ROWAN INSTITUTIONAL REVIEW BOARDS FAQ

1. What is an IRB?
Institutional Review Boards (IRBs) also known as independent ethics committee, is a committee that is charged by the institution to review, approve or disapprove or require changes to secure approval and monitor biomedical, social and behavioral research involving human research subjects. IRB review serves an important role in the protection of the rights and welfare of human research subjects. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

Research reviewed by the IRB may also be subject to other review and approval or disapproval by administrative officials at Rowan University. However, those officials may not approve research that has not been approved by the IRB for Human Participants.

2. How do I know if I am conducting research with human participants?
According to Rowan University Policy and federal regulations, research is defined as “…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Activities which meet this definition constitute research for this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

According to regulations, “Human subject means living individuals about whom an investigator (whether professional or student) conducting research obtains:
1. Data through intervention or interaction with the individual,
2. Identifiable private information.”

Obtaining means, receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes an investigator's use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator.

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes (e.g., providing stimuli to gauge reaction and response).

Interaction includes communication or interpersonal contact between investigator and subject (for example, surveys and interviews). Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of a participant is associated with the information or may readily be ascertained by the investigator) in order for obtaining the information to constitute research involving human subjects.

To determine whether the activity is research involving human subjects, please refer to the decision tree in the following website: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1. If you are
unsure if your project involves research with human subjects, please consult with IRB staff that can provide guidance in making this determination.

3. What does “individually identifiable” mean as it pertains to private information or specimens, as stated in the definition of a human subject?

According to the “Guidance on Research Involving Coded Private Information or Biological Specimens” (http://www.hhs.gov/ohrp/policy/cdebiol.pdf), OHRP generally considers private information or specimens to be individually identifiable when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Conversely, OHRP considers private information or specimens not to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Under the HHS Protection of Human Subjects Regulations, if an investigator obtains private information about living individuals for research purposes and that private information retains a link to individually identifying information, such private information ordinarily would be considered by OHRP to be individually identifiable to the investigator. However, OHRP does not ordinarily consider such information to be individually identifiable to the investigator if (1) the investigator and the holder of the individually identifying information sign an agreement prohibiting the release of individually identifying information to the investigator under any circumstances, or (2) there are other legal requirements prohibiting the release of the link to the investigator.

4. When am I required to submit a proposal involving research with human participants to the IRB?

All research projects that will involve human participants must be submitted through eIRB for review and approval before beginning the study. This includes proposed research involving existing data and previously collected human fluid and tissue samples, as well as any advertising or other recruitment procedures.

5. My study involves a simple survey; do I need to submit my proposal to the IRB?

Almost all surveys that involve interventions or interactions whether using identifiers or without the use of identifiers (anonymous), are subject to review and approval by the IRB since they are active collection of data. On the contrary, if you are surveying or collecting existing information or biological specimens without the use of identifiers, such projects will be reviewed under exempt review Category. Please read FAQ# 3 above if coded information or specimens are used in your research.

6. I am a graduate/undergraduate or medical student at Rowan. Do research projects conducted by a student need IRB approval?

Student research when it meets research and human subject definition as described under FAQ #2 above needs IRB approval. All research conducted by any student will be conducted under the advisorship of their professor. Those professors will be the principal investigators of the project; students can be co-investigators or coordinators.

If the project is to be used in a classroom setting only to teach research methods as curricular activities, the project may not constitute human participant research. However, this means that at no point during or after the conclusion of the course can the results or the data be used for publication, presentation, or
other research purposes. Therefore, students should discuss these limitations with their instructor or faculty advisor so that they can determine whether IRB review is necessary.

7. I am a researcher and I am a participant in my own study. Does this require an IRB review since this involves self-experimentation?
All experiments including self-experimentation require IRB review to evaluate risks, harm and assure safety of all participants. The Common Rule and Food and Drug Administration (FDA) do not regard research on oneself as different from research involving other human subjects. Certain invasive experiments may pose additional risk in self-experimentation. Therefore, the IRB may request for a separate consent for self-experiments for the investigator to explain what potential risks are expected in self-experimentation, how those risks be mitigated and what potential benefit may be gained from self-experimentation. The consent form must say that “I am aware that the procedures are considered to constitute research on human subjects. I am performing these procedures on myself voluntarily.”

8. I am conducting a quality control/quality improvement study. Do I need to go through IRB approval to conduct this study?
Quality Assurance (QA) activities are done to assure known quality. These activities are mechanisms to assure that organizations function optimally. Quality Improvement (QI) activities are done to improve quality of programs, improve services, or improve the provision of medical care, customer service, etc. QA/QI projects are usually done for internal purposes only. However, some QA/QI projects may fall under the federal definition of research, and therefore, may require IRB review.

To determine whether QA/QI activities involving human participants or individually-identifiable data must be submitted to the IRB, consider the following definition of research. Note that QA/QI activities, regardless of whether they meet the definition of research, should not pose any risk to individuals, infringe on individual privacy, or breach individual confidentiality.

If the QA/QI projects are systematic and leads to generalizable knowledge and the findings are shared outside of institution, department or division, then the project is considered human subject research requiring IRB review. On the contrary, if the data is used solely to administrative purposes and not disseminated outside the institution, they are considered normal conduct of work and they do not require IRB review. However, in all cases it is advisable to contact the IRB office to receive an opinion whether IRB review is necessary.

9. What is an “exempt” from IRB review protocol? What are the requirements?
The federal regulations identify categories of research methods that can be exempted from IRB review. These categories imply that the protocol is minimally risky and certain aspects of the study do not require the Board’s continuous review. However, the institution as required by regulations requires investigators to submit a request for Exemption from an IRB review to make sure that the proposed study meets one of the categories of exempt review, which is generally determined by a person who has the expertise and experience to make this determination. Exempt status does not, however, lessen the ethical obligations to subjects as articulated in the Belmont Report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) and in disciplinary codes of professional conduct. Thus, depending on the circumstances, investigators performing exempt studies may need to make provisions to obtain informed consent, protect confidentiality, minimize risks, and address problems or complaints. Exempt review studies do not require annual continuing review. Please note that for each change that is proposed or occurs during the execution of the research
activity, the investigator may need to consult with the IRB office to determine if the change affects the eligibility of the research activity to continue to be exempt from IRB review and approval.

10. What is an “Expedited” review? What are requirements?
The federal regulations identify categories of research methods that meet Expedited review. The requirements are: 1) present no more than minimal privacy, psychological and/or physical risk to human subjects, and 2) involve only procedures listed in one or more of the expedited categories, may be reviewed by the IRB through the expedited review procedure authorized by federal regulations (OHRP and FDA). The activities listed should not be deemed to be of minimal risk simply because they are included on the expedited checklist. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The categories in the expedited checklist apply regardless of the age of the subjects, except as noted. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The expedited review procedure may not be used for classified research involving human subjects. The standard requirements for informed consent and authorization (or their waiver, alteration, or exception) apply regardless of the type of review.

11. What is a “Full Board” review? What are the requirements?
Any research study that involves human subjects, but does not qualify as a non-research study project, any research project that is subject to FDA or Common Rule definition of human subjects research and any human subject research that is above minimal risk, and does not qualify under exempt or expedited review categories, require full board review.

12. What is a continuing review?
Continuing Review (also known as “Periodic Review”) is a reevaluation of an approved study conducted at least once a year, as mandated by federal regulations. Continuing review is required so long as the study is ongoing, that is, until research-related interactions and interventions with human subjects or the obtaining and analysis of identifiable private information described in the IRB-approved research plan have been completed.

This review allows the IRB to monitor the progress of the study and ensure that it continues to meet the requirements for approval. The continuing review process starts after the Principal Investigator submits the continuing review form to the IRB Office.

Note: To ensure that there is adequate time for the IRB to process the continuing review, the form should be submitted at least 30 days before the study’s expiration date. The IRB office through e-IRB email will send 60 and 30 day notices before the protocol expires. The expiration date is located on the main study page of the study in eIRB. It is also on the initial IRB approval letter, or the last continuing review approval letter.

If continuing reviews are not submitted in time, the protocol will expire. No research activities may be
conducted until the continuing review is approved by the IRB. There is a limited time for submitting continuing review if the protocol has lapsed. The IRB reserves the right to close the study if continuing review is not submitted within 60 days of the expiration. If continuing review has lapsed and if the investigator intends to continue the study, a new IRB application must be submitted and approved by the IRB before the study can recommence.

13. I want to make a change to the approved protocol. How can I do that?
Do not implement any changes to the protocol without the IRB approval. To make a change, you can submit a modification on the eIRB describing what changes are going to be made and how the change overall affects the risk to subjects and whether the changes necessitates revision of the consent documents.

Upload in the eIRB all of the documents revised or added as a result of the proposed change such as consent/permission, assent, recruitment or ads, revised protocols, survey questionnaires, etc., with changes. Also upload a highlighted copy so that the reviewers can identify where changes are made.

If the change is to increase the number of subjects, justify why the change is necessary and indicate the number of subjects for which approval is requested. If the change is to add new personnel or removing approved personnel make appropriate change in the modified eIRB application. If the request is to change the principal investigator, justify this change is needed.

14. I am going on sabbatical or my study sponsor wants to “inactivate” a protocol. Can this be done?
If so, how can I reactivate the study that has been “inactive”?
You can submit a request to inactivate the study at any time. If the study has already enrolled subjects, your inactivation request must include a summary of activities up to the point of request to inactivate including number of subjects enrolled and any history of adverse events with those subjects. When you make a request to reactivate the study, indicate why you are reactivating and are there any changes made to reactivate the study. IRB may request for a new application, if there are overt changes to the protocol.

15. Can the IRB approve a project “retroactively”?
No. There is no provision in the federal regulations that allow for IRB approval of research that has already been conducted. If data was collected for purposes that the IRB determines to be non-research (e.g., program evaluations for library or educational programs not initially intended to be used for research), IRB approval can be sought for the data analysis going forward.

16. How long will it take for me to obtain approval to do my study?
That depends on the nature of your study and the characteristics of the people you intend to recruit. Research projects that involve only minimal risks are eligible for expedited review, for which you should allow at least 3 weeks for IRB review.

Research projects that involve greater than minimal risk to participants will need to go to the full board for review, which is scheduled for the third Wednesday (Glassboro campus) or third Thursday (RowanSOM campus) of every month. For applications requiring full board review, you should allow at least 4-6 weeks for review and approval of your study.
17. How does an IRB protocol review look like?
IRB reviews protocols using “reasonable person” standards. The IRB evaluates every research protocol according to the ethical principles described in the Belmont Report. Basically, this means the IRB considers whether the risks and benefits of a study are acceptable and managed appropriately, and whether individuals being asked to participate are adequately informed about the research and its possible risks. Additional items IRB reviews include whether the study includes vulnerable subjects such as children, pregnant women, prisoners, conflict of interest, recruitment methods, etc.

Considered another way, the review may include plans from the point of view of a subject, or an observer concerned about responsible research. Who are the subjects and how are they recruited? Could they be lured or coerced to participate? Is it through an institution that may have responsibilities toward them (e.g., a school or hospital) and should be consulted? Do they understand, in advance, what they are agreeing to participate in and give their consent willingly? What will they actually do, and what is done to them, during the study? Is it possible that the experience might be injurious, painful, uncomfortable, needlessly boring, embarrassing, offensive, or otherwise stressful? Might there be long-term consequences? Could the subject be endangered, compromised or embarrassed if information collected leaked out? There are many possible considerations, but they should not be difficult to understand if one assumes the subject’s perspective. The IRB’s role is to look at the study from this perspective and to ensure that proper precautions are taken to protect individuals when they agree to participate in research.

18. When may I begin data collection for my study?
You must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis. A memo will be sent to you via e-mail when your project has IRB approval.

19. If I am collaborating with another institution, do I need to submit my application to Rowan IRB?
If you are a member of Rowan University faculty or staff, or a student, and you are the person responsible for the conduct of the study (PI), you must get Rowan IRB approval to conduct your research regardless of where the research takes place. Investigators should contact the IRB office whenever collaborative research is occurring. Separate applications for each institution may be necessary; however, in order to avoid duplicate review, an IRB Authorization Agreement may be arranged with the other institution to establish one IRB as the designated IRB to review and approve the research. If you are a member of Rowan University faculty or staff, or a student, and you are NOT the person responsible for the conduct of the study (PI), but you are only a collaborator and recruiting subjects at Rowan, you must submit the IRB application naming yourself as the PI. However, in order to avoid duplicate review, an IRB Authorization Agreement may be arranged with the other institution to establish that the outside IRB as the designated IRB to review and approve the research.

20. I am conducting research in another country. Do I have to obtain IRB review and approval from Rowan?
Yes. If you are a member of the Rowan University faculty or staff, or a student, and if you are the person responsible for the conduct of the study (PI), you must get Rowan IRB approval to conduct your research regardless of where the research takes place. Please be aware that your study may have to be approved by a local IRB or ethics committee in the country where you will be conducting the research.

21. I want to make an application using eIRB. Is there an investigator manual to take me through the process of application?
The eIRB website has several manuals available for navigating the eIRB. The website address is: http://www.rowan.edu/som/hsp/. On the website, click on “eIRB” link followed by “Training Material” link. Training manuals are posted here.

22. I am new to eIRB. Is there a website where I can get help?
If you have any questions regarding your eIRB submission, you can either contact the IRB office at Glassboro or Stratford campus for assistance. eIRB systems requirement FAQs are posted at: http://www.rowan.edu/som/hsp/som-eirb/help.html.

23. Who can I talk to if I have a question about my research project involving human participants?
The IRB staffs at Glassboro and Stratford are available to provide assistance to investigators who are engaged in research with human participants. Contact information is posted on the website www.rown.edu/irb. You can also explore the IRB website for detailed information about the IRB Standard Operating Procedures (SOPs), policies and procedures, forms, meeting schedule and other important information.

24. Are there sample protocols and consent forms available for IRB submissions?
There is no such thing as “one protocol fits all” sample. The IRB members and staff will answer any questions you may have during the preparation of your protocol and consent form. In addition, the IRB office has prepared an IRB guidance book, which is posted on the IRB website, eIRB FAQs and eIRB help. We encourage you to take advantage of those materials to construct your application, protocol and consent form.

25. What is an informed consent?
Informed consent is an important part of the research process. It is a dynamic interactive process between the researcher and the participant in which potential subjects are provided with a document to make a true informed decision about whether or not to participate in a research study. Informed consent should be clear and explain the nature of the research project; why they are the best candidates for that specific research, what risks, benefits, and alternatives are associated with research and explain what rights they have either to agree or not agree to participate in research. Consent form must be written and presented in a language that is understandable to the subject so that the participant will agree to participate in the study without coercion. The IRB site provides several templates to assist the investigator in the design of the informed consent.

When children are subjects of a study, parental permission is required in lieu of adult consent form. In general, parental permission does not differ from adult consent form. When children are adolescents, IRB may consider an adult consent form to be an acceptable form of consenting.

26. What is an assent?
“Assent” means a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. In other words, the child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way. The IRB has the discretion to judge children’s capacity to assent for all of the children to be involved in a proposed research activity, or on an individual basis.
Researchers should take into account (IRB too) the nature of the proposed activity and the ages, maturity, and psychological state of the children involved when constructing the asset form. For children whose age and maturity level limits their ability to fully comprehend the nature of the research activity but who are still capable of being consulted about participation in research, it may be appropriate to focus on conveying an accurate picture of what the actual experience of participation in research is likely to be (for example, what the experience will be, how long it will take, whether it might involve any pain or discomfort). The assent procedure should reflect a reasonable effort to enable the child to understand, to the degree they are capable, what their participation in research would involve.

27. What is a “waiver” of consent?
In some special circumstance, the IRB may allow a waiver, or an alteration for the requirement for informed consent. In order to secure a waiver, the researcher should make a request to the IRB requesting for a waiver or alteration for the requirement for informed consent. In order to secure the waiver/alteration, the research must involve no more than minimal risk, research could not be practically conducted without the waiver/alteration and whenever appropriate, the subjects will be provided with additional pertinent information for the participation. Please note that the IRBs carefully review the waiver request and IRBs will document that a waiver is being applied and how the criteria for a waiver are being present.

A request for waiver will not approved by the IRB when the study involves the potentially identifiable student’s education record per FERPA regulations. Generally, educational agencies and institutions must have written permission from the student (or parent if the student is a minor) in order to release any personally identifiable information from a student's education record unless it meets one of a list of specified conditions for which release is allowed. (For example studies to improve instruction conducted by organizations for or on behalf of the educational agency or institution). Other than under such a condition, if an investigator from a local university's college of education requests a waiver of consent to review the educational records (grades and GPA) of students at the university for the past 20 years and maintain identifiers for a research project, the rights granted to students under the federal legislation of FERPA would be violated and the criteria for waiver of informed consent at 45 CFR 46.116(d)(2) could not be met.

28. Do I always have to obtain the informed consent of research participants?
In general, yes, but there are some limited exceptions. The IRB is responsible for ensuring that basic ethical principles are abided by in all research. The expectation that the informed consent of research participants be obtained is based upon the Belmont principle of respect for persons, and regarded as extremely important in conducting ethical research. The IRB has the authority to waive some or all of the federal requirements for informed consent in certain extenuating circumstances. A request for waiver of informed consent must be specifically justified by the researcher in the proposal to the IRB.

29. I am not collecting any identifying information. Do I still need an informed consent form?
Yes. If the proposed study is truly "anonymous" - no coding for identifiers (e.g., names, social security numbers, driver’s license numbers, etc.), a modified informed consent form (often called an information sheet) may be used. That is, all of the elements of consent must be documented for the participant, but the signature line is replaced with a statement informing the participant that completion and return of the survey is considered implied consent. If, however, the procedures involve risk or biological sample collections that contain subject identifies, a written consent may be required.
30. What is "implied" consent?
Implied consent is the tacit indication that a person has knowingly agreed to participate in research by performing a research activity or task. By completing the research task (e.g., completion of a questionnaire, interview, survey, etc.), the participant has provided consent to participate in the research.

Implied consent is actually a type of a waiver of documentation of informed consent. Before granting such a waiver, the IRB may require the researcher to provide the participants with a written summary or an information sheet about the research, including: (1) purpose of research; (2) time involved; (3) assessment of minimal risk; (4) statement regarding benefit to participants; (5) contact for questions about the research; and (6) contact for questions about rights as a research participant.

There are a number of instances where this type of consent is helpful. For example, you wish to mail out a survey. The survey does not ask for any identifiable information. The cover letter accompanying the survey could be written in such a manner as to serve as the "implied" informed consent form. The letter would need to contain a statement indicating that completion and return of the survey implies consent to participate in the research.

31. How is the consent process handled for Internet-Based research?
For Internet-based surveys, it is sometimes appropriate to use implied informed consent. Participants would still need to be presented with the consent information, but would be informed that their consent is implied by submitting the completed survey.

If, for study design purposes, the researcher needs to keep track of who participated or if the IRB determines that some sort of documented consent is required, instead of "signed" informed consent, the researcher may email the consent form to participants who may then type their name and the date into the spaces provided on the consent form, and return it to the researcher via email. This process may be appropriate for data collected via email, chat rooms, online interviews, etc. Alternatively, some Internet-based survey vendors and/or software packages provide a means to record whether a respondent has consented to participate before beginning a survey (e.g., a date/time stamp feature).

32. What are the consent requirements for phone based research?
IRB approval for phone-based consent may vary depending upon the nature of the research activity. For protocols involving oral consent the following information is required to be communicated to the participant:

- study purpose and procedures involved
- what will participant be asked to do - as well as the amount of time participant will spend
- the voluntary nature of participation in the study
- the participant is free to withdraw at any time
- the information collected will remain confidential
- offer the participant contact information for the researcher and/or the IRB

It may be pertinent to request the PI to offer additional information depending on the nature of the study. It is up to the IRB to suggest additional information to be included in order to further protect the participant.
33. What is HIPAA? What is HIPAA authorization for research? What is HIPAA waiver of authorization for research?
The HIPAA Privacy Rule establishes the conditions under which protected health information may be used or disclosed by covered entities for research purposes. The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. Where research is concerned, the Privacy Rule protects the privacy of individually identifiable health information, while at the same time ensuring that researchers continue to have access to medical information necessary to conduct vital research.

In the course of conducting research, researchers may obtain, create, use, and/or disclose individually identifiable health information (PHI). Under the Privacy Rule, covered entities (hospital and clinics) are permitted to use and disclose protected health information for research with individual authorization, or without individual authorization under limited circumstances set forth in the Privacy Rule. To use or disclose protected health information without authorization by the research participant, a covered entity must obtain HIPAA waiver of authorization. HIPAA rule applies to all members of RowanSOM.

HIPAA privacy rule contains other components such as “preparatory to research”, “limited data set agreements” and “Decedents Health Information.” Please contact the Privacy Officer or the IRB office to obtain more information on the application of HIPAA regulations on HIPAA and medical research.

34. What are the IRB requirements for training?
At Rowan University, all investigators and research staff must successfully complete the CITI Program for training in the ethical conduct of research with human participants and update it at least once every three years. There are three levels of training depending upon the type activity: 1. IRB Chairs and members training; 2. Social and behavioral training and 3. Biomedical and basic science training. A refresher course must be taken every three years. A reminder for refresher will be sent by CITI official.

35. Who is required to complete the human participants training?
All faculty, students, and staff proposing to use human participants in research under the auspices of Rowan University are required to complete the human participants training. Approvals for including human participants in proposed research projects will be not be granted until this training has been completed and verified by the IRB office. For additional information on CITI training, go to: http://www.rowan.edu/som/hsp/education/index.html.

In addition, the Office of Research Compliance offers periodic workshops on human subjects protection and IRB process. Individuals are encouraged to attend these workshops.

36. In the case of a potential unanticipated problem involving risks to participants or others, when is the principal investigator expected to report this occurrence to the IRB?
Serious adverse events must be reported to the IRB immediately through eIRB, with a written report by the PI following within 24 hours of the PI’s becoming aware of the event. Serious adverse events are (1) death of a research participant; or (2) serious injury to a research participant.

All other non-serious unanticipated problems should be reported to the IRB within 2 weeks of the first awareness of the problem by the Protocol PI or another researcher, ORIA, or a member of the IRB. Prompt reporting is important, as unanticipated problems often require some modification of study
procedures, protocols, and/or informed consent processes. Such modifications require the review and approval of the IRB.

The Unexpected Event Report form is available on the eIRB website.

37. Can the IRB temporarily or permanently discontinue a research project as result of an unanticipated problem involving risks to participants or others?
Yes. If an unanticipated problem poses a risk(s) to the participants or others, the IRB may temporarily discontinue a research project until a thorough investigation has been conducted. Dependent on the investigation, the IRB may request changes to a research study or permanently discontinue the research study. Please see SOP #6, Suspensions and Terminations of IRB Approval of Research Protocols.

38. Can the IRB request revisions to the approved research study and the informed consent form as a result of an unanticipated problem?
Yes. As a result of the IRB's investigation of the unanticipated problem, revisions to the approved research study and the informed consent form may be requested.

For more information and answers to your questions please see our website.