*

- Please **type or word process** your responses to your application form. Electronic templates are available online at the WU IRB Website/Forms or paper copies are available from the IRB Administrative Assistant. Designate a project Principal Investigator. Enter the principal investigator's contact information on application form page 1. Make sure the contact email address is a working address, and one that the Principal Investigator checks regularly.
- Designate a project Principal Investigator. Enter the principal investigator's contact information on application form page 1. Make sure the contact email address is a working address, and one that the Principal Investigator checks regularly.
  - List the names of all other researcher on your team (see glossary for definition of "researchers".
- All student applicants must specify a WU research sponsor and the sponsor's email address.
- Researchers not enrolled in or employed by Wheeling University must specify a WU research sponsor and the sponsor's email address.
- Take time to carefully review the items listed within the checklist in "Part D. Informed Consent Documents." If a require element does not apply to your study, mark it with N/A on the application form.

[1] Data should be kept in a secured (locked and private) location for two years and then destroyed.

- Include a copy of your IRB training completion certificate with your supplementary materials.
- Obtain the proper signatures. Make sure that your research sponsor carefully reviews your application. Your application approval will be delayed if the IRB chair reviews your materials and requires modifications.
- Submit five (5) copies of: the completed application form, a brief abstract of the research design (purposes, goals, benefits, risks, subject population), informed consent document, and exact copies of instruments to IRB, c/o Ms. Jackie Davis, IRB Administrative Assistant, Donahue Hall Room 102. Formal Applications are due 14 days prior to the scheduled IRB meetings. Monthly meeting schedules are posted on the IRB web site. The committee will not review applications received less than 14 days prior to the meeting until the next month.

## *Research Sponsor's Responsibilities:*

Application approval will be delayed if the IRB reviews application materials and requires modifications. Please carefully review application materials for accuracy and completeness. Use the checklist to pre-screen for frequently encountered application errors.

| √ - *Research Sponsor Checklist* | |
|---|---|
| **Make sure that:** | |
| | Contact information is legible, accurate, and complete. |
| | Research sponsor's name and email address appear on page 1. |
| | Research type and subtypes are clearly indicated. |
| | If research concerns minors, restrictions are followed. |
| | The informed consent form contains all applicable required elements. |
| | Non-applicable required are clearly indicated with an N/A on the application within "Section D." |
| | If the researchers are working with a collaborating, external institution or organization, the application must contain a consent form signed by an individual with signature authority or provisions to obtain such signatures. No WU study that involves external institutions is approved by the IRB until the IRB receives an informed consent from signed by an institutional representative with signature authority or an acceptable alternative practice is proposed. |
| | Materials include copy of IRB training certificate for every researcher. |

## *Board procedure:*

- The IRB secretary will receive the application.
- An official Formal Review identification number will be assigned.
- The date the application is received will be documented

- The IRB will review the proposal (see below). A decision regarding approval/request for additional information will be forwarded to the researcher and research sponsor by an IRB Chair or IRB designee.
- In the case of an incomplete or improperly prepared proposal, or of requested revisions, a response from the investigator is expected with **30 days** from the date the notice is sent by the IRB Chair. In extreme circumstances, additional time may be granted at the discretion of the IRB.

### *Review procedure:*

- The IRB committee will review the application for completeness. Incomplete or improperly prepared applications will be returned to the principal investigator.
- Formal Applications will be reviewed at the next monthly meeting, providing the application was received 14 days prior to the scheduled meeting.
- The IRB committee will review all materials and discuss the application.
- The informed consent documents will be compared with the required elements.
- The IRB committee will make a decision on whether or not the research application is accepted as is, accepted pending suitable revisions, or not accepted.

## Standard Informed Consent Form

The purpose of an Informed Consent Form is to provide participants with a written source of information for future reference and to document that informed consent indeed occurred prior to the participant's participation. The form generally serves as a basis for the initial presentation of the study to the potential participant. Typically, informed consent is signed and dated by the participant or the participant's authorized representative at the time of consent. A copy of the Informed Consent Form should be given to the participant and a copy maintained by the investigator.

Some common problems with the Informed Consent Form include the use of jargon, technical, or scientific terms that a layperson would not understand. Ordinary language should replace technical terms (e.g., upper extremities are better referred to as arms, hematoma as a bruise, venipuncture as taking blood from your arm with a needle). But perhaps the most common problem with Informed Consent Forms is that they are written at a reading level several grades higher than the average participant would understand. Informed Consent Forms should be written at a reading level that potential participants would understand. For most studies, an eighth grade reading level is suggested. Most word processing programs can determine a document's reading level.

## Safeguarding Confidentiality

An issue of primary importance is the protection of confidentiality, especially in a wide range of social and behavioral studies. These studies include personality inventories, interviews, questionnaires, or the use of observation, photographs and film, taped records, or stored data.

The investigator must have sound plans to protect the participant's identity as well as the confidentiality of the research records. Care should be taken to explain the mechanisms that have been devised, for example, the use of numbering or code systems or safely locked files in private offices. Furthermore, the investigator should describe who has access to the data and under what circumstances a code system may be broken. Without appropriate safeguards, problems may arise from long-term retention of records. In special circumstances requiring additional safeguards to prevent potential criminal prosecution of the participating human participant, the IRB may require the destruction of all data that can identify the participants.

# Recruitment and Participant Compensation

## *Recruitment*

Recruitment materials, including brochures, flyers, advertisements, audiotapes, videotapes, letters to potential participants, and letters to other individuals such as physicians who may refer potential participants to the study must not contain coercive language or incentives. The information provided should be an accurate presentation of the research study purpose and/or procedures. For example, if the study involves comparing an investigational drug to a placebo, the advertisement should not mention the study drug only. Rather, it should indicate that some participants in the study would receive a placebo, or describe the purpose of the study as comparing the investigational drug to a placebo.

Advertising is considered the beginning of the informed consent process. Any recruitment processes and advertising materials aimed at recruiting potential participants into a study (including audio or video tapes) must be reviewed and approved by the IRB prior to being used.

The recruitment process includes the methods planned for identifying and contacting potential participants as well as the sites where the recruiting and advertising materials will be placed. In the case of advertisements to be taped or filmed for broadcast, investigators should seek IRB approval for the script and storyboard, if applicable, in advance of taping in order to avoid the possible expense of re-taping due to unapprovable wording.

## *Participant Compensation*

Payment for participation in research may not be offered to the participant as a means of coercive persuasion. Rather, it should be a form of recognition for the investment of the participant's time, loss of wages, or other inconvenience incurred. Accordingly, compensation may not be withheld contingent on the participant's completion of the study. In most cases involving continued participation, compensation should be given on a reasonable prorated basis to avoid the impression that the investigator is coercing the participant to continue in a study or is punishing the participant for non-compliance.

### *Non-English Speaking Participants*

When appealing to non-English speaking participants, the study must reflect the methods for assuring full understanding, possibly with the assistance of an interpreter, or by using translated Informed Consent Form(s).

If non-English speaking participants are unexpectedly encountered, investigators should carefully consider the ethical/legal ramifications of enrolling participants (when a language barrier exists). If the participant does not clearly understand the information presented, the participant's consent will not truly be informed and may not be legally effective.

## Initial Application Submission

Investigators are required to submit an application for IRB review PRIOR to initiating a research study. All application forms can be obtained from the IRB website or hard copies can be obtained from the IRB Administrative Assistant. Instructions for completing the form are located within the IRB Handbook. Applications must be typewritten, neatly hand written or word-processed using the current version of the form. Investigators should start from the application forms located on the IRB website. All forms are dated and the website contains the current version.

## Signatures

The principal investigator, in whose name a study is approved, must sign the application assuring compliance with all Federal, state, and University policies as they apply to the study.

The signature of the department chair/head is also required on the application. If the department head/chair is the principal investigator, he/she may sign as both the investigator and the department head/chair. The department chair/head indicates that he/she has reviewed the application, that it is ready for IRB review, and that the department assumes responsibility for oversight of the study.

A student researcher may be listed as the principal investigator on the application form, but a faculty or staff member must sign the application as the research sponsor. The research sponsor indicates that s/he has reviewed the application, it is ready for IRB review, and he/she assumes responsibility for oversight of the student's study. A department head/chair signature is also needed for IRB applications.

## General Guidance

The IRB expects the investigator to respond to all items on the application. The most common problem with the applications is that not enough detail is provided for the IRB Chair or committee to evaluate the study's purpose and/or procedures. In particular, investigators are encouraged to provide detailed information regarding how potential participants are initially identified, and how consent is obtained. There is no such thing as providing too much detail when describing study procedures! The more complete the initial description is, the less likely that time will be spent with correspondence back and forth between the investigator and IRB members and/or IRB Chair to fill in the details.

The application itself contains detailed instructions regarding supporting documents that are required. The IRB Chair or IRB members are available to respond to questions by e-mail or phone. Investigators with unique situations are encouraged to contact the IRB chair. The IRB chair is always willing to review applications and supporting materials in the development stage, prior to actual submission.

## Limitations on IRB-Approved Studies

An approved study is limited in its conduct to the recruitment activities and study procedures that were described in the initial application. If the investigator wishes to change the study recruitment activities or procedures from what was initially described, s/he should submit a modification for IRB review.

Each study is approved for a specified period of time and research activity may not continue beyond that date without approval from the IRB.

All studies are approved to enroll only the number of participants indicated in the application. If the investigator finds that actual enrollment is approaching that limit, a modification should be submitted requesting an increase in the number of participants to be enrolled in the study. Note that "enrollment" is defined as anyone who has signed an Informed Consent Form, whether or not that individual actually completes the study.

Finally, only the current, approved consent form may be used for documenting informed consent. Documenting consent on a consent form different than the one submitted to the IRB committee is not permitted and does not constitute valid consent.

## Appeal of IRB Decision

The WJU IRB is committed to working with investigators to solve problematic issues in study design, recruitment, and procedures such that the IRB can make the required findings for approving the research study. The IRB may approve a research study pending specific required changes in procedures or in the Informed Consent Form. If the IRB decides to disapprove a research activity, it shall include, in its written notification, a statement of the reasons for its decision. The investigator may appeal the decision of the IRB in writing. The investigator should provide a rationale for the appeal and any other relevant supporting documentation. At the discretion of the IRB Chair, the investigator may also make such an appeal in person to the IRB. The IRB will notify the investigator in writing of the discussion and vote on the appealed issue(s).

## Surveys, Questionnaires and Interview Studies

Not all survey, questionnaire, or interview research is minimal risk. For example, a survey or interview that asks questions about sensitive topics (e.g., childhood abuse, sexual functioning) may cause emotional stress or discomfort to participants and could require full IRB review.

Some survey research may be classified as exempt from the regulations if the information obtained is recorded in a way that the participant cannot be identified (either directly or through a code numbers or link); in other words, if the research data are anonymous.

The term anonymous is sometimes confused with the term confidential. In human participant research, anonymous means that at no time during the data collection could someone determine who provided the information. If a link existed at any time, even if the link is subsequently destroyed, the IRB cannot consider the information anonymous.

A survey or interview study may also be considered exempt from the regulations even when data is not anonymous if it could not reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation. If the study is not anonymous and contains information that, if known, could be damaging as described above, but it does not rise to the level of more than minimal risk, it may be given expedited review and approval. The IRB makes the final determination.

For minimal risk mail-out or web-based surveys or questionnaires, it may be appropriate to request that the IRB Chair or his/her designee waive the requirement for the participant's signature on an Informed Consent Form. When the participant's signature requirement is waived, generally the investigator provides all of the required elements of consent in a cover letter, with a statement that returning the survey or questionnaire will be considered voluntary agreement to participate.

## The Impact of the Privacy Rule on Research

The Privacy Rule, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), regulates the way certain health care groups, organizations or businesses, called covered entities under the Rule, handle individually identifiable health information known as protected health information (PHI). Researchers should be aware of the Privacy Rule because it establishes the conditions under which covered entities can use or disclose PHI for many purposes, including for research. Although not all researchers will have to comply with the Privacy Rule, the way the Rule protects PHI could affect certain aspects of research.

## Reporting Misconduct and Non-Compliance

Unanticipated problems or scientific misconduct involving risk to human subjects or other people are to be reported to the chairperson of the IRB. Any instance of serious or continuing non-compliance with the IRB policies, procedures, requirements, or determinations of the IRB will be reported to the chairperson of the IRB and the President of the University.