

**6th Edition!**  
New Information

Institutional Review Board (IRB)

# Quick Reference Guide



Compliance Topics for  
Investigators Conducting  
Human Research

**USF** UNIVERSITY OF  
SOUTH FLORIDA

# Table of Contents

Principal Investigator Responsibilities .....3  
Obtaining & Documenting Informed Consent.....4  
**Important Revision:** Retention of Informed Consent Documents &  
    IRB Records .....5  
Proposed Changes in Previously Approved Research Studies .....6  
Notifying the IRB Concerning an Investigator Leaving.....7  
IRB Progress Reports.....8  
Unanticipated Problems/Adverse Events.....10  
Research Conducted at Sites Not Owned or Operated by the  
    University or Its Affiliates .....12  
NIH-Sponsored Multicenter Clinical Trials .....14  
Recruitment of Pregnant Women .....15  
IRB Approval for Open Research Accounts .....15  
Children as Research Subjects .....16  
Emergency Use of an FDA-Regulated Investigational Article .....18  
Notifying the Institution of IRB Actions and Findings.....19  
Research Involving Medical Students or Medical Residents  
    as Subjects .....20  
Submission of IRB Certification to External Funding Agencies ...21  
Completed Research Activities .....21  
Recruitment of Traumatized or Sedated Subjects  
    in Emergency Room Settings .....22  
HIV Screening and Research on AIDS .....23  
IRB Administration Contacts .....Back Cover

This Quick Reference Guide is designed to answer your questions about the USF Institutional Review Boards (IRB) policies and procedures and to outline investigator responsibilities after IRB approval has been obtained. Please read this guide carefully and keep it on file for easy reference by you and your staff.

For more detailed information, visit our **IRB Web Site** at <http://www.research.usf.edu/cs/irb.htm> or call the IRB office at (813) 974-9343. IRB contacts are listed on the back cover.

## Principal Investigator Responsibilities

As Principal Investigator (PI) for your recently approved research activities, you are responsible for all of the following:

- Protecting the rights and welfare of human research participants
- Ensuring that you and each member of your research team have met and keep current the requirements for education in human research protections
- Complying with all IRB decisions, conditions, and requirements
- Ensuring that each member of your research team complies with IRB decisions, conditions, and requirements
- Ensuring that all research procedures are implemented as approved in the IRB protocol
- Obtaining and documenting informed consent/assent
- Submitting a modification request and receiving IRB approval prior to initiating any change in recruitment, procedures, consent document, etc.
- Reporting the progress of approved research prior to the end of the current approval period (IRB Progress Report)
- Promptly reporting any injuries, adverse events, participant complaints or concerns, unanticipated problems, or protocol-related information which may involve risks or harm to participants
- Reporting closure/completion of a study (IRB Progress Report - Final Review)
- Retaining complete signed consent documents for at least six years if using Protected Health Information (PHI) and all IRB research records for at least three years after study closure

## Obtaining & Documenting Informed Consent

The Principal Investigator (PI) is responsible for obtaining informed consent/assent from each potential participant before any research activity occurs. Unless the requirement for informed consent is formally waived by the IRB, the consent/assent must be documented on an IRB approved consent/assent form which has a valid “IRB approval” stamp. A consent/assent form is valid when the document bears the IRB approval stamp showing the current, valid IRB approval period.

The PI can designate a co-investigator or members of the research staff to act on his/her behalf, provided those individuals are fully knowledgeable about the research and can answer potential participants’ questions appropriately. These delegated responsibilities must be presented to the IRB for approval. If co-investigators or research staff are designated to obtain consent/assent, they must be identified in the IRB Application on the Key Personnel page. It is critically important that individuals obtaining informed consent be appropriately trained and qualified to initiate that process.



It is important that the most recent, valid IRB approved consent/assent document is copied and the consent process is documented on one of those copies. After initial approval, if there is an IRB approved modification to the informed consent, the newly revised informed consent/assent document will reflect the new dates for which the revised form is valid.

## Retention of Informed Consent Documents & IRB Records

Unless the research falls within the purview of the Food and Drug Administration (FDA), the investigator is responsible for retaining the complete signed consent and assent documents and all IRB research records for at least three years after the final IRB approval period has expired. **Signed consent/assent documents that include HIPAA Authorization must be retained for six years.**

For research which falls under FDA authority, the investigator is responsible for retaining the signed consent/assent documents and IRB research records for the period specified in the applicable FDA regulations. To obtain a list of the records that must be retained, contact the Division of Research Integrity & Compliance IRB office at (813) 974-9343.



A complete informed consent form is defined as all pages present, with the form signed and dated by the subject (or legal representative), the person authorized to obtain informed consent (listed and approved on the IRB Application), and, when specifically communicated to the investigator as a requirement by the IRB, by a witness. [45CFR46.115(b); 21CFR56.115(b)]

It is the responsibility of the Principal Investigator to ensure that the consent document is stored in accordance with procedures of the facility in which the research is conducted (example: the original in the patient's medical record). However, the Principal Investigator must maintain a complete copy of all consent documents in his/her research records.

## Proposed Changes in Previously Approved Research Studies

Changes in advertising, recruitment, screening, research procedures, or the informed consent/assent document cannot be initiated by the investigator without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participant. One copy of a request to make changes to an approved study should be submitted to the Division of Research Integrity & Compliance on a Modification Request form (<http://www.research.usf.edu/cs/irb.htm>). The form will require the following information:

- the IRB number;
- the date the form is completed;
- the exact title of protocol as originally submitted to the IRB;
- a complete description of the nature of the changes and a summary of how those changes impact participants' rights and well-being, with all changes in the supporting documents highlighted;
- the signature of the Principal Investigator;
- if the proposed changes necessitate a change in the consent/assent form, a revised consent/assent form in which the revisions are underlined or highlighted;
- indication of whether participants will be re-consented, and if so, when and how that will occur; and
- one clean copy of the revised consent/assent form without underlining or highlighting.



The request is reviewed by the chairperson or a designated representative, unless the nature of the proposed changes warrants review by the full board. The investigator is notified in writing of the IRB decision. If approved, the clean copy of the revised consent/assent document(s) with the new valid “IRB Approval” stamp will accompany the approval letter.

**NOTE:** A proposed change in Principal Investigator should be reported immediately to the IRB. Also, if the address or contact person to whom correspondence should be sent is to change, or if the research study is expected to extend beyond the period of time initially approved by the IRB, the investigator should submit a request for these changes by completing the appropriate sections of the Modification Request form. If the request involves the addition of new personnel, the form should have attached the documentation required (e.g., CV, educational documentation, etc.) to add that person to the protocol.

## Notifying the IRB Concerning an Investigator Leaving the Institution

If the Principal Investigator plans to leave the University (or an Affiliate site) and intends to continue the research activities at another institution, he/she must notify the Division of Research Integrity & Compliance IRB office so that the active file can be closed out. An IRB Progress Report - Final Review must be completed and sent to the IRB prior to the investigator leaving USF (or the Affiliate) so that any questions the IRB may have can be appropriately addressed by the Principal Investigator.

If the research activities are to be continued at the University or Affiliate site under the direction of another investigator, a request for approval of a change in investigator must be submitted to the IRB prior to that change. When possible, the signature of the departing Principal Investigator and the new Principal Investigator should be included on the Modification Request Form. This assures the IRB that both parties are aware of the change. The submission and review procedures to be followed are described above in the section on **Proposed Changes in Previously Approved Research Studies**.

## IRB Progress Reports

According to federal regulations and institutional policies, any ongoing research involving humans must be re-reviewed by the IRB at intervals appropriate to the degree of risk, but not less than once annually.

Continuing IRB approval is required while long-term follow-up of participants continues, even when the research is permanently closed to the enrollment of new participants and participants have completed all research-related interventions. Continuing IRB approval is also required when the remaining research activities are limited to data analysis.

Failure to submit an IRB Progress Report is considered an issue of non-compliance and is subject to actions/sanctions by the IRB. The IRB's Progress Report review procedures are as follows:

- A. At intervals specified by the IRB (typically 90 days prior to the end of the current approval), the Division of Research Integrity & Compliance sends the Principal Investigator and contact person a courtesy reminder notice that he/she is responsible for completing and submitting an IRB Progress Report (<http://www.research.usf.edu/cs/irb.htm>).
- B. It is the PI's responsibility to complete and return the form prior to the date specified in the reminder notice to the Division of Research Integrity & Compliance, with a copy of the last two signed consent forms. In addition, a clean copy of the consent/assent form to be used during the next approval period should accompany the report. Additional materials required for review are specified on the IRB Progress Report form. The form must be signed by the Principal Investigator.
- C. It is the responsibility of the Principal Investigator to provide, at the time of review of the IRB Progress Report, documentation that educational training in human research protections has been obtained for all personnel involved in the research project. These documents will be required before the Progress Report will be forwarded to the IRB for consideration.
- D. The IRB Progress Report and informed consent/assent forms are first screened by the Division of Research Integrity & Compliance IRB staff. If the application is incomplete or there are questions

about the materials submitted, the IRB staff will note this to the IRB Chairperson and contact the Principal Investigator for the additional information/clarification. Once all documentation is complete, the protocol will be submitted to the IRB for review. If the IRB determines that there have been no significant changes or problems associated with the study, the study will be granted a continuing approval for a specified period (cannot be longer than one year). Once IRB approval is granted, an approval letter and when applicable, the informed consent/assent document(s), stamped with the new, valid “IRB Approval” stamp, will be forwarded to the investigator.

- E. If the research is supported by an external funding agency that requires additional certification, the investigator submits those documents with the Progress Report. The forms will be prepared by the IRB staff and returned to the investigator with the IRB approval letter. It is the Principal Investigator’s responsibility to transmit the form(s) to the agency.
- F. If, after review of the Progress Report and associated materials, it is determined that additional information is needed or that irregularities have arisen which affect the rights and/or welfare of the human participants, the IRB may take the following action:
- Request revisions and/or additional information;
  - Request that the investigator attend the next IRB meeting during which discussion of the application will occur;
  - Suspend approval pending further investigation by the IRB;
  - Terminate IRB approval.
- G. If the investigator fails to submit the IRB Progress Report or fails to respond in a timely fashion to a request for additional information/clarification, IRB approval will expire. Notification of expired IRB approval will be sent to the PI, the PI’s chairperson, and, if appropriate, the funding agency. Once IRB approval has expired, all research procedures must be halted (unless the IRB determines that this would place participants at risk) and research activities must immediately cease. These activities include recruitment, enrollment, implementation of research interventions or interactions, data collection, and data analysis. If the IRB approval expires, the Principal Investigator must provide the IRB with a list of participants who would be harmed if the research activities are stopped. To avert harm, the IRB will determine which participants can continue. To reinstate an expired approval, a

new Application for Initial Review must be submitted, reviewed, and approved before any research activities can resume for that project.

Failure to submit an IRB Progress Report will also result in suspension of the PI's ability to submit subsequent IRB applications.

## **New!** Unanticipated Problems Involving Risks to Participants and Others

Principal Investigators are responsible for immediately reporting to the IRB (and, if applicable, the FDA) any unanticipated problems involving risks to participants or others including protocol-related serious adverse events.

**Unanticipated Problem** - any event or outcome that was previously unforeseen and indicates that participants or others are at an increased risk of harm. OHRP considers unanticipated problems in general to include any incident, experience, or outcome that is unexpected, related or possibly related to participation in research, and results in increased risk of harm.

**Unexpected Event** - not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application); any adverse experience, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended (based on 21 CFR 312.32(a)):

- Any breaches in confidentiality that would place the participant or others at risk.
- Any change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
- Any change to the protocol that was taken without prior IRB approval to eliminate apparent immediate hazard to a research participant.
- Incarceration of a participant when enrolled on a study not approved under Subpart C provisions.

**Related or Possibly Related Event** - there is at least a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research. USF extends this definition to a minimum of 30 days post-administration of the test article or intervention.

**Increased Risk of Harm** - the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social) than was previously known or recognized.

**Serious Adverse Event** - any research-related event (occurring at any dose or level of intervention) that results in any of the following outcomes:

- Death (must be reported within 2 business days of the PI becoming aware of the event);
- Life-threatening event - any adverse experience that places the participant, in the view of the PI, at immediate risk of death from the reaction as it occurred, i.e., it does not include a reaction that, had it occurred in a more severe form, might have caused death ( based on 21 CFR 312.32(a)) (must report within 2 business days of the PI becoming aware of the event);
- Inpatient hospitalization or prolongation of existing hospitalization (must report within 2 business days of the PI becoming aware of the event);
- A persistent or significant disability/incapacity - a substantial disruption of a person's ability to conduct normal life functions (must report within 2 business days of the PI becoming aware of the event);
- A congenital anomaly/birth defect (must report within 2 business days of the PI becoming aware of the event);
- Any event, based upon the judgment of the principal investigator, that jeopardizes the well-being of the human research participant or others and may require medical or surgical intervention to prevent one of the outcomes listed above (must report within 2 business days of the PI becoming aware of the event);
- Unexpected change to the risks or potential benefits: Any publication in the literature, safety monitoring report, interim result, or other finding that indicates an unexpected change to the risks or potential benefits of the research (must be reported within 5 days of the PI becoming aware of the event). Examples include but are not limited to:

- An interim analysis or safety monitoring report indicating that harms or benefits may differ than those initially reviewed and approved by the IRB;
- Published work from another (related in some manner) study which purports findings which differ from the proposed risks or benefits initially reviewed and approved by the IRB for the study at hand).
- Any complaint of a participant that indicates an unanticipated risk or one which cannot be resolved by the research staff.
- Any unanticipated adverse device effect.
- Any change in the informed consent/assent document as a result of new information or newly identified risks or benefits.
- Any other information that might represent unanticipated problems involving risks to participants or others.

**Administrative Hold** - A directive of the FDA, the sponsor, the facility at which the research is being conducted, a DSMB, or a convened IRB, IRB chair, or a facility's Institutional Official, to temporarily stop some or all research activities pending a specified action. Administrative holds are usually based on identification of information that may place participants at risk unless additional safeguards are put in place. Must be reported within 5 days of the PI becoming aware of the event.

### **Event Reporting System (ERS)**

In order to report an event/problem, the PI must be registered and have an activated ERS account. ERS access, registration, and instructions are at <http://www.research.usf.edu/cs/irb.htm>. The ERS prompts the PI to provide critical facts about the event and instructs the PI on how to supply supplemental information regarding the event.

## **Research Conducted at Sites Not Owned or Operated by the University or Its Affiliates**

### **HHS Funded Research**

Human research projects funded by the Department of Health and Human Services (HHS) which involve collecting data at sites not owned and operated by the University of South Florida or USF Affiliates are not covered by the University of South Florida Federalwide Assurance. The

HHS requires that all performance sites independently assure the HHS of the intent to comply with federal regulations for the protection of humans in research.

The HHS agency responsible for approving the written assurance is the Office for Human Research Protections (OHRP). The OHRP has different assurance mechanisms which include Inter-Institutional Authorization Agreements and Independent Investigator Agreements. The mechanism varies depending upon a number of issues. These “assurance” requirements are promulgated by the OHRP. They apply only to HHS funded research (e.g., National Institutes of Health such as the National Cancer Institute or National Institute of Allergy and Infectious Diseases cooperative group protocols, Centers for Disease Control and Prevention).

HHS funded investigators are responsible for ensuring that all sites at which data will be collected have an approved Federalwide Assurance. If you have questions or need assistance, contact the Division of Research Integrity & Compliance at (813) 974-3234.

### **Non-HHS Funded and Unfunded Research**

When a USF investigator or a USF Affiliate investigator collects data from or about humans for research purposes at a site other than that which is owned or operated by USF (or the Affiliate, respectively), a letter of support must be obtained from the off-site facility.

The IRB is charged with assuring that human subjects are protected when participating in research. Part of that protection includes assessing the appropriateness of the proposed procedures in relationship to the requested site. The IRB is also charged with assuring that the research is appropriate for the population targeted for the research. Finally, the IRB must be assured that there are adequate “rescue” provisions for participants who experience an adverse or unanticipated event while participating in research at that location.

Since IRB members cannot visit every proposed off-site facility, the IRB meets its obligations by having an administrator from the facility serve as a consultant to the IRB. This administrator is asked to make recommendations addressing the issues of appropriateness of the facility and the targeted population. This consultation is then conveyed to the IRB through a letter of support.

The letter of support holds great value for the IRB: it creates a consulting relationship between the IRB and the off-site facility through the administrator. To ensure that the letter of support adequately addresses issues relevant to IRB review, it must contain the following:

- A. A statement that the administrator has reviewed the research and has found it appropriate for the population targeted at that facility.
- B. A statement that (if, in fact, it is true) there are appropriate resources available, whether it be a room in which interviews can be conducted or time resources for the potential participant, to allow the Principal Investigator to conduct the research in the IRB approved manner.
- C. A statement that there are adequate provisions to handle unanticipated problems including serious adverse events, based on the risks associated with the research.

If you have questions regarding off-site research, please contact the Division of Research Integrity & Compliance at (813) 974-9343.

## **NIH-Sponsored Multicenter Clinical Trials**

The Office for Human Research Protections (OHRP) requires that for each cooperative group study submitted to the IRB for consideration, the IRB must receive a copy of the NIH-approved sample informed consent document for review. The IRB must ensure that the “Risks” section and the “Alternatives” section of the NIH-sample consent form are included in the USF version. If, in the USF consent document, the PI deletes or substantively modifies the information concerning risks or alternative procedures contained in the NIH sample informed consent document, those changes must be justified in writing by the investigator and approved by the IRB. For trials sponsored by the National Cancer Institute (NCI), investigators must forward copies of such IRB-approved changes, with their justifications to the appropriate Cooperative Group headquarters.

## Recruitment of Pregnant Women

Pregnant women are considered a vulnerable population and additional safeguards must be built into research to recognize and protect their autonomy. Federal regulations specify when it is appropriate to recruit and/or enroll pregnant women. These regulations are designed to protect both the pregnant woman and her unborn fetus. The IRB must take into consideration nine additional requirements before approval can be granted for research involving pregnant women. When research involving pregnant women holds no prospect of direct benefit, the IRB must be able to determine and document that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

For more information regarding the recruitment and enrollment of pregnant women in research, contact the Division of Research Integrity & Compliance at (813) 974-9343.

### Recruitment of Pregnant Women from TGH

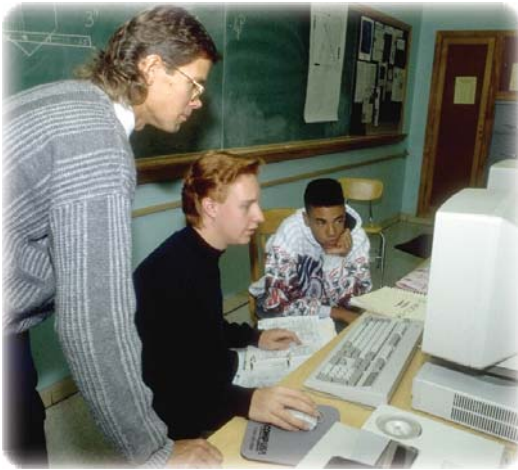
If your research project involves the recruitment of pregnant women from Tampa General Hospital (TGH), additional demographic information must be collected at the time of informed consent, provided to the USF College of Medicine, and submitted to the IRB with the Progress Report. This information is: the subject's name, address, telephone number, highest level of education, and occupation.

## IRB Approval for Open Research Accounts

IRB approval must be kept current during any period that a supporting USF account remains open, against which research charges can be placed. It is the opinion of the IRB that if a research account needs to remain open, there is the possibility that data collected from or about human participants may be reviewed, manipulated, or validated. Such actions require IRB approval.

## Children as Research Participants

When seeking to enroll children in research, parental permission must first be obtained, to protect the rights of the child. Children are persons who have not attained the legal age for consent to treatments or procedures involved in research. Anyone under 18



years of age is considered to be a child, unless emancipated under Florida law. Unless legally emancipated, by Florida law, children are not considered autonomous individuals. In conducting research there must be respect for all individuals who volunteer to act as research participants, even when they may not be fully autonomous.

**Permission** means the agreement of parent(s) or a child's guardian to allow participation of their child or ward in research. "Parent" means a child's biological or adoptive parent.

**Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. However, in the state of Florida, a guardian's permission is not enough to consent to research procedures. A ward's participation in research must be specifically granted by the court.

**Assent** is a child's affirmative agreement to participate in research. "Mere failure to object should not be construed as assent." [45 CFR 46.102(b)]

USF IRB has adopted the following policy for obtaining assent from children (unless the requirement is formally waived by the IRB):

- children under the age of seven should have the research explained to them in terms relative to their age and understanding;

- children ages 7 to 11 should have the research explained and assent verbally obtained with that assent documented in the child's research records; and
- children ages 12 to 17 should be provided an assent document that contains the basic requirements of informed consent in the level of language understandable to their age, education, and level of experience.

### **Emancipated Minors**

Florida law refers to the federal definition of a child as an individual under the age of 18 years. Florida law uses the term “minor.” A child under 18 years of age who has been declared emancipated by a court of law or who is or has been married is considered to be an emancipated minor and can give consent for participation in research. Emancipated minors or married minors do not need parental consent to participate in research. If a married or emancipated minor is to be enrolled in a research project, the IRB approved consent form should be used to document informed consent. However, as with all individuals, the PI (or those acting in his/her behalf) must make sure that the minor understands the language used in the consent form and, if necessary, take and document extra steps to ensure that the information presented is at a reading level comparable to the minor's abilities.

### **Pregnant Children**

Children who are pregnant are considered by Florida law “pregnant minors” and can give consent (without parental consent) to participate in research that is directly related to the pregnancy or the well-being of the fetus. However, the child is not considered “emancipated” in general, except for the purposes stated. This means investigators must seek parental permission to enroll a pregnant child in research that is unrelated to the pregnancy or the well-being of the fetus.

More information on regulations and USF policies on enrolling children in research as well as parental consent and child assent templates may be obtained at <http://www.research.usf.edu/cs/irb.htm> or by contacting the Division of Research Integrity & Compliance at (813) 974-9343.

## Emergency Use of an FDA-Regulated Investigational Article

The Food and Drug Administration (FDA) and the Department of Health and Human Services have a variety of regulations governing the use of an investigational drug/device/procedure for clinical purposes or in emergency situations. In response to the federal requirements, the Medical IRBs have adopted policies and procedures which must be adhered to in single patient clinical emergency use situations.

It is the policy of the IRB, whenever possible, to convene and give full board review to the emergency use of a test article. However, the IRB will allow a one-time (single course of treatment with one patient) emergency use of a test article without prospective full IRB review and approval if the following conditions can be met:

- it is a life-threatening situation in which no standard acceptable treatment is available;
- the IRB is notified that there is intent to use the test article; and
- it is determined by the investigator and an independent physician that there is not sufficient time to obtain IRB approval.

Whenever possible, the IRB should at least be notified prior to the use of the test article. If a physician treats a patient using a test article without prior IRB approval, FDA considers such person to be a research participant and requires reporting of safety data to the sponsor and FDA. However, data collected on this individual should be limited to safety information. Any subsequent use of the test article at a facility under the purview of the USF IRB (regardless of who is administering the test article) requires prior IRB review.

In accordance with USF HRPP policy, if the test article is administered, the following must occur:

- written notification must be submitted to the IRB attesting that the patient was confronted with a life-threatening situation that required immediate medical intervention;

- informed consent must be properly executed and documented or a statement attesting that the informed consent document could not be obtained because of difficulty in communication with the patient and insufficient time to contact the patient's legally authorized representative;
- confirmation from an independent physician that no alternative method of approved or generally recognized therapy was available to provide an equal or greater likelihood of saving the patient's life;
- a description of how the test article was used must be submitted to the IRB for consideration; and
- an IRB application submitted for further treatment (if applicable).

This information must be submitted to the IRB within five working days of the administration of the test article. Notification should not be construed as an IRB approval but should be used for tracking purposes, to verify that the physician filed a report within the five-day time frame required by Food and Drug Administration regulations [21 CFR 56.104(c)].

Contact the Division of Research Integrity & Compliance IRB office (813) 974-9343 or go to <http://www.research.usf.edu/cs/irb/policies/402.pdf> for a copy of the IRB policy.

## Notifying the Institution of IRB Actions and Findings

In accordance with 45 Code of Federal Regulations (CFR) 46.103(b)(4), the Division of Research Integrity & Compliance forwards to the Institutional Official, Dr. Karen A. Holbrook, Vice President for Research and Innovation, copies of all IRB meeting minutes which document the IRBs' findings and actions. A permanent copy of those minutes are maintained in the Division of Research Integrity & Compliance office.

The Vice President for Research provides several means of communicating complaints or concerns regarding the human research protections program. The Principal Investigator, any member of the research team, or participants in research projects can voice any complaints or concerns they have to the HRPP Manager or Director, Division of Research Integrity & Compliance, the IRB Chairperson at (813) 974-9343, or directly to the Vice President for Research at (813) 974-5570 or by e-mail at [kholbrook@research.usf.edu](mailto:kholbrook@research.usf.edu)

## Research Involving Medical Students or Medical Residents as Subjects

If an investigator plans to conduct research on USF Medical Students, the investigator must obtain approval from the College of Medicine (COM) Student Affairs Committee prior to approaching that population for recruitment and enrollment. Also, if an investigator plans to conduct research on USF COM Residents, the investigator must obtain the approval from the COM Graduate Medical Education Committee before recruitment can begin.



## Submission of IRB Certification to External Funding Agencies

After final IRB approval has been obtained, it is the investigator's responsibility to submit the proper certification to the sponsor. If more than a copy of the IRB Approval Letter is required, the investigator should contact the Division of Research Integrity & Compliance IRB office and provide the certification document. The Division of Research Integrity & Compliance IRB office will prepare the form and obtain the appropriate signature(s). The investigator is responsible for transmitting the form to the agency.

To prepare a federal certification form (HHS 310) for those grants/contracts which fund more than one IRB protocol, the Principal Investigator must provide the Division of Research Integrity & Compliance IRB office with a list of IRB numbers which apply to that particular grant/contract. These numbers will be cross-checked by the Division of Research Integrity & Compliance IRB office for approval before certification is issued. Once IRB approval has been verified for each of the studies listed, the appropriate documentation will be prepared. The investigator is responsible for transmitting the certification to the agency.

## Completed Research Activities

When the research project is completed, the PI must notify the Division of Research Integrity & Compliance by submitting an IRB Progress Report (form available at <http://www.research.usf.edu/cs/irb.htm>). If no report is submitted, at the end of the current IRB approval period, the IRB files will reflect that IRB approval expired and notification that IRB approval has expired will be sent to the PI, the PI's Chairperson, and, if applicable, the funding agency. The IRB will determine if the research participants should be notified that IRB approval has expired. Failure to submit an IRB Progress Report will result in suspension of the PI's ability to submit subsequent IRB applications.

## Recruitment of Traumatized or Sedated Subjects in Emergency Room Settings

Cognitive and decision-making abilities can be impaired by the stress of a traumatic event and by certain levels of sedation. These external factors can impact an individual's ability to give true informed consent. The investigator who encounters a potential research participant under these circumstances must take special precautions to ensure that the consent given by the patient is voluntary and informed. Voluntary and informed consent may not be possible in every circumstance. This is especially true when recruiting emergency room patients.

An investigator who is presented with a patient suffering from pain (either physical or emotional) or having experienced a traumatic event must take extreme care to protect the interest of the patient, to provide optimum care and to avoid creating an environment of duress or coercion. Therefore, notwithstanding the research opportunity, it is unethical for an investigator to withhold an analgesic or anesthetic in order to obtain consent. The investigator must recognize under these circumstances that he/she has a potential conflict of interest in determining what is best for the patient. All decisions must be based solely on what is best for the patient's welfare.

If a patient is under sedation and the investigator believes that there is a question of competency, the investigator must consult with two professionally qualified persons ("consultants") who are not part of the study team in the presence of one witness regarding the competency of the patient to give informed consent. The two consultants must include either two physicians or one physician and one professional staff member, such as a nurse. If the consultants agree that the potential research participant is physically and mentally able to communicate a willful and knowing decision about participating in the research study, the



consent process may proceed. If the consultants do not agree, or if the consultants agree that the potential research participant lacks the capacity to make a willful and knowing decision to participate in the research study, a surrogate or proxy must be asked to give consent on behalf of the patient.

For complete information about the IRB's recruitment policy for patients in emergency room settings, please contact the Division of Research Integrity & Compliance at (813) 974-9343.

## HIV Screening and Research on AIDS

For research involving HIV screening and/or AIDS research, there are additional federal, state, and IRB requirements for designing and implementing the research and for obtaining informed consent. It is important in developing the informed consent for research involving HIV screening and/or AIDS research, that it is clearly defined who will be given information about positive screens and what the limits of confidentiality might be in such cases. It is also important that the potential participant is informed of what counseling services are available, should a positive screening result occur. Contact the Division of Research Integrity & Compliance at (813) 974-9343 to obtain a copy of the requirements for HIV screening and the National Institutes of Health Policy Statements on AIDS research.

# Human Research Protections Program IRB Administration Contacts

**Phone:** (813) 974-9343    **Fax:** (813) 974-5618

---

Bercu, M.D., Barry.....	Medical IRB Chair.....	974-9343
	<a href="mailto:bbercu@research.usf.edu">bbercu@research.usf.edu</a>	
Byers, Cheryl .....	Director, Division of Research Integrity & Compliance .....	974-3234
	<a href="mailto:cbyers@research.usf.edu">cbyers@research.usf.edu</a>	
Haller, Joanna.....	HRPP Manager .....	974-7821
	<a href="mailto:jhaller@research.usf.edu">jhaller@research.usf.edu</a>	
Kutash, Ph.D., Krista ...	Social & Behavioral IRB Chair .....	974-4622
	<a href="mailto:kutash@mirage.fmhi.usf.edu">kutash@mirage.fmhi.usf.edu</a>	
Witanachchi, Vinita.....	Assistant Director, HIPAA.....	974-5478
	<a href="mailto:vwitanachchi@research.usf.edu">vwitanachchi@research.usf.edu</a>	
Zych, Henry .....	IRB Coordinator, Office Manager .....	974-7454
	<a href="mailto:hzych@research.usf.edu">hzych@research.usf.edu</a>	

---

Best, Brenda.....	IRB Support.....	974-9343
	<a href="mailto:bbest@research.usf.edu">bbest@research.usf.edu</a>	
Croxton, Cara.....	IRB Support.....	974-2036
	<a href="mailto:ccroxton@research.usf.edu">ccroxton@research.usf.edu</a>	
Davis, Anna.....	Social & Behavioral IRB .....	974-5642
	<a href="mailto:annadavis@research.usf.edu">annadavis@research.usf.edu</a>	
Geiger, Dana .....	Medical IRB-C .....	974-5741
	<a href="mailto:dgeiger@research.usf.edu">dgeiger@research.usf.edu</a>	
Hutchinson, Brandy .....	IRB Support.....	974-5638
	<a href="mailto:bhutchinson@research.usf.edu">bhutchinson@research.usf.edu</a>	
Lepsky-Perla, Valentina	Expedited/Exempt Studies.....	974-3216
	<a href="mailto:vlperla@research.usf.edu">vlperla@research.usf.edu</a>	
Menzel, Various .....	Social & Behavioral IRB .....	974-6433
	<a href="mailto:ymenzel@research.usf.edu">ymenzel@research.usf.edu</a>	
Partap, Sandra .....	Medical IRB-D .....	974-5272
	<a href="mailto:spartap@research.usf.edu">spartap@research.usf.edu</a>	
Valentin, Johanna .....	Medical IRB-A .....	974-7486
	<a href="mailto:jvalentin@research.usf.edu">jvalentin@research.usf.edu</a>	

Revised: 6-9-09