


JHSPH IRB Policies

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		Document Status FINAL	Revision Date
Policy No. 101.01	Title: Exempt Research	Date of Approval 12/1/08	Approved By Janet DiPietro


The JHSPH requires that all human research projects must be either reviewed and approved by an IRB prior to initiation, or be found by an IRB to be exempt from federal regulations and from JHSPH exceptions to the federal exempt categories. The JHSPH has determined that research which may qualify as exempt research under federal regulations may not be considered exempt research at this institution. Guidance regarding research that may be exempt from federal regulations and that is not considered exempt at the JHSPH shall be provided to researchers.

The JHSPH IRB has been granted the authority to review proposed research and determine whether it qualifies for an exemption under federal regulation and under local exemption criteria. Further, the IRB is authorized to determine that proposed research which qualifies for an exemption under federal regulation and

local exemption criteria should be referred for an expedited or convened review process. The IRB review process for proposed exempt research will be documented. Documentation will include the IRB's determination that the research will be conducted in accord with the ethical principles described in the Belmont report.


The JHSPH IRB will interpret the following concepts in the regulations as follows:

- “Publicly available” sources, under Exempt Category 4, means information that is available to any person without prior qualification or certification.
- Under Exempt Category 4, “subjects cannot be identified, directly or through identifiers linked to the subjects” means that the investigator has not recorded any of the 18 HIPAA identifiers associated with the subject, nor has the investigator retained any link or code to those identifiers (see: <http://www.jhsph.edu/HIPAA/FAQ#identifiers>).

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 101.02	Title: Disclosure of Research Lab Test Results	Date of Approval 12/1/08	Approved By Janet DiPietro

If a human subjects research activity includes laboratory testing of blood or specimens collected from study participants, the participants must be informed as to whether the results of those tests will be disclosed. JHSPH investigators will comply with Clinical Laboratory Improvement Act (CLIA) requirements and Maryland State law applicable to laboratory testing. Interpretation of the requirements to meet CLIA standards and State law are made by the JHSPH IRB in consultation with the General Counsels' Offices. Under the current interpretation of these requirements, investigators may not disclose or report results of research tests when such tests have been performed in laboratories that have not been CLIA-certified and do not have a state laboratory license. A JHSPH investigator may not disclose or report such research laboratory test results to either subjects, patients, families, or the care givers of subjects or patients. The JHSPH IRB will not approve a request from an investigator to disclose research test results obtained from non-certified or non-licensed laboratories to individual participants. The IRB may approve a request on a case-by-case basis to allow all participants to receive a form letter indicating that clinical testing is now available and they may wish to have testing conducted at a certified clinical laboratory.

Disclosure of laboratory testing conducted outside of the United States will be permitted if the testing is performed in laboratories that meet national standards where the lab is located, or international validation standards.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 101.03	Title: IRB Review of Human Subjects Research	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB must review and approve all human research projects in which JHSPH is engaged prior to initiation. “Human research” means any activity that under the DHHS regulations represents “research [1]” that involves “human subjects [2] ,” or any activity that under FDA regulations represents “research[3] ” that involves “human subjects[4] ”. JHSPH becomes "engaged" in human research when its employees, faculty, staff, or other agents [5] (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.

The JHSPH IRB staff and IRB members review submissions to determine if projects are human research as defined above. Also, staff may advise investigators by telephone or email as to whether a project is human research as defined above and whether to submit an Application through PHIRST for JHSPH IRB review. The JHSPH IRB will provide the PI with written documentation of its determinations.

* * * * *


[1] Under the DHHS regulations “research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 CFR 46.101(d)

[2] Under the DHHS regulations “human subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment (including social and behavioral interventions) that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. 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 the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. 45 CFR 46.101(f)

[3] Under the FDA regulations “research” means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part. 21 CFR 50.3(c) and 21 CFR 56.102(c) (Note: Activities are subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the FDC act when they involve any use of a drug or medical device other than the use of an approved drug or device in the course of medical practice)


[4] Under the FDA regulations “human subject” means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. 21 CFR 50.3(g) and 21 CFR 56.102(e). For clinical investigations involving medical devices, the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit, human subject also means a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.

[5] According to OHRP guidance “agents” include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status Approved	Revision Date
Policy No. 101.04	Title: Public Health Practice and Public Health Research	Date of Approval 12/15/08	Approved By Janet DiPietro

Activities that are performed by JHSPH faculty, staff, and students in the design, implementation, and/or evaluation of public health and health service delivery programs can be, from a regulatory perspective, either “public health practice” or “human subjects research” depending on certain characteristics. (For the purposes of this policy, “public health research” and “human subjects research” are the same.) There is overlap between these two determinations and discerning which projects are public health practice and which are human subjects research can be challenging at times. For example, JHSPH faculty often enter into contracts with a public health authority (federal, state, local or international) for the purpose of evaluating public health services that the public health authority has the responsibility and duty to deliver. Some of these evaluations are “practice” and some are “human subjects research.” The JHSPH IRB is authorized to make determinations of practice vs. research as part of its initial review of a new protocol.

The most fundamental criterion distinguishing practice from research is the primary intent of the activities. As defined by the Common Rule in 45 CFR 46, “research” means “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” The JHSPH IRB will use the faculty’s description of the proposed activities, with particular attention to the articulated intent of the activities, as the primary evidence driving its determination of practice vs. research.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 102.01	Title: Review of Certain “Not Human Subjects Research” Activities	Date of Approval 12/1/08	Approved By Janet DiPietro

The federal regulations at 45 CFR 46.102(f) define a “human subject” to be a “living individual about whom an investigator...obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” In some circumstances, JHSPH investigators may collect data from living humans that is not about living humans, but the very act of providing data to investigators could pose a risk to the informants. Accordingly, Principal Investigators of research that involves prospective data collection from human participants (e.g., key informant surveys) should consider whether the interaction with the informant could be perceived negatively by others (e.g., family, social networks, employer, local community) and thus expose the participant to risk of social stigma, alienation, retaliation, political harm, civil or criminal liability, or other negative consequences. Although this type of research activity would not be “human subjects research” under the regulations, investigators conducting this kind of opinion or survey research that could pose a risk of harm to informants should submit the research activity to the JHSPH IRB. The IRB will consider the risk to the informants posed by providing information to researchers. If the risk is minimal, the JHSPH IRB will determine that the study is NSHR. If the risk to informants is more than minimal, the JHSPH IRB will serve in an advisory capacity to the Institutional Official. It will make recommendations to the PI as to how those risks might be minimized, and will make its findings available to the Institutional Official.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 102.02	Title: Course-Sponsored Human Subjects Research Projects - for Educational Purposes Only	Date of Approval 12/1/08	Approved By Janet DiPietro

Some JHSPH courses designed to teach or use methodology of human subjects research involve student projects which are designed to obtain private information from human subjects. The results of these projects will not be “generalized”; they will not be published or otherwise broadly disseminated. These projects do not meet the regulatory definition of “human subjects research”, but the institution requires the projects to apply the same ethical standards as are required for human subjects research projects reviewed and approved by the JHSPH IRB.

Faculty teaching courses that include human subjects research methodology and exercises must submit to the JHSPH IRB a description of the coursework which will involve human subjects. The description should include examples of the types of projects that students will pursue, with particular attention to the details of recruitment, informed consent, protection of subject privacy, and confidentiality of data. The JHSPH IRB will review the faculty submission to determine whether or not the proposed project is or is not “human subjects research” under the regulations. Once that determination is final, the faculty member may proceed with the course materials. If the project is determined to be “not research” or “not human subjects research”, the IRB will forward the information to the Associate Dean for Research so that the Associate Dean will monitor and track all such projects.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.01	Title: Human Subjects Protection Program	Date of Approval 12/1/08	Approved By Janet DiPietro


The President of The Johns Hopkins University (JHU) has delegated authority to develop, implement, and monitor all human subjects protection programs (HSPP) to the Deans of the Divisions of the University, including the JHSPH. The Dean of the JHSPH has delegated this authority to an Institutional Official, the Associate Dean for Research. The IO has the authority and independence to ensure implementation and maintenance of the HSPP and JHSPH IRB structure and function.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.02	Title: Student Investigators	Date of Approval 9/18/08	Approved By Janet DiPietro

JHSPH students, in their capacity as students, are not agents or employees of the institution. A student may not serve as principal investigator for human subjects research projects. A student may be involved in human subjects research in one of two ways. 1) As a student investigator who is undertaking a research project in partial fulfillment of the requirements of his or her degree program or for other educational reasons, and has a faculty advisor to supervise the process and take ultimate responsibility for the conduct of the study. In this situation, the PI must provide to the IRB details about the oversight of the student investigator’s activities. 2) As a study team member performing routine staff duties like record keeping, data collection or analysis, or lab work. At times, a student’s contribution to a research project may rise to the level of a co-investigator; however for IRB purposes, students retain the designation as student investigator in PHIRST. Whatever their role, the student has the same compliance training requirements that any other research team member must provide.

In order to ensure that all student-initiated projects receive appropriate review, all such projects must be submitted to the IRB for a determination as to whether it qualifies as “Not Research” (NR), “Not Human Subjects Research” (NHSR), “Human Subjects Research (HSR) Exempt from IRB Review”, or HSR requiring IRB review. The student and PI may use the IRB guidance flowchart posted on the IRB website (also available from the IRB office) to give them some idea as to what that determination is likely to be, but the determination itself must be made by the IRB. The IRB office will provide the student documentation of its determination.

If a JHSPH student is listed as study team member on a human subjects research application at a different institution, the PI of that protocol and the approving IRB of that institution are responsible for the student’s involvement in the research. The JHSPH IRB will not review the human subjects research application because the JHSPH is not “engaged” in the research. Copies of the IRB approval letter, research plan, and any documentation of the student’s participation as a researcher should be submitted to the JHSPH Graduate Research and Education Office, and retained in the student file.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.03	Title: JHSPH Assurance of Compliance with DHHS and FDA Regulations	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH will provide written assurance documents to the Office of Human Research Protection (OHRP) to comply with the requirement of 45 CFR 46.103. Assurance documents will be maintained and renewed in accordance with regulations.


As stated in the Federal Wide Assurances on file with OHRP, the JHSPH is guided by the ethical principles stated in the Belmont Report and codified by the Department of Health and Human Services (DHHS) regulations at 45 CFR 46, and the FDA regulations in 21 CFR 50 and 56. The JHSPH adheres to the guidance provided by the OHRP and by the FDA as part of that commitment. Additionally, the JHSPH IRB will provide additional protections to studies involving students and employees. This fundamental commitment to the protection of human subjects applies to all human subject research conducted by a JHSPH faculty member, regardless of funding source or site of the research. All projects conducted by JHSPH faculty which meet the definition of research and that involve human subjects will be reviewed by the JHSPH IRB. The JHSPH IRB may rely on other organizations to provide IRB review. Such reliance shall be documented in written IRB review agreements, and the terms of the agreements shall be reflected in the JHSPH assurance documents, as applicable.

The JHSPH IRB, and any IRB delegated by JHSPH to review human subjects research, has the authority to:


1. Approve, require modifications to secure approval, or disapprove, all human subjects research activities overseen and conducted by JHSPH.
2. Suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants.
3. Observe, or have a third party observe, the consent process.
4. Observe, or have a third party observe, the conduct of the research.

JHSPH IRB Independence

Officials of the JHSPH may not approve research if it has not been approved by the IRB; officials of the JHSPH may disapprove research that has been approved by the IRB.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.04	Title: List of IRB Members	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH shall maintain a list of IRB primary and alternate members for each of its internal Boards. Both Boards will have at least 5 members, and will be diverse in terms of gender and scientific expertise. There will also be at least one member who is non-scientific and one who is unaffiliated with the institution and who has no family member that is affiliated with Hopkins. The list shall include the following information: name; earned degrees; representative capacity; indications of experience (such as board certifications) and employment status of each member. Alternate members shall receive the same membership training as primary members. Alternate members who attend a convened meeting shall be identified in minutes of the meeting. Lists of primary and alternate members shall be updated each year upon reappointment as an IRB member. Any changes to IRB membership will be reported to the OHRP in a timely fashion.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.05	Title: IRB Meeting Procedures	Date of Approval 12/1/08	Approved By Janet DiPietro

The Institutional Official (IO), the Director of the JHSPH IRB, and the Chairs of the JHSPH IRBs are responsible for establishing JHSPH IRB meeting procedures. These procedures include preparing the agendas for the meetings, assembling and distributing the meeting packets, selecting the primary reviewer, recording and processing the minutes of the meeting, and communicating with investigators. Convened meetings for all JHSPH IRBs shall occur weekly, unless circumstances dictate a meeting must be cancelled (examples: lack of quorum, University holidays, weather-related changes, etc.)

The JHSPH IRB meeting will begin when a quorum is present, including a non-scientific member. The Chair or Vice Chair will open the meeting and call each application or item of business before the committee. In the event that the Chair is called from the room or leaves early, the Vice Chair may continue the meeting. If both the Chair and the Vice Chair are out of the room, the meeting may continue so long as a quorum exists.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.06	Title: Reports of Unanticipated Problems Involving Risks to Participants or to Others (Problem/Event Reporting)	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH requires researchers to comply with all applicable local, state, and federal regulations in the conduct of research studies. As part of this requirement, researchers are required to submit to the JHSPH IRB written reports of events that meet the definition of “unanticipated problems involving risks to participants and others.” Principal investigators must report such problems/events to the IRB promptly, as well as to applicable regulatory agencies, sponsors, and institutional officials.

Events labeled as “reportable events” in research involving investigational drugs or devices may or may not meet the definition of an “unanticipated problem.” In such cases, the PI must report the event to the JHSPH IRB if it meets the definition of an unanticipated problem or if a sponsor or regulatory authority requires report to the IRB.

Definitions

A. “Unanticipated problems involving risks to participants or others” is defined as:

(1) The information is **unexpected** in terms of nature, severity, or frequency, given:

- a) the research procedures described in the protocol and informed consent document; and
- b) the characteristics of the subject population being studied;

and

(2) The information about the event indicates that participants or others are at **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

B. “Prompt reporting” is defined to be “as soon as possible after the PI learns of the event”, but in all cases within 10 working days.

C. Reportable Problem/Events

The JHSPH PI must promptly report the following unanticipated problems or events:

1. Event (including on-site and off-site adverse event reports, injuries, side effects, breaches of confidentiality, or other problems) that occurs any time during or after the research study, which in the opinion of the principal investigator:
 - a. Involved harm to one or more participants or others, or placed one or more participants or others at increased risk of harm;
 - b. Is unexpected (an event is “unexpected” when it is not described with specificity in the protocol and informed consent document; or if described with specificity, it occurs beyond the expected frequency and/or severity identified); and
 - c. Is related to the research procedures (an event is “related to the research procedures” if in the opinion of the principal investigator, it was more likely than not to be caused by the research procedures.)
2. Information that indicates a change to the risk:benefit ratio of the research. For example:
 - a. An interim analysis indicates that participants have a lower rate of response to treatment than initially expected
 - b. Safety monitoring indicates that a particular side effect is more severe, or more frequent than initially expected
 - c. A paper is published from another study that shows that an arm of the research study is of no therapeutic value
3. Change(s) in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
4. Change(s) to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research participant
5. Incarceration of a participant
6. Event that requires prompt reporting to the sponsor
7. Complaint of a participant when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team

8. Protocol violation (a term often used by NIH or commercial sponsors, meaning an accidental or unintentional change to the IRB approved protocol) that placed one or more participants at increased risk, or has the potential to occur again
9. An unanticipated adverse device effect as defined by FDA at 21 CFR Part 812.3(s).

Form of Report

The PI should submit a written report of the unanticipated problem/event to the JHSPH IRB using the Problem/Event Report Form. Reports may be accepted by hard copy, e-mail, or phone (if the report is of an urgent nature) with a report form to follow.

Review of Problem/Event Reports

The JSHPH IRB will review each reported problem/event to determine if it meets the definition of an unanticipated problem involving risks to participants or others. Review of a problem/event may require use of a consultant, or assistance from the division or department chair, to collect additional information before a determination is made.


Action will be taken to address the problem. The range of actions may be taken by the Institutional Official, other senior JHSPH officials charged with taking action, or the IRB. The range of actions includes items listed below, but the list does not preclude taking additional actions as determined on a case-by-case basis.

- Administrative hold on the study pending IRB receipt of further information from the PI in a time period not to exceed 90 days
- Modification of the protocol
- Modification of the information disclosed during the consent process
- Providing additional information to current participants (this must be done whenever the information may relate to participants' willingness to continue participation)
- Making arrangements for clinical care outside the research or additional follow-up for participants
- Providing additional information to past participants
- Requiring current participants to re-consent to participation
- Alteration of the frequency of continuing review
- Observation of the research or the consent process
- Requiring additional training of the investigator
- Notification of investigators at other sites
- Obtaining additional information
- Termination or suspension of the research. Such action will be reported to the Institutional Official (IO).

The IO will be informed when a determination has been made that a problem/event meets the definition of an unanticipated problem involving risks to participants or

others. The IO will fulfill the requirements to report the action to federal departments or agencies as required by regulation and with JHSPH policy.

If a determination is made that a problem/event reported to the IRB does not meet the definition of an unanticipated problem involving risks to participants or others, no further action needs to be taken and a report to the IO is not required.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.07	Title: Investigator Non-Compliance and Protocol Deviations	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB can only approve applications that meet the criteria set forth in government regulations, JHSPH policies, and other federal, state, and local law and regulations. IRB approval notices to the Principal Investigator (PI) detail any special conditions or requirements for conduct of the research, and provide a time limit on the approval period. The PI is responsible for conducting the approved research in accord with the IRB's requirements. If the PI departs from approved study procedures, the PI must report that departure as either an "unanticipated problem that posed risk to subjects or others", as an incident of non-compliance, or as a "protocol deviation".

This policy deals with non-compliance and protocol deviations. A companion policy, 103.06 "Reports of Unanticipated Problems Involving Risks to Participants or Others," deals with unanticipated problems. This policy distinguishes those events from incidents of "investigator non-compliance", both of which must promptly be reported to the IRB, and from administrative and minor "protocol deviations" which do not require prompt report to the IRB.

This policy clarifies all three possible situations – unanticipated problems, non-compliance, and protocol deviations – and provides explicit guidance on required actions.

Definitions

Non-compliance (minor, serious, and continuing):

"Non-compliance" is defined as:

- failure on the part of the PI, any member of the study team, or any individual involved in research review or oversight to follow the terms of JHSPH IRB approval (including the approved Research Plan and Consent Process), or
- failure of the PI, any member of the study team, or any individual involved in research review or oversight to abide by applicable laws or regulations or JHSPH policies, including failure to submit research for IRB review and approval prior to commencing research.

“Minor non-compliance” is defined to be reported incidents, or events, which are not either serious or continuing non-compliance.

“Serious non-compliance” is defined to be failure to comply with laws or regulations, JHSPH policies, or the requirements or determinations of the IRB, when that failure actually or potentially increases risk to participants or adversely affects the rights and welfare of the participants. A single instance of non-compliance may be determined by the IRB to be serious non-compliance (i.e., continuing non-compliance is not a necessary prerequisite of serious non-compliance). The JHSPH IRB is obligated to report incidents of serious non-compliance to the sponsor and to federal authorities.

“Continuing non-compliance” is defined to be a pattern of behavior or minor non-compliance issues (even when none of them rise to serious non-compliance) that, if unaddressed, may compromise the integrity of human research protections applicable to ongoing or future studies. The JHSPH IRB is obligated to report continuing non-compliance to the sponsor and to federal authorities.

Protocol Deviations:

The term “protocol deviation” is not defined by either the HHS human subjects regulations ([45 CFR 46](#)) or the FDA human subjects regulations ([21 CFR 50](#)). For JHSPH purposes, a protocol deviation is a ***minor or administrative*** departure (see definitions below) from the protocol procedures approved by the IRB that was made by the PI without prior IRB approval. In this context, “minor or administrative” protocol deviations are defined as those that **do not “affect the scientific soundness of the research plan or the rights, safety, or welfare of human subjects.”** Examples of minor or administrative deviations could include: follow up visits that occurred outside the protocol-required time frame because of the participant’s schedule, or blood samples obtained at times close to but not precisely at the time points specified in the protocol.

If a protocol deviation occurs (i.e., an event that meets this definition), the deviation should be reported to the JHSPH IRB at the time the Progress Report is submitted. Use the *Protocol Deviation Summary Sheet* to report these deviations with the Progress Report.

Please note that eligibility exceptions (or eligibility waivers granted by a sponsor) for enrollment of a specific individual who does not meet the inclusion/exclusion criteria in the IRB-approved protocol are not “protocol deviations”. Rather, they are considered non-compliance, because eligibility exceptions are considered changes in research that require IRB review and approval before a subject who does not meet the approved protocol inclusion/exclusion criteria may be enrolled.

Unanticipated Problems:

“Unanticipated problems involving risks to participants or others” is defined as:

(1) The event is **unexpected** in terms of nature, severity, or frequency, given:

a) the research procedures described in the protocol and informed consent document; and

b) the characteristics of the subject population being studied;

and

(2) The information about the event indicates that participants or others are at **greater risk of harm** (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unanticipated problems and their reporting are handled in Policy 103.06. In the context of the present policy (103.07 Non-Compliance), one type of unanticipated problem is a “protocol violation” (a term often used by NIH or commercial sponsors, meaning an accidental or unintentional change to the IRB approved protocol) that places one or more participants at increased risk, or has the potential to occur again. This type of unanticipated problem is a form of non-compliance, and both 103.06 and 103.07 apply.

Reporting Non-Compliance

There may be different reasons why a PI or study team member decides to depart from approved protocol procedures, and the consequence of that decision will depend upon the circumstances. A departure from the approved protocol that constitutes an “unanticipated problem involving risks to subjects or to others” (see Policy 103.06) or is “non-compliance” must be reported promptly to the IRB using the *Problem/Event Report*, as follows:

1. Emergency situations: When a departure from the approved protocol occurs in an **emergency situation**, such as when it is required to protect the life or physical well-being of a participant, the sponsor and the reviewing IRB must be notified as soon as possible, but in no event later than 5 days after the **emergency** occurs. [[21 CFR 812.150\(a\)\(4\)](#) .]

2. Substantive, non-emergency departures without prior approval: A planned departure from approved procedures that does not involve an emergency situation (e.g., is “non-emergency”) and represents a substantive change in the protocol as approved by the IRB must be submitted as an Amendment. The IRB must approve the request before the proposed change is implemented. If a major, non-emergency departure from approved procedures occurs (either by accident or intent) without prior IRB approval, the event is considered to be non-compliance. The PI’s failure to report promptly any major, non-emergency departure from approved procedures, for which the PI did not obtain prior approval, is itself an incident of non-compliance.

IRB Review of Allegations and Reports of Non-Compliance

The IO, IRB or other JHSPH offices or staff may be notified informally or may receive a non-written allegation of non-compliance. An allegation of non-compliance is an assertion by a second party of an incident of non-compliance. The IO or IRB may authorize the JHSPH Compliance Monitors to conduct a fact-finding effort to determine whether the allegation has a basis in fact. An allegation determined to have a basis in fact and to meet the definition of non-compliance must be forwarded to the IRB for review. An allegation determined not to have a basis in fact will be forwarded to the IO for response to the source of the allegation. An allegation for which it is not possible to adequately determine the facts will be forwarded to the IO or other JHSPH officials for a determination on the appropriate mechanism for fact-finding about the allegation.

The IRB will review written reports of non-compliance or allegations of non-compliance that have a basis in fact. Written reports of non-compliance may be originated by a PI, study team, other staff or offices, sponsors, or collaborators. All written reports, regardless of origin, will be reviewed by the IRB at a convened session. The IRB is authorized to collect additional information before making a determination. The IRB may collect information using a variety of methods. The IRB may communicate directly with the PI and study team, or require the PI and study team to meet with the IRB to discuss the report. The IRB may request an audit or ask the IO to conduct an investigation.

The IRB may determine the non-compliance reported is: minor non-compliance, serious non-compliance, or is part of a pattern of continuing non-compliance. An IRB finding of minor non-compliance may include a determination of what appropriate corrective actions, if any, should be implemented by the PI and study team. The IRB may require a range of actions to correct the minor non-compliance. The IRB may determine a corrective action plan should include, as appropriate:

- Additional training of the PI or the study team
- Additional supervision of the PI
- A limit on the number of research activities conducted by the PI
- A limit on the number of participants who may be enrolled by the PI


When the IRB determines there has been serious or continuing non-compliance, the IRB will determine what steps must be taken, if any, to protect enrolled participants. The IRB will determine the elements of a corrective action plan to address the non-compliance and prevent recurrence. The IRB may take the following actions in the case of serious or continuing non-compliance:

- Modify the study protocol
- Modify information that must be disclosed in a consent document
- Provide information about the non-compliance to current study participants, when such information may affect willingness to continue participation
- Require re-consent of all participants

- Modify the continuing review schedule
- Monitor the research activities
- Monitor the consent process
- Suspend the conduct of research until corrective actions are implemented
- Terminate the research

An IRB determination of serious non-compliance or continuing non-compliance must be reported to the IO. Reports to the IO will be sent within 30 days of the IRB's determination of serious or continuing non-compliance.

The IO is authorized to determine whether a corrective action plan recommended by an IRB should include additional measures. The IO is not authorized to change the IRB's determination of serious or continuing non-compliance. The IO will report the IRB's determination of serious or continuing non-compliance to the appropriate agencies (typically including OHRP and the sponsor). In cases where the IRB makes a determination that non-compliance is not serious or continuing, the IO is authorized to take additional action, which may include suspending or terminating the research.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.08	Title: Reporting to OHRP, the FDA, and other Federal Sponsors	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH has the responsibility to report unanticipated problems involving risk to subjects or others under Policy 103.06, serious or continuing non-compliance under Policy 103.07, and suspension or termination of approved research under Policy 113.01, to the appropriate federal agencies. The Institutional Official (IO) is authorized as the individual who will submit reports when an IRB has made a determination under the three cited policies. In cases where the JHSPH IRB and IO determine that additional information is required before submitting a final report, a preliminary report may be made to the appropriate officials, supporting federal agency (as applicable), OHRP, and FDA (as applicable), within one month of the IRB's determination.

A draft preliminary or final report will be prepared for review by the IO and General Counsels (GCs). The draft report will contain the following information:

- The nature of the event
- The findings of the organization
- The actions taken by the organization and IRB, including plans to protect the rights and welfare of the participants
- The reasons for the organization's and IRB's actions
- The plans for continued oversight or investigation or action.

The draft report will be finalized by the IO and the GCs. The IO will sign the report within 20 days of the agreed upon final revision of the report. The final report will be submitted to the OHRP if the research is conducted, funded, or overseen by DHHS; to FDA, if the research is regulated by FDA; and to other agencies that are signatories to the Common Rule, if the research is conducted, funded or overseen by such agencies. A copy of the report will be sent to the reviewing IRB, ORA if the project is funded by an outside sponsor, and the PI. The IO may determine the report should be provided to the Chair of the Department to which the PI is appointed as faculty and to the Dean of the JHSPH. If the event involves unauthorized use, loss, or disclosure of PHI, a copy will be sent to the HIPAA Privacy Officer.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.09	Title: Amendments to IRB Approved Research	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB must review and approve proposed changes in approved research prior to initiation of any changes. Changes in research may encompass amendments, addenda, deletions, or revisions to either the research plan or consent document(s) associated with a study. If, however, a change in research is necessary to eliminate apparent immediate hazards to a research participant, the PI may proceed with the change without prior IRB review. It is the responsibility of the PI to inform the IRB promptly of the change and the IRB must determine if the modified research is consistent with ensuring participants' continued welfare.

Changes to study instruments (not consent documents) will be processed in accordance with JHSPH IRB Policy 109.2, "Minor and Administrative Changes to Study Instruments."


To initiate a change to approved research, the PI must submit an Amendment Application for the IRB to review. Minor and administrative changes will be reviewed through an expedited review process; all other amendments will be reviewed by an IRB. Changes in research involving drugs, biologics, or CAMs must be reviewed by the designated IRB P&T member for either an expedited review or a convened review. The P&T member may serve the dual role of primary reviewer and P&T reviewer. Changes or modifications reviewed through an expedited review process will be reported periodically to the IRB members. Complete files of the research project will be made available to any member upon request for further review.

The JHSPH IRB conducting review of amendments is authorized to alter the approval period for the research based on degree of risk posed by the change in research or to retain the original approval period granted at initial review. The IRB may require revisions to consent documents and require notification to enrolled participants of approved changes in research that may affect the participants' decision to continue in the research.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.10	Title: Ancillary Committee Reviews	Date of Approval 12/1/08	Approved By Janet DiPietro

All required JHU ancillary committee reviews, such as Conflict of Interest (COI), Pharmacy & Therapeutics (P&T), Institutional Biosafety Committee (IBC), Clinical Radiation Research Committee (CRRC), and so on, must be completed before the JHSPH IRB approves a study. The committees will provide information about their reviews, and the IRB will include those findings in its deliberation.


Certain ancillary reviews, such as that conducted by the Baltimore City Health Department internal ethics committee, will proceed following JHSPH IRB approval of a study. The Institution Official periodically reviews ancillary committee review requirements to assure that the process and communications proceed smoothly.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status	Revision Date
Policy No.	Title:	Date of Approval	Approved By
103.11	Conflict of Interest	12/1/08	Janet DiPietro

Each JHSPH investigator must disclose to the Conflict of Interest Committee all financial and fiduciary interests that might appear to present a conflict of interest related to research activities. The JHSPH policy on Conflict of Interest gives authority to the Committee to impose specific management requirements to conflicts of interest associated with conduct of human subjects research protocols. The JHSPH IRB office will work with the Conflict of Interest Committee to ensure that conflicts associated with research protocols are identified and reviewed by the Committee before JHSPH IRB review is completed. The JHSPH IRB may not take final action on new applications until COI review is complete and management recommendations are finalized. The JHSPH IRB may accept COI management terms or may impose additional restrictions. The JHSPH IRB may not approve a study with a level of conflict of management that is less than that recommended by the COI.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.12	Title: Human Subjects Research Compliance Training	Date of Approval 12/1/08	Approved By Janet DiPietro

Human Subjects Research Compliance Training and Certification is required for all JHSPH research investigators who conduct research involving human participants and their research staff, the IRB Chairs, vice-Chairs, members, management, and staff. In addition to named investigators, research staff includes individuals who have direct contact with human subjects, including those involved in survey administration, focus groups, and the consent process. For studies conducted in locales that have limited access to the current required internet-based training, the PI may propose an alternative training program to ensure that all research staff are trained in human subjects research ethics. The JHSPH IRB will accept module-based training from other institutions, and will also consider in-person training conducted by the PI or other senior research staff members. If such in-person training will be used, the PI must submit to the IRB a summary of the topics that the training will include. The IRB will use its discretion to determine whether the information provided is appropriate for training for the specific study under review.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.13	Title: Data and Safety Monitoring of JHSPH Studies	Date of Approval 12/1/08	Approved By Janet DiPietro

All human subjects research submitted to the JHSPH IRB must include a data and safety monitoring plan that is appropriate to the risk level of the proposed research. The IRB will determine whether an activity represents minimal risk or more than minimal risk to participants and then determine whether a data safety monitoring plan is required.

In research that involves no more than minimal risk, a monitoring plan is usually not required. The IRB requires a data and safety monitoring plan for most, if not all, projects that present more than minimal risk to participants. When research represents more than minimal risk, the research plan should include information such as procedures for analysis and interpretation of data, actions the responsible party will take concerning specific events or end points, time points for review, and reporting mechanism. The IRB may consider a range of options as appropriate monitoring plans as noted below:

- The principal investigator will have sole responsibility for monitoring, or
- A group of designated JH faculty/staff will have responsibility for monitoring, or
- An independent individual or group of non-JH individuals will have responsibility for monitoring, or
- A designated medical monitor, or group of monitors, for commercially funded or for not-for-profit sponsored studies will have responsibility for monitoring, or
- The SKCCC Clinical Research Office will perform data and safety monitoring for the project, or
- A formal Data and Safety Monitoring Board (DSMB) will have responsibility for monitoring.

In the event that a formal DSMB is to be constituted by a federal funding agency, or by a clinical consortia conducting the protocol, or is required by the IRB, the IRB may determine that a formal DSMB represents sufficient data and safety monitoring oversight. Names of specific members of a DSMB need not be provided to the IRB as long as the DSMB description contains sufficient information about individuals who will be selected to serve on the DSMB. The IRB's decision regarding the adequacy of the plan will be recorded in the minutes of the convened meeting.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.14	Title: Faculty Departure from JHSPH	Date of Approval 12/1/08	Approved By Janet DiPietro


The JHSPH is “engaged in research” when one or more of its employees or agents directly intervenes or interacts with human subjects; and when an employee provides, obtains, accesses, receives, or possesses a living human subject’s identifiable private information (uncoded or linked to a code) for non-exempt research purposes.

When a faculty member leaves the institution, that person is no longer an “employee or agent” of the institution, and the JHSPH IRB no longer has jurisdiction over that investigator. “Adjunct” faculty members are not “employees or agents” of the institution. Faculty members must notify the JHSPH IRB when they are leaving the institution, and must formally terminate any active research application for which they serve as PI, or submit an amendment which identifies the JHSPH faculty member who will assume the responsibility as PI for the study. Departing faculty members must also make sure that the PIs for any studies for which they serve as co-investigators submit amendments to the IRB removing them from the study.

Upon departure, the faculty member may not conduct the research without submitting a research application to another IRB; otherwise that person is conducting research without IRB approval. The individual faculty member, as a PI or a co-investigator, must have IRB approval to conduct the research. This is true even if a second institution has approved the research for a second PI.


Departing faculty members should also be aware of the University’s data retention and transfer policies, available for review here:

http://jhuresearch.jhu.edu/Data_Management_Policy.pdf.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.15	Title: Visitors to the JHSPH IRB	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB will permit visitors to attend IRB meetings. The following procedures must be in place to protect the privacy and confidentiality of deliberations:

- IRB staff should be notified to allow screening of the agenda
- The presence of the visitor should be noted in the minutes
- Visitors will be asked to sign a confidentiality statement and will be asked to leave the room for discussions that should only occur in executive session.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.16	Title: Institutional Support for the JHSPH IRB	Date of Approval 12/1/08	Approved By Janet DiPietro


The JHSPH will provide financial and non-financial support for the Human Research Protection Program. Types of support provided shall include sufficient meeting space to support IRB review functions, staff to support IRB functions, IT support for an electronic application system, legal and monitoring expertise, and establishment of a sufficient number of IRBs to efficiently review human research applications.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.18	Title: Policy Development and Communication	Date of Approval 12/1/08	Approved By Janet DiPietro


The Institutional Official (IO) has the authority to develop, implement and monitor the Human Research Protection Program (HRPP). The HRPP at JHSPH will be conducted in accordance with federal, state and local law and regulations. The Director of the JHSPH IRB staff will meet on a regular basis with the General Counsels of the JHU and the Johns Hopkins Health Systems (JHHS). This meeting will focus on review of policies and procedures to assure compliance with federal, state, and local laws and regulations. New guidance and alerts from the OHRP and the FDA, and other information relevant to the HRPP, will also be discussed. The meeting will provide an opportunity to address any legal issues associated with the conduct of human subject research at JHSPH, and develop new or amended guidance, policies and/or procedures as needed.

The Director of the JHSPH IRB will keep the IO informed of IRB findings and actions by regular provision of IRB meeting minutes. The IO will meet with the Director of the IRB and the Chairs of IRB FC and IRB X on a regular basis to discuss policies, procedures, and guidance. The IO will meet as needed with the General Counsels of the Organization. Such input shall be advisory in nature. The IO has the authority to issue policy, guidance, and procedures that govern the HRPP and the associated IRB review processes. Policies will be approved by the IO and noted with the approval date; policies will become effective on the date approved. A hard copy of each approved, dated, and initialed policy will be retained in the IO's office. The IO may delegate authority to approve OHSR guidance and operating procedures to the Director of the JHSPH IRB or other senior administrative staff as determined appropriate.

JHSPH IRB staff will track all changes to HRPP policies, procedures, and guidance using a revision and approved date tracking system.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.19	Title: Pharmacy & Therapeutics Review	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB requires review and approval by a representative of the Pharmacy and Therapeutics (P&T) Committee for any use of drugs, biologics, or complimentary and alternative medicines (CAMs) in a research protocol prior to final IRB action on a protocol. This objective will be accomplished by ensuring that IRB FC shall have a member who is also a member of the P&T Committee. When a P&T member for the IRB FC must be absent from a meeting, a P&T Committee alternate may serve as a designated alternate and attend the meeting. In cases where a P&T IRB member or alternate cannot attend a convened meeting, the IRB will table applications that include drugs used in clinical investigation until the next meeting when the P&T IRB member can attend. JHSPH IRB X reviews research that qualifies as a minimal risk activity which may be reviewed through an expedited review process. JHSPH IRB X may review applications that include a marketed drug only if it obtains a written consult from a P&T/IRB member from IRB FC. The P&T IRB members will provide information to the P&T Committees of the three JHM hospitals (JHH, JHBMC, and HCGH) to assure proper communication regarding drug research approved for conduct at the Hospitals.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.19a	Title: Drug Use and Control in Clinical Investigation (DUCI)	Date of Approval 12/1/08	Approved By Janet DiPietro

Definitions:

Dispensing Drugs: This occurs when a supply of drug that is not patient-specific, or that requires manipulation (counting, mixing, preparing, etc.), is given to a specific patient. By law, dispensing may only be done by a pharmacist, physician, nurse practitioner, podiatrist, or dentist. Examples of dispensing drugs include: (a) selecting a quantity of drug from a general bulk supply and placing it in another container for a patient, and (b) reconstituting a drug with a quantity of water before giving it to the patient.

Distributing Drugs: A drug is distributed when it is given to the patient in a pre-labeled container with specific patient identification (patient's name or patient-specific identification code), and does not require manipulation (counting, mixing, preparing, etc.) before giving it to the patient. Drugs may only be distributed upon the order of an authorized prescriber and should be distributed only by a nurse, physician assistant or other personnel trained to do so by the principal investigator.

DUCI (Drug Used in a Clinical Investigation): Any drug, biological, botanical or other substance used specifically for a clinical investigation as described in the investigational protocol. Such drugs shall be either commercially available or not commercially available and used according to, or outside of, FDA-approved indications.

IDS pharmacist: Refers to a pharmacist in investigational drug services at JHM.

Investigational Drug: Any drug for which the Food and Drug Administration has granted Investigational New Drug (IND) status.

Pharmacy: Refers to a pharmacy controlled by Johns Hopkins Medicine.

General

All clinical research conducted by full-time faculty members of The Johns Hopkins University (JHU) shall be reviewed by an IRB as specified by the reciprocity agreement dated July 12, 2002. Clinical research conducted by faculty members of JHSPH are obliged to obtain JHSPH IRB approval of all human subjects activities conducted under the auspices of their Hopkins'

appointment, by which is meant use of Hopkins' personnel or space or the use of the faculty appointment in correspondence, agreements with sponsors, etc.

The Pharmacy and Therapeutics Committee Members of the JHM and Bloomberg School of Public Health (JHSPH) Institutional Review Boards (IRB)

1. The membership of all JHM and JHSPH IRBs reviewing Research Protocol applications involving a DUCI will include at least one member who serves jointly on the IRB and either the site-specific P&T Committee or Investigational Drug Service (IDS) ["P&T/IDS IRB member"].
2. All applications reviewed by a JHM or JHSPH IRB involving the clinical use of DUCIs require approval by an IRB before they may begin. The P&T/IDS IRB member shall review the DUCI-associated drug issues either (i) prior to the IRB meeting and have the review incorporated into the IRB review process, or (ii) at the convened IRB meeting. The review process conducted by the P&T/IDS IRB member must include specific IRB issues related to (a) drug safety, (b) drug management, (c) study design, (d) IND status, (e) drug data sheet review for INDs, (f) informed consent documents, and (g) any other relevant material.
3. The IRB will be responsible for reviewing reports of unanticipated problems (including adverse drug effects that occur during a clinical investigation) in accord with the JHSPH policy on Reports of Unanticipated Problems (Policy 103.6).

Selection Process and Qualifications of the P&T/IDS IRB member on a JHM or JHSPH IRB

4. P&T Committee members or IDS members selected to serve as P&T/IDS members shall be appointed by the Institutional Official. The Institutional Official shall consult with the Chair of the site-specific P&T Committee/IDS to identify individuals who may be appointed as IRB members, but IO has the final appointment authority.
5. Selection of candidates for P&T/IDS members shall include in the evaluation: (a) expertise in the concepts of pharmacology and study design (as may be indicated by the attainment of relevant academic degrees or by specific training); or clinical investigation experience; or at least two years of IDS activity, (b) commitment to attendance at 80% or more of convened IRB meetings, and (c) demonstrated ability to effectively communicate and to think clearly regarding medication-related issues.

P&T/IDS IRB Member Approval of Studies Involving Devices

6. Device studies that do not contain a DUCI do not require review and approval by the P&T/IDS IRB member.
7. In cases where a device study includes a DUCI, the study must be approved per paragraph 2 above. In such cases of review of a device study that includes a DUCI, the P&T/IDS IRB member will base approval on the appropriateness of use involving the drug(s) and not on the use of the device per se.

Reports of the P&T/IDS IRB Member to the P&T Committee

8. The P&T/IDS IRB members are fully accountable and responsible to their respective organization P&T Committees. An appropriate mechanism for reporting liaison activities to the P&T Committee must be established by each P&T Committee.

Storage, Control, Preparation and Dispensing of Drugs Used in Clinical Trials

9. Inpatient Studies:

a. INDs: The pharmacy shall store, control, prepare and dispense all investigational drugs and all study specific drug inventory supplied by a study sponsor. Exceptions may be granted by the P&T/IDS IRB member (see below).

b. Non-INDs: For DUCIs that are not investigational drugs or study specific inventory supplied by a sponsor, the pharmacy may be required to control and dispense the medication if the P&T/IDS IRB member believes this to be appropriate.

10. Outpatient Studies: All outpatient DUCIs requiring manipulation (e.g., mixing, formulating, counting, compounding, etc.) shall be stored, controlled, prepared and dispensed by the pharmacy unless an exception is granted by the P&T/IDS IRB member (see below).

11. In a situation where an investigator wishes to store, control or dispense the DUCI, the investigator must describe, at the time of application submission, the procedures for performing these functions. In situations where the investigator may want to control dispensing of a DUCI, such as when a medication needs to be dispensed urgently or the study is conducted at a distant geographic site, both the P&T/IDS IRB member and the IRB must approve this arrangement.

The Drug Data Sheet (DDS)

12. A drug data sheet shall be completed for all investigational new drugs. The purpose of the DDS is to provide sufficient information to allow the investigational drug to be administered safely.

13. Completed drug data sheets shall be reviewed by a P&T/IDS IRB member as part of the application review process.

14. Clinicians administering an investigational new drug shall be familiar with the contents of the DDS prior to drug administration. If the investigational product will be administered in a JH facility, the DDS shall be placed into every study patient's paper medical record. It is the responsibility of the principal investigator to assure that the most current version of the DDS is placed into the inpatient paper chart of study subjects.

Authorization to Prescribe an Investigational Drug

15. Principal investigators shall identify those individuals authorized to prescribe investigational drugs used in their study. For each investigational drug, a DDS shall be completed and shall indicate those authorized to prescribe the investigational drug or indicate the location of a current list of those authorized to prescribe.

16. Anyone who dispenses or administers an investigational drug shall verify that the prescriber is authorized to do so prior to dispensing or administering the drug.

Principal Investigator Auditing

17. In situations where an investigator has been approved to control a DUCI at a JHH, JHBMC, Howard County General Hospital, or JHUSOM facility, an IDS pharmacist shall audit the storage, control, preparation and dispensing of the investigational drug to assure that all regulatory and hospital requirements are met.

18. For studies based at a JHH, JHBMC, Howard County General Hospital, or JHU SOM facility where DUCIs are controlled by the principal investigator, audits of studies shall be conducted (a) prior to the study beginning, (b) within 1 month of the beginning of patient accrual, (c) within one month of each yearly renewal, and (d) upon termination of the study. If unsatisfactory audit findings are discovered which cannot be resolved during the audit, additional audits shall be scheduled until the identified problem(s) is resolved. Audit results should be forwarded to the IRB.

19. When a principal investigator receives a study audit report from a regulatory agency or from a study sponsor (or agent of the sponsor), the principal investigator must provide a copy of the report to the IRB within 5 working days.

20. When a principal investigator receives a notice that the FDA wishes to audit/inspect study records, the IRB must be notified before the inspection visit occurs.

Pharmacy Quality Control


21. In situations where a Hopkins pharmacy controls a DUCI, an IDS pharmacist will perform monthly quality control of the procedures used by the pharmacy. A pharmacist, who is not directly involved with dispensing the DUCI(s) in question, will perform quality control.

Communication of Audit Findings


22. Audit findings shall be reported at least quarterly to the IRB Chairs, to P&T Committee chairs, and to P&T/IDS IRB members.

Funding

23. The principal investigator has fundamental responsibility to secure funding for clinical investigation. Resource assessment and indemnification issues affecting the viability of each clinical investigation involving DUCIs will not be the responsibility of the P&T/IDS IRB member.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.20	Title: Investigational Drug Service (IDS)	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH requires IDS procedures to protect subjects enrolled in studies involving drugs, biologics, botanicals, complementary and alternative medicines (CAMs) and other substances. The IDS staff has been delegated responsibility for assuring that the receipt, dispensing, and record keeping requirements for investigational drugs conform with Organization requirements. The JHSPH IRB staff will share with IDS information regarding investigational drugs used in research protocols. In addition, staff of the IDS will have access to the JHSPH IRB database to facilitate this communication and will report audit results to the JHSPH IRB.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.21	Title: Review of Radiation Procedures	Date of Approval 12/1/08	Approved By Janet DiPietro

Research conducted by JHSPH investigators using procedures that deliver ionizing radiation to subjects must have additional pre-review before IRB action. This pre-review always includes a review by the JHSPH IRB radiation consultant. For protocols where the procedures are conducted at Johns Hopkins Medical Institution facilities, the JHMI broad scope license to administer ionizing radiation includes a further review requirement applicable to new research protocols or to existing approved protocols that incorporate a change in radiation exposure. This review responsibility has been delegated to the CRRC (Clinical Radiation Research Committee) and its subgroup, the RDRC (Radioactive Drug Research Committee).

Studies submitted to the JHSPH IRB for review that include the use of ionizing radiation require the provision of radiation dosimetry information. JHSPH staff is responsible for initiating IRB radiation consultant, CRRC or RDRC review and providing copies of research applications to the Secretary of these two committees. Questions/concerns raised in the radiation review are sent to investigators by the JHSPH IRB. The JHSPH IRB will not take final action on an application that involves radiation until the radiation review is complete.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.22	Title: Institutional Biosafety Committee	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH requires individuals who collect and/or ship specimens to register with the Institutional Biosafety Committee. This requirement extends to research protocols. The JHSPH IRB will inform investigators of this requirement.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.23	Title: Documentation Required from Collaborating Sites	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH requires research team members described in each protocol to be qualified to perform the research procedures that they have agreed to perform. The PI is responsible for assembling a team that has the proper qualifications and has documentation of training in human subjects research ethics. In addition, the individuals performing medical procedures at Johns Hopkins sites must be credentialed to perform those procedures; if Fellows are part of the study team, the PI must adhere to the Hopkins policy regarding involvement of Fellows in clinical research. JHSPH IRB questions regarding credentials will be referred to the appropriate offices for response.

The JHSPH is cognizant of the responsibility to assure that collaborative institutions have performed required IRB/Ethics Committee reviews and have on file with OHRP appropriate assurance documents. Investigators are required to submit approvals from off site IRBs/Ethics Committees, as well as any required administrative approval for conduct of research at non-Hopkins facilities. If such documentation is pending, the JHSPH IRB may approve the study with administrative changes. JHSPH IRB staff is responsible for communicating with investigators to assure that documentation is provided before final approval and release of consent documentation.

When the investigator plans to conduct research at any site not under the control of the JHSPH (e.g. school, nursing home, health care facility, private practice, clinical setting overseas, etc.), the following information must be provided to the JHSPH IRB:

- Name of site
- Name of contact at the site
- Contact information (phone or email)
- Has the site provided permission to conduct the research at that site?
- Does site have an IRB?
- Has the site's IRB approved the research?
- Does the site plan to rely on the JHSPH IRB?

In order to grant final approval, IRB staff will ensure that:


- All sites have provided permission to conduct the research at the site
- If the site has an IRB, the IRB has either approved the research, or the site has deferred approval to the JHSPH IRB.

If a site has not granted permission, the IRB staff will contact the investigators to indicate that final approval will be withheld until the site has provided permission. Future information regarding the site's permission will be documented in writing and maintained in the protocol file.

If a site has an IRB and does not plan to rely on the JHSPH IRB, the IRB staff will inform the investigators that final approval will be withheld until the site's IRB has approved the research. Future information regarding approval by the site's IRB will be documented in writing and maintained in the protocol file.


If a site does not have an IRB or plans to rely on the JHSPH IRB, the JHSPH IRB will serve as the IRB of record.

If any problems arise with external sites, IRB staff will communicate with the contact person named on the application.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.24	Title: Principal Investigator	Date of Approval 12/1/08	Approved By Janet DiPietro

Only JHSPH full-time faculty members may serve as a principal investigator (PI) for research studies that involve human subjects. Once the JHSPH IRB reviews and approves a study involving human participants, the principal investigator (PI) is solely responsible for the conduct of the study as described in the research plan, and in compliance with institution policy, federal regulations, and state, local, or international laws. As part of its assessment of a research application, the JHSPH IRB will consider the PI's qualifications and expertise to determine whether the faculty member may serve as PI for a particular research investigation. All communications with the IRB concerning the research plan and associated documents, except those which deal with administrative issues, must originate from the PI.

The role of the JHSPH PI may vary, depending upon whether the study described in an application is a single site study, one site in a multi-site study, or is the coordinating center for a multi-site study and should be explained in the research plan. When appropriate, the PI may include collaborating co-investigators from JHSPH or other institutions and may hire or otherwise include research study staff to assist in the implementation of the study procedures and maintenance of the study records. If the study will be conducted at a non-JHSPH site, a management plan must be provided for ensuring that the study will be conducted as approved by the JHSPH IRB.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.25	Title: Registration of Clinical Trials	Date of Approval 12/1/08	Approved By Janet DiPietro


All clinical trials approved by the JHSPH IRB shall be registered at <http://www.clinicaltrials.gov>, unless prohibited by contract with a commercial sponsor. The definition of a clinical trial for purposes of this policy is "Any research study that prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes." Health outcomes include any biomedical or health-related measures, including pharmacokinetic measures and adverse events. This incorporates requirements imposed by the September, 2007 FDA Amendments Act, which affected new and ongoing trials as of January 25, 2008. This policy additionally incorporates the International Committee of Medical Journal Editors (ICMJE) policy applying to all trials beginning enrollment on or after July 1, 2008.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.26	Title: Electronic Submission of Research Applications	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB Office accepts new research applications from JHSPH faculty members through the electronic PHIRST system. PHIRST applications must contain a research plan which clearly presents the proposed research study; any consent documentation required for the study; recruitment materials that will be used to inform potential participants about the study; grant and collaboration documents, and all data collection instruments proposed for the study. The PI is also required to identify the funding source, if any, for the study, the collaborative relationships associated with the project, and any other IRB approvals associated with the project. All information must be submitted to the JHSPH IRB, through PHIRST, by the PI, not by any other member of the study team. Information and uploaded documents obtained and reviewed as part of IRB functions are treated as confidential.

The “application” portion of the PHIRST submission asks the PI to respond to some questions about the study population and the level of risk associated with the research procedures. The PI’s responses to these questions will be used only by the IRB office in its administrative effort to assign the application to the appropriate level of review; the IRB staff and the IRB members will make their own assessments and are not bound by the PI’s responses. The IRB will not require changes to the application if the responses are not correct. The JHSPH IRB’s determinations are made independently of the PI’s responses.


PHIRST resides on a secure computer network controlled by JHSPH. Access to the PHIRST system is controlled by the JHSPH IRB Office. Access to PHIRST is limited to individuals on a need to know basis. All staff of the JHSPH IRB Office and all IRB members must sign a confidentiality agreement as part of their IRB activities. All non-IRB staff granted access to the PHIRST system must agree to abide by the confidentiality terms stated when access is granted. The information will not be discussed or disclosed outside of the JHSPH review process. Any confidential information from PHIRST distributed by IRB staff to members is done on the JHSPH secure internal email system.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 103.27	Title: FDA Regulated Device Research	Date of Approval 12/1/08	Approved By Janet DiPietro

Research involving medical devices must be reviewed and approved by the JHSPH IRB before the research may begin. The IRB will determine whether the research represents non-significant risk (NSR) device research or significant risk device research. The IRB will record the rationale for a NSR assessment on the review sheet for determinations made at an expedited review session. The IRB will document the NSR determination in the minutes for convened discussions. Proposals that are determined to represent significant risk device research may not proceed without submission of an Investigational Device Exemption (IDE) application to the FDA and subsequent receipt of confirmation of the FDA decision on the application.

The JHSPH requires a monitoring process for receipt, dispensing, and record keeping concerning devices that are studied using an IDE granted by FDA. The monitoring process shall be performed at the direction of the Institutional Official.

Researchers who serve as a sponsor/investigator for an IDE research project are required by the JHSPH to follow FDA regulations 21 CFR 812 Subpart C applicable to sponsor responsibilities. Monitoring of these studies will be performed at the direction of the Institutional Official.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 107.01	Title: IRB Member and IRB Office Staff Qualifications	Date of Approval 12/1/08	Approved By Janet DiPietro

JHSPH IRB Members

The JHSPH IRB follows the Federal regulations, 45 CFR 46.107 and 21 CFR 56.107, that require the Institutional Review Board (IRB) to have at least five members. Those members shall have the following characteristics:

- Varied backgrounds, including: professional expertise; diversity of race, gender, and culture; sensitivity to local community issues and attitudes.
- Ability to ascertain the acceptability of proposed research scientifically, and in terms of institutional commitments and policies, applicable law, and standards of professional conduct and practice.
- Expertise required to provide the IRB with information not only about specialized areas of research, but also about working with various types of research participants, including vulnerable populations.

At least one member of the IRB must have a primary interest in science; and at least one must have a primary interest that is nonscientific in nature. Each IRB must have at least one member who is not affiliated with Johns Hopkins and who is not part of the immediate family of someone who is affiliated with Johns Hopkins. Each JHSPH IRB that reviews studies involving investigational or marketed drugs, biologics, botanicals, complementary or alternative medicines, or gene therapy, will have an appointed member from the Pharmacy & Therapeutics (P&T) committee.

The Institutional Official has the authority to appoint Chairs and Vice-Chairs of each IRB, the members and alternate members of the IRBs. The factors that the Institutional Official will consider for the leadership appointments (Chairs and Vice-Chairs) include: academic status and record of leadership, expertise, willingness to commit the time required, experience with IRB and human research protection issues, administrative abilities, and personal capacity to listen and guide multiple opinions expressed in a meeting format. The Institutional Official will also take into account member expertise with NIH Study Section review of scientific merit, statistical design expertise, and protocol development expertise. The IRB members with scientific expertise will be

selected in consultation with the IRB Chairs, and faculty leadership. The Institutional Official will consider the range of scientific expertise required on the IRBs based upon the types of applications submitted. The non-scientific members will be selected based upon recommendations from current and former nonscientific IRB members or other members of the IRB community.


Any IRB member who has a conflict of interest with a matter under IRB review must recuse him or herself from consideration of that issue.

The IRB may invite consultants with special expertise or experience in working with vulnerable populations, or who have special expertise working in certain parts of the world, to present information before the IRB or participate in meeting deliberations. Consultants may not vote with the IRB.

The Institutional Official will periodically assess the performance of individual members, and will ask members to evaluate the performance of the Chairs and Vice-Chairs. These assessments will be conducted by survey and by personal interview. Any adjustment in committee membership will be determined in the Spring of each year. Membership selection shall be nondiscriminatory such that no selection is made on the basis of gender (45 CFR 46.107(b)).

JHSPH IRB Staff


The JHSPH IRB staff shall include administrative personnel to manage the processing of the applications to the JHSPH IRB and senior staff to review submissions for regulatory and institutional policy compliance. The Director of the IRB will be responsible for both the operations of the IRB Office and for assisting the Institutional Official with compliance issues. The Director, the Institutional Official, and the Chairs and Vice-Chairs of the IRBs will work in executive session to develop policies and procedures to guide the human subject protection program at the JHSPH. This executive committee will also address subject and investigator complaints, and assist with FDA and DHHS inquiries and audits.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 107.02	Title: Consultants to the IRB	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB may request the assistance of a consultant in preparing for discussion of a research protocol in accordance with DHHS regulations at [45 CFR 46.107](#) and FDA regulations at [21 CFR 56.107](#). If the IRB does not include a member who has worked with a particular vulnerable population, has the appropriate scientific expertise, or has experience working in a particular part of the world where the proposed research may take place, it may request a consult.


Consultations may be formal requests for written comments or email requests and will be documented in the protocol file. Consultants may not vote with the IRB members. The IRB may not request the opinion from a consultant who has a financial conflict of interest. If the consultant has a personal conflict in that s/he knows the study, has reviewed it in the past for other purposes, or is a colleague of the PI, that conflict should be disclosed to the IRB, and the IRB may still take the consultant's comments into consideration. The consultant must confirm for the IRB requesting the consult that that no financial conflict exists. The consultant then will be forwarded the applicable study information.

When an application is submitted for JHSPH IRB review that involves research populations outside the U.S., the IRB may accept the review by the local IRB or Ethics Board to satisfy the local context review requirement. The IRB will request from the JHSPH investigator a copy of the local approval document. The IRB will obtain a consult from an individual familiar with the cultural background, local context, and community attitudes of the country in which the research will be conducted if there is no local entity to review the study or if the entity cannot provide an approval document.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 107.03	Title: Training IRB Members and Chairs	Date of Approval 12/1/08	Approved By Janet DiPietro

In addition to the human subjects compliance training that the JHSPH IRB requires for all investigators and staff at JHSPH, each new IRB member, alternate member, or Chair must complete the JHSPH IRB Orientation program, which will be conducted by an existing Chair or Vice-Chair, and the Director of the IRB. JHSPH IRB members will be trained in convened and expedited review regulatory criteria and may not serve as an expedited reviewer until the Chair for their committee determines that they have adequate experience to serve as a reviewer. JHSPH IRB members will be provided with copies of Robert Amdur's *Institutional Review Board Member Handbook, 2/e*. JHSPH IRB Chairs and members will be provided with funds to allow them to participate in local or national conferences co-sponsored by OHRP and/or the FDA which focus on human subject protection issues.

The Institution Official (IO), with the assistance of the IRB Director, will facilitate periodic self-assessments of IRB chairs, members, and overall committee function. This information will be considered as part of the IRB committee appointment process.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 108.1	Title: Quorum, Voting Status, Attendance of IRB Members	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB will follow general corporate law guidelines using total board membership when considering quorum and alternate voting. A meeting cannot proceed without a quorum, which is one more than half the total committee membership, and without the presence of at least one non-scientific member. Members may attend IRB meetings via teleconferencing. For example, if the IRB has 12 members, quorum will be 7; if the IRB has 11 members, quorum will be 6. Alternate members may substitute for IRB members who are unable to attend a meeting. Alternates may vote for an identified primary member in the primary member's absence. The minutes of the convened meetings will identify when an alternate substitutes for a primary member and votes at the meeting.

Vote Counts and Attendance

Member attendance will be recorded at each meeting and the meeting minutes shall identify any individual who serves as an alternate member for a primary member. The presence of any member "attending" via teleconference will be recorded in the attendance records. Total attendance will be correlated with the vote counts for accuracy.

Any member who has a personal or financial conflict of interest with a study under review must disclose that conflict prior to the discussion of the study. The conflicted person may answer questions about the study, if appropriate, but must leave the room for the final discussion and the vote on the study.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status	Revision Date
Policy No.	Title:	Date of Approval	Approved By
109.01	Delegation of Authority to JHSPH IRB	12/1/08	Janet DiPietro

The Institution Official (IO) has authorized the JHSPH IRB to review human subjects research projects conducted by JHSPH faculty. All faculty must submit for JHSPH IRB review any human subjects research project, regardless of funding source (or lack thereof) and/or location at which the research will be conducted. JHSPH IRB approval or acknowledgement is required before a project may begin.

All human subjects research conducted at JHSPH will be reviewed, prospectively approved, and subject to continuing oversight and review at least annually by the JHSPH IRB, unless determined to be exempt from under JHSPH policy. The review will address all the criteria listed in 45 CFR 46.111 and 21 CFR 56.111: that risks to subjects are minimized through sound research design and are reasonable in relation to anticipated benefits and knowledge gained; that the selection of subjects is equitable such that no population or subpopulation bears an imbalance of the burden of research or enjoys an inequitable share of the benefits; that the informed consent process and documentation plan is appropriate; that the safety of the study is protected by an appropriate plan and monitored by an independent party, if needed; that the privacy of subjects and the confidentiality of study data are protected; and that adequate protections are in place for vulnerable populations. The IRB will evaluate whether resources are adequate to protect participant's rights and welfare.

The JHSPH IRB may approve, approve with specific changes (approved with administrative changes), require modification to secure approval ("table"), or disapprove proposals. JHSPH IRB review and approval of projects and exemption determinations are required BEFORE the research begins. The IRB may suspend, place restrictions upon, or terminate approval of research activities falling within its jurisdiction that are not being conducted in accordance with JHSPH IRB requirements or which have been associated with unexpected adverse events. The IRB may have the consent process, or the research procedures, of any study observed by a third party if the IRB determines that such observation is indicated. The decisions of the IRB shall be conveyed to primary investigators in writing. The primary investigator will notify any sponsors or other interested parties, such as those involved in multi-center studies, as necessary, of IRB decisions. 45 CFR 46.109(d)

An IRB decision to table or disapprove a study must be conveyed to the investigator with an explanation of the reasons for its decision. IRB disapproval must be made at a convened meeting and may not be overruled by any other JHSPH authority. The investigator has the opportunity to respond to that explanation in person or in writing. The IRB's decision, after reviewing the PI's response, is final.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 109.02	Title: IRB Communications to Investigators	Date of Approval 12/1/08	Approved By Janet DiPietro

Approval Notices and Approval Stamp

The JHSPH IRB will provide its approval of a new application, progress report, amendment/addendum or other changes in a study in writing to the principal investigator. An approval notice will be on JHSPH IRB letterhead but does not require signature of the chair. Approved consent forms and approved print advertisements for recruiting research study participants must carry the IRB approval stamp unless the IRB waives this requirement. The IRB approval stamp indicates that the document has been reviewed and approved by the IRB. The stamp is only used on finalized documents.


Disapproval Notices

Disapproval of a research protocol or activities associated with that research will be documented and communicated in writing by means of an IRB Letter of Disapproval, which will be sent to the investigator. The letter must identify what has been disapproved and include the reason that the research was disapproved. All Letters of Disapproval must provide an opportunity for the investigator to address the IRB in person or in writing regarding its action.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 109.03	Title: Complaints from Research Participants, Study Staff, PIs, or the Community	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRBs, as part of the duty to review research applications, will receive and respond to complaints or other communication from research participants, investigators or research staff, or members of the community. These communications may present questions, complaints, or other issues of concern that the IRB must help to resolve. Principal Investigators must report all complaints from subjects or others involved in research to the IRB through the Progress Report or any other appropriate communication.

The Director of the IRB, in consultation with the General Counsels, will make the determination whether the issue raised poses risk to human subjects, what other JHSPH officials should be informed, and what steps should be taken to address the concerns. The Director of the IRB will work with the Institution Official to contact the Principal Investigator for the study and to collect all needed information.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 109.04	Title: Allegations of Undue Influence over the JHSPH IRB	Date of Approval 12/1/08	Approved By Janet DiPietro

JHSPH IRB review processes, and the implementation of JHSPH IRB policies and procedures, are to be conducted objectively and without undue influence over deliberations or processes. IRB members, IRB staff, investigators, or research participants who believe that an attempt has been made to unduly influence IRB decisions, review processes, or application of policies and procedures may contact the Institutional Official (IO) or IRB staff to report a concern. The IO, or JHSPH IRB Director, or other delegated senior staff members will review reports. Outcome of the review will be documented, the complainant provided with a response, and a corrective action plan instituted if deemed necessary.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 109.05	Title: Minor and Administrative Changes to Approved Study Instruments	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB must review all study instruments (survey scripts, questionnaires, interview guides, data collection materials, etc.) before they can be used in a research study. Once approved, the instrument will be stamped (or labeled with the IRB logo) “approved” by the JHSPH staff so that the PI has a record of the approval, but the PI may use an unstamped version in the field. The IRB understands that an approved instrument may need modification once implemented, and will permit the following types of changes to be made without prior IRB review, so long as the PI submits a tracked version of the modified instrument at the time of continuing review:

- Rewording of certain provisions to clarify meaning;
- Correcting grammatical or typographical errors; and
- Removing items, so long as they were not required by the IRB to be included in the instrument.

Modification of this sort will be regarded as “minor and administrative” protocol deviations which may be summarized for the IRB as part of the PI’s Progress Report.

Additions to approved instruments are not considered to be “minor and administrative” protocol changes and must be submitted to the IRB prior to implementation. The IRB will use a “fast track” review process if the changes do not increase the risk to subjects and if the changes do not alter the aims of the study. The fast track process involves review by an experienced IRB member within a few days of submission. Additions that do not qualify for fast track review will be processed in the standard way for review by an IRB. For example, if a study on diabetes involves a questionnaire, and the PI wishes to add a question about smoking status as a risk factor for diabetes, the IRB will employ the fast track process in order to have the submission reviewed within a couple of days. If the questionnaire adds a question about illicit drug use as a risk factor for diabetes, that question adds risk to the subject because there are potential social and legal consequences to the subject if there is a breach of confidentiality. A new question about possession of firearms would not qualify for fast track review because it does not relate to the original aim of the study. More information on the “Fast Track” process is available on the JHSPH IRB website under “Policies and Guidance.”

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 109.06	Title: Continuing Review of IRB Approved Research	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB will comply with 45 CFR 46.109(e) by conducting continuing review of approved research at intervals appropriate to the degree of risk posed by the study, but not less than once per year. The IRB is authorized to conduct the process in accord with federal regulations using either (1) an expedited review process, or (2) a convened review process, as appropriate. This continuing review process is mandatory.

The IRB may approve research for a defined time period of not more than one year minus one day. IRB approval of research automatically expires at the end of the designated approval period determined at the initial review or any subsequent review. In determining how often this review should occur, the JHSPH IRB will consider the risks posed by the study intervention, what type of safety monitoring is provided in the protocol, and any other factors which affect the health and welfare of the study participants. Once the period of approval is established, it will be communicated to the investigator in writing in the approval notification.


The PI of an approved study must submit a Progress Report before IRB approval lapses and with enough time prior to that date to permit adequate IRB review. To allow enough time for review, the IRB recommends submission of progress reports eight weeks prior to the IRB approval lapse date. The Progress Report must contain enough information to allow the IRB to determine whether the research may continue, should be modified, or should be terminated. The IRB may determine that significant new findings regarding the research might relate to participants' willingness to continue taking part in the research. In such cases the IRB has the authority to require provision of such information to participants.

If the IRB has approved consent forms using the new JHSPH IRB template, and the PI has enrolled subjects during the approval period, the PI must submit a copy of a signed consent form (with the participant's name blacked out) with the Progress Report so the IRB can be sure that the correct, approved consent form is being used to enroll participants.

Approval automatically lapses if a Progress Report is not submitted for IRB review prior to the end date of the current approval period. The IRB has the authority to allow continued participation of subjects in research for which IRB approval has lapsed while the continuing review process proceeds if there is an overriding safety concern or

ethical issues exist that indicate it is in the best interest of the participants to continue. In such cases where participants may continue in the research, data analysis must stop until the IRB completes the review process. The IRB does not have the authority to allow new enrollment during the continuing review process after the approval lapse date.

Information submitted by the investigator may include discrepancies or may not be able to be verified by the IRB. In such cases, the IRB may request verification of information from sources other than the investigators, for example, from the Department Chair or from the monitors under the Institutional Official's direction. Verification may be required if the IRB finds inconsistency with data submitted from previous years, determines there is a history of serious non-compliance with continuing review requirements, or believes material changes have occurred since the last IRB approval of a protocol. The IRB may also request verification for any other cause, or may request verification without cause. The IRB has the authority to monitor the data produced by the study, the consent process, and the research itself either through the IRB office or using independent consultants.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 109.07	Title: Lapsed IRB Approvals	Date of Approval 12/1/08	Approved By Janet DiPietro


The JHSPH requires IRB approval before any study activity involving human subjects may begin, and then mandates ongoing review of each study on a timely basis. If the IRB determines that documented informed consent is required, investigators may use only valid, approved consent forms.

The Principal Investigator must submit a progress report within 364 days of the previous IRB approval, unless the IRB has required reporting on a more frequent basis. If the PI fails to submit the progress report on a timely basis, the JHSPH IRB does not have the authority to grant an extension for that submission; the IRB approval for that application will lapse. No study activity may occur after lapse of IRB approval. Any consent forms approved for use in the study will not longer be valid. The PI must submit a new research application through PHIRST.


If IRB approval lapses after the PI submits the progress report, and before it is approved, OHRP and FDA place specific limitations on the conduct of the research. In general, no research activity may occur until the IRB approves the progress report. New enrollment must stop when IRB approval lapses. The IRB, however, may take an action permitting continuation of study activity with enrolled participants under certain limited circumstances.

- OHRP “Guidance on Continuing Review” dated July, 2002: study activity may continue for a brief time if it is in the “best interest” of the study participants.
- FDA’s “Guidance for Institutional Review Boards and Clinical Investigators – 1998 Update” is slightly different, but expresses the same concept: if the investigator is actively pursuing renewal with the IRB and the IRB believes that an over-riding safety concern or ethical issue is involved, the Organization allows the IRB to permit the study to continue for the brief time required to complete the review process.

The PI may request that the JHSPH IRB consider permitting continued study activity pending the outcome of the continuing review. The PI will be notified by the IRB if it determines that the study activity may continue after lapse, and the length of time the activity may continue.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 109.08	Title: IRB Monitoring of Ongoing Research	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB has the authority to monitor ongoing IRB approved research at the institution. “Monitoring” includes auditing study documents, observing the consent process, and evaluating the implementation of all aspects of the IRB approved research plan. The Compliance staff under the Institutional Official’s authority may observe consent processes, observe ongoing research procedures, interview research staff and participants, and evaluate study records as needed.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 110.01	Title: IRB Review of Research Using an Expedited Process	Date of Approval 12/1/08	Approved By Janet DiPietro


The JHSPH IRB may use an expedited review process in accord with DHHS and FDA regulations. Only research that (1) meets the regulatory definition of research involving “no more than minimal risk”, and (2) meets the criteria for one of the nine categories of research listed in the document “Categories Of Research That May Be Reviewed By The Institutional Review Board (IRB) Through An Expedited Review Procedure,” published by DHHS and FDA in the Federal Register, are eligible for an expedited review process. An expedited review process may be conducted for initial new applications, continuing review applications, or proposed minor changes in previously approved research.

An expedited review may be conducted by any member of the IRB whom the Chair determines has the required expertise, experience, and training. Reviews of research involving a drug, biologic, or CAM, must also be performed by the P&T member. The reviewer conducting the expedited review process has the authority to approve or table a study submission, but may not disapprove a submission. New applications, continuing review applications, or proposed changes in already approved research that a reviewer finds may not be approvable must be referred for discussion at an IRB meeting.

Research approved initially through a convened process may reach a stage which qualifies for an expedited review process. This may occur when any of the following are true:


- The IRB determines at a convened meeting that the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects.
- The IRB determines that the remaining research activities are limited to data analysis.
- The IRB determines, and documents in the minutes, that the research involves no greater than minimal risk and no additional risks have been identified.

A list of all actions taken through an expedited review process will be provided to the IRB at a convened meeting. Any member of the IRB may request re-review of research approved using an expedited process. If such a request is made, the project will be scheduled for convened meeting discussion.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.01	Title: Convened Meeting Primary Reviewer System	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB will use a primary reviewer system to execute its convened meeting protocol review responsibilities for new review, continuing review, or amendment review. A primary reviewer will be identified for each study and will be assigned a specific application submission to prepare for presentation at the convened meeting.


The primary reviewer will consider the criteria for approval set forth in DHHS 45 CFR 46.111 and FDA 21 CFR 56.111, as applicable. Documentation of convened review outcome will be part of the JHSPH IRB file.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.02	Title: Payment to Participants	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH allows payment or remuneration to individuals who participate in research projects. The JHSPH IRB is authorized to review the amount and schedule of any proposed payment and to determine that it is fair and not an undue inducement to participate. Remuneration for participation in research should be reasonable and the amount paid should be comparable to other research projects involving similar time, effort, and inconvenience. For studies for which financial remuneration is a major reason for participation, and which represent minimum risk to the participants, the JHSPH IRB may approve remuneration that is sufficient to engage participants. Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn.

The IRB may approve research that includes a proposed bonus for completion and may determine that such payment would not unduly induce participants to stay in the study when they otherwise might have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document. Payment for participation in a trial offered by a sponsor may not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing. Payment for participation may not include a discounted price for the provision of medical treatment.


The IRB will not approve payment using raffles or lotteries or other similar mechanisms because participants will be rewarded unequally.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.04	Title: Recruitment of Students and Employees	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH recognizes the ethical concerns that arise when Johns Hopkins students, postdoctoral fellows, or staff enroll as volunteers in Johns Hopkins research. These concerns relate primarily to the risks of possible undue pressure to enroll and potential loss of confidentiality. Recruitment of students must conform to the Johns Hopkins University “[Policy Governing Recruitment and Enrollment of Students in Research Involving Human Subjects](#)”, and must be approved by the JHSPH IRB.

Recruitment of employees, defined as employees of the University or Health System, must conform to the Johns Hopkins University “[Policy Governing Recruitment and Enrollment of Employees in Research Involving Human Subjects](#)” and must be approved by the JHSPH IRB.

The JHSPH IRB has the authority to grant individual exceptions for studies where there may be therapeutic benefit but greater than minimal risk. Such exceptions are to be submitted for review by the IRB.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.05	Title: Scientific Review	Date of Approval 12/1/08	Approved By Janet DiPietro


The JHSPH requires compliance with [DHHS 45 CFR 46.111\(a\)\(1\)](#) and [FDA 21 CFR 56.111\(a\)\(1\)](#) regarding determinations that an IRB must make when reviewing human subjects research. The JHSPH IRB is required to consider whether risks to participants are minimized, in part, by using procedures consistent with sound research design. The IRB review process will include an assessment of whether the research question asked in a proposed human subjects research project is valid and whether the study design appears to be appropriate. This regulatory requirement does not mean that the IRB will perform a level of review comparable to the NIH peer review process.

Many applications sent to the JHM IRBs have had prior scientific review by one of the following entities:

- NIH Study Section
- FDA Review Committee
- Company Protocol Review Committee, independent of the investigators, for industry-sponsored protocols
- Protocol Review Subcommittee of the GCRC
- Clinical Research Committee of the Sidney Kimmel Comprehensive Cancer Center

The JHSPH IRB may consider such prior reviews to affirm in the review process that the research design is sound.


If outside scientific review has not been done and the reviewing IRB members have the expertise required to review a study, the IRB will be responsible for evaluating whether risks to subjects are minimized using sound scientific design. The reviewing IRB may use an outside consultant to supplement its review. The consultant shall be outside the IRB but may be within the Institution. Prospective consultants may not have any conflicts of interest, personal or financial, with the study, investigator, or sponsor. The consultant's response will be available to the IRB during final deliberations on the study, and the IRB's determinations will be documented in the minutes.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.07	Title: Sample Size	Date of Approval 12/1/08	Approved By Janet DiPietro

Principal Investigators must provide information regarding the number of participants to be enrolled in a research study. This number should be large enough to account for drop-outs, screen failures, or other complications that affect eligibility. Once accrual for the study reaches the number approved by the IRB, enrollment must cease. Enrollment of participants beyond the number of participants in the original, approved research plan is considered non-compliance. The approved sample size is defined as the number of participants who sign the informed consent document, are enrolled using an oral consent process, or are “enrolled” with an IRB approved waiver of consent, as well as individuals who consent to being “screened” for eligibility.

While the anticipated sample size must be appropriate to answer the scientific question, failure to attain the original sample size does not constitute non-compliance. However, based on the magnitude of the under-enrollment, the IRB may ask for information on how this might affect the study’s ability to answer the research question.


An increase to the number of participants approved in the original research plan requires an amendment to the IRB for review before enrolling the additional participants. The JHSPH IRB has the authority to modify the sample size. Enrollment may not continue above the original sample size until the IRB approves the amendment, which may be eligible for an expedited review by the JHSPH IRB.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.08	Title: Vulnerable Populations	Date of Approval 12/1/08	Approved By Janet DiPietro

Research conducted by JHSPH investigators often involves inclusion of populations that are referenced in federal regulations as “vulnerable populations.” The populations noted in DHHS 45 CFR 46 and FDA 21 CFR 56 include the following: children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. FDA regulations also include in the list of vulnerable persons “handicapped” persons. The JHSPH IRB will follow and document the application of specific DHHS and FDA regulations pertaining to criteria required for IRB review and approval of research involving children, prisoners, and pregnant women/human fetuses/neonates. If a project involves children, pregnant women/fetuses/neonates, or prisoners and is not federally funded, the JHSPH IRB will review it under the same criteria as federally funded studies. The IRB will have a prisoner representative present for the discussion of any research involving prisoners.


Federal regulations do not exist that outline specific criteria to be applied by an IRB when a project will enroll adult mentally disabled persons, adult economically or educationally disadvantaged persons, or international participants who may not speak English and who live under different cultural precepts. The JHSPH IRB has the authority to issue and apply guidance for classes of vulnerable populations for which specific regulations do not exist.

For research involving participants who are vulnerable to coercion and undue influence and who are able to give consent, the IRB will permit their inclusion if the population is not specifically targeted as a matter of convenience, and the study recruitment and consent processes provide appropriate safeguards to minimize coercion and undue influence.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.09	Title: Investigators as Study Subjects	Date of Approval 12/1/08	Approved By Janet DiPietro

JHSPH faculty who wish to become involved as experimental participants in their own research projects should consider themselves to be “human participants.” The JHSPH IRB is authorized to review and approve faculty participation. Such review must occur before research procedures begin in an IRB approved study. There are two reasons for the required IRB review of proposed self-experimentation:


- 1) To protect faculty and staff from taking unwarranted risks in the excitement of generating new knowledge. Under these circumstances investigators are enthused about the prospect of new knowledge and concern for any associated risk may be minimized or escape attention; and
- 2) To protect the integrity of the research enterprise.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.10	Title: Minimizing Risks in Human Subjects Research	Date of Approval 12/1/08	Approved By Janet DiPietro

JHSPH research involving human subjects should employ sound research principles and should minimize risks associated with participation. In minimizing risks, the JSHPH IRB will consider physical, psychological, legal, economic and social risks. JHSPH investigators should be aware of the risks associated with study procedures and consider how to minimize risks to subjects by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.

For example:

- Substitute less risky procedures for riskier procedures when possible to answer the study question
- Use the minimum number of procedures to answer the study question
- Enroll of the minimum number of subjects needed to answer the study question
- Modify the inclusion/exclusion criteria to exclude participants who might be at increased risk if they undergo the research procedures, or include participants who might be at less risk if they undergo the research procedures.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.11	Title: Conflict of Interest of IRB Members	Date of Approval 12/1/08	Approved By Janet DiPietro

JHSPH IRB members will not review, participate in the discussion of, or vote upon any research protocol for which they serve as principal investigator or co-investigator, or which is sponsored by a company in which the committee member holds a financial interest, meaning anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). Uncompensated relationships giving rise to a conflict of interest, such as board of directors or other executive service, would similarly disqualify a member. Additional conflicts may include:

- Involvement in the design, conduct, or reporting of the research;
- Involvement of immediate family members in the design, conduct, or reporting of the research; or
- Other involvement in the funding of the research, such as participating in the decision-making about providing grants or other awards to support the research.


IRB members with these types of conflict of interest may provide information about the protocol as requested by the IRB, then shall recuse themselves from the meeting during the discussion and vote on all such studies.

When a member, or a member's spouse, relative or partner, is the Principal Investigator on a study to be reviewed, the conflicted IRB member must leave the room for the IRB's final discussion and vote.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.12	Title: Protecting Participant Privacy and Data Confidentiality	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH must review provisions for protecting the confidentiality of identifiable research data and patient health information as required by 45 CFR 46.111(a)(7) and 21 CFR 56.111(a)(7), HIPAA, and state and local law. The IRB is authorized to ask the investigator to describe plans for protecting subject privacy and data confidentiality. If the study involves situations in which the participant has an expectation of personal privacy, the research plan should clarify how that privacy will be protected. The investigator's plan must preserve the subject's right to choose how and when his or her private information will be used, withheld, or disclosed. The consent process must disclose to participants the potential risks of a breach of the subject's right to privacy and data confidentiality. The IRB may determine additional methods as needed to minimize the risk.

The JHSPH IRB may request that the PI apply for a Certificate of Confidentiality to protect research data from legal process. The PI must obtain the Certificate prior to beginning enrollment unless the IRB approves an alternate plan. When appropriate, the PI also must clarify in the consent document that the PI voluntarily will report any information disclosed by a participant about child abuse or neglect, or threats of harm to self or others.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 111.13	Title: Recruiting Study Subjects	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB will review recruitment plans for research projects to ensure appropriate selection of subjects across age, gender, and ethnicity. To that end, the research application must provide the characteristics of the participant population, anticipated accrual, age ranges, health status, gender, and criteria for inclusion or exclusion. The JHSPH IRB is authorized to review the purposes of the research, the setting of the research, and whether the population to be recruited is appropriate to achieve those purposes under the specified plan. The IRB will evaluate whether the proposed population is vulnerable to coercion or undue influence. Regulatory determinations will be made if a project proposes to recruit pregnant women (45 CFR 46 Subpart B), prisoners (45 CFR 46 Subpart C), or children (45 CFR 46 Subpart D, and 21 CFR 50 Subpart D).

The JHSPH IRB will assess the recruitment plan to ensure that it is compliant with federal regulations as well as HIPAA Privacy Policies, and the institutional policies governing recruitment of students and employees (JHSPH Policy 111.04). The JHSPH IRB prohibits payments to a non-participant in exchange for the referral of a potential participant (“finder’s fees”).

All advertising, letters to potential participants, or other recruitment material must be reviewed and approved by the IRB before they are used. Flyers and other advertising materials must be marked as approved by the IRB before distribution or posting. In certain circumstances, the IRB may agree to the use of those approved documents by the PI without the approval stamp.

When direct advertising is to be used, the IRB must review the information contained in the advertisement and the mode of its communication. The IRB must review the final copy of printed advertisements. The IRB must review and approve the wording of a recorded (video or audio) advertisement prior to recording to preclude the need to re-record because of inappropriate wording. The IRB may subsequently review the final recorded message prepared from IRB-approved text for final approval.

The IRB must review advertising to assure that the advertising:


- Is not unduly coercive and does not promise a certainty of outcomes beyond what is outlined in the consent and the protocol.
- Makes no claims, either explicitly or implicitly, that the drug, biologic, device or other research procedures are safe or effective for the purposes under

investigation, or that the test article or other research procedures are known to be equivalent or superior to any other drug, biologic, device, or procedure.

- Does not use terms such as "new treatment," "new medication" or "new drug" without explaining that the test article or the research procedures are investigational or experimental.
- Does not promise "free medical treatment," when the intent is only to say subjects will not be charged for taking part in the investigation.
- Does not emphasize the payment or the amount to be paid, by such means as larger or bold type, although it may state that subjects will be paid the amount of payment.

Advertisement to recruit subjects should be limited to the information the prospective subjects need to determine their eligibility and interest. When appropriately worded, the following items may be included in advertisements.

1. The name and address of the investigator and/or research facility
2. The condition under study and/or the purpose of the research
3. In summary form, the criteria that will be used to determine eligibility for the study
4. A brief list of participation benefits, if any (e.g., a no-cost health examination)
5. The time or other commitment required of the subjects
6. The location of the research and the person or office to contact for further information.


 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 112.01	Title: Review of IRB Approved Research by Institution Officials	Date of Approval 12/1/08	Approved By Janet DiPietro

Review of IRB approved research may be conducted by senior Institutional officials. :

- Institutional Official (Associate Dean for Research),
- Dean of the JHSPH
- Deans of the JHU Schools at which the approved research is to be conducted,
- President of JHHS, and/or the President of the respective JHHS hospital at which the research is to be conducted
- General Counsels of JHU or JHHS (when research is conducted at a JHHS facility)

These officials have been granted the authority to disapprove JHSPH IRB approved research projects. Such actions will be communicated to the PI, with an explanation of the rationale for disapproval. Communications of institutional disapproval may be provided to the PI in writing, or by e-mail communication.

An action taken by an institutional official to disapprove an IRB approved project is final and no further appeal is possible. The PI of a disapproved research project may submit a new application to the JHSPH IRB that includes modifications to address the reason for Institutional disapproval. Institutional officials may not approve research that has been disapproved by the IRB.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 113.01	Title: Suspension or Termination of IRB Approved Research	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB may suspend or terminate human subjects research projects. The IRB may determine that a project should be suspended or terminated due to: unanticipated problems involving risk to subjects or others under Policy 103.06, serious or continuing non-compliance under Policy 103.07, findings presented in the continuing review process or amendment review process (e.g., new scientific information or a DSMB report), or problems identified in a monitoring process.

The Institutional Official (IO), or an IRB chair, has the authority to suspend or terminate human subjects research when an event occurs and, in his or her judgment, taking such action cannot wait until a convened IRB meeting in order to protect the rights and welfare of participants. An action taken by the IO or an IRB chair to suspend or terminate research will be reported to the reviewing IRB at the next convened meeting.

“Suspension” of research is defined as a temporary or permanent halt to some or all research procedures, short of a termination, until the IRB determines whether the research may recommence (with or without modifications to the research) or whether the research must be terminated.


“Termination” of research means a permanent stop to the research and all research-related activities. In the context of this policy, “termination” means an early stop to the research, short of the “natural” end of the study, for cause.

Suspension or termination of approval shall be documented in a written notice to the PI. The notice of suspension or termination of IRB approved research must include a statement of the reasons for the action. The communication to the PI will offer to the PI an opportunity to respond to the decision. The communication will ask the PI to provide a plan for ensuring that the rights and welfare of all currently enrolled, or previously enrolled (if appropriate), participants are protected.

The IRB will determine and inform the PI of steps to be taken as a result of suspension or termination of the research. Steps could include:

- Notification of currently enrolled participants that the study has been terminated by a written communication approved by the IRB. In this case, communication to participants will explain the rationale for the action taken;
- Withdrawal of participants, considering the rights and welfare of those individuals before such a step is taken;
- Informing the participants of any follow-up procedures permitted or required by the IRB for participant safety; and
- Submission of reports to the IRB and the sponsor of any adverse events/outcomes that occurred during period when suspension or termination occurred.


The IRB must report in writing the suspension or termination to the Institutional Official (IO). Reports to the IO must be sent within 30 days of the IRB's determination to suspend or terminate, or sooner in cases where the rights and welfare of enrolled participants requires immediate attention by the IO and the Institution. The IO will follow JHSPH policy regarding reporting the suspension or termination of a study to federal agencies.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 114.02	Title: Cooperative Research and Multi-Center Studies	Date of Approval 12/1/08	Approved By Janet DiPietro

As part of its responsibility for safeguarding the rights and welfare of human participants in research, the JHSPH IRB has the option of participating in cooperative research projects by entering into joint review arrangements, relying upon the review of another qualified IRB, or making similar arrangements to avoid duplication of IRB effort. The JHSPH IRB will amend its FWA to reflect its reliance upon the review of another qualified IRB for a specific research study.

Communication among sites in a multi-center study promotes participant safety. The JHSPH IRB will ask investigators to specify who is responsible for coordinating communication among the multiple sites, especially communication about human subject protection issues. If Hopkins is not a lead site or coordinating center, the IRB will ask the Hopkins PI to explain how important human subjects protection issues will be communicated to the Hopkins site. When Hopkins serves as the coordinating center, the IRB should confirm that the research plan indicates how the following issues are addressed:

- Central review of each site's local IRB approval documents and consent forms;
- For federally funded research, confirmation that each participating site has on file an FWA with OHRP;
- Method for assuring that all sites have the most current version of the research plan;
- System to confirm that amendments to the protocol will be communicated to all sites;
- Plan for collection and management of data from all sites; and
- Process for reporting and evaluating protocol events and deviations from participating sites.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 115.01	Title: IRB Record Keeping	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB Office shall maintain documentation of all IRB activities in accordance with federal regulations 45 CFR 46.115 and 21 CFR 56.115. The IRB Office shall keep the following records:

1. Copies of all research applications, research plans (and when applicable, federal funding applications) reviewed; and all material and documents submitted with the proposals for IRB review, including:


- Approved sample consent documents
- Progress reports submitted by investigators
- Amendments to approved research
- Reports of injuries, complaints, and other events (whether anticipated or unanticipated)
- Final study reports

2. Minutes of IRB meetings that document discussions and decisions about research under review. A minutes template shall be used to document:

- Attendance at the meeting for each vote
- Conflict of interest determinations
- Device risk determinations
- Drug issues
- Regulatory risk determinations for children, pregnant women/fetuses, and prisoners, or other identified vulnerable populations
- Justification for waiver or alteration of informed consent or documentation of informed consent
- The basis for requiring changes to proposed research, tabling decisions, or disapproval of research
- Discussion of controverted issues and their resolution
- Actions taken by the IRB
- The vote on these actions including the number of members voting for, against, and abstaining

3. Copies of all correspondence between the IRB and investigators, DSMB, and other entities involved in the research or institutional officials (as applicable)
4. A list of all IRB members, both primary members and alternates. The list shall identify the member's name, earned degrees, member category (non-scientist, physician scientist, or other scientist), research experience, experience and expertise applicable to IRB deliberations, and knowledge of or experience working with vulnerable populations. For non-JHSPH affiliated members, affiliation status and whether the member or an immediate family member is affiliated with a division within the Johns Hopkins University or medical institutions. The list should also indicate which members may substitute or alternate for other members.
5. Written JHSPH IRB policies and operations procedures.
6. Statements of significant new findings required to be provided to research participants as required by regulations.

All JHSPH IRB records associated with specific research proposals are retained indefinitely. An off site storage facility shall be used to store archived materials. All records shall be accessible and available for inspection by authorized agency personnel at reasonable times and in a reasonable manner.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 115.02	Title: Record Retention Requirements for Investigators	Date of Approval 12/1/08	Approved By Janet DiPietro

All principal investigators must maintain copies of all research documents in accordance with federal requirements and institutional policies. Principal investigators are responsible for establishing and maintaining procedures to ensure that research records are protected and secure.

The following is a list of requirements regarding the length of time records must be retained for specific types of research:

Institutional Policy

Johns Hopkins University Policy on Access and Retention of Research Data and Materials: Investigators from all divisions of the University must adhere to the Access and Retention policy. The policy can be found at the following website: http://jhuresearch.jhu.edu/Data_Management_Policy.pdf

HIPAA: Since HIPAA entitles participants to an accounting of all uses and disclosures of Protected Health Information (PHI) for six years after their participation in a study is completed, records for all studies that involve PHI from a Johns Hopkins covered entity should be retained for at least seven years. For PHI received from all other covered entities, investigators should check their agreement with the covered entity for any tracking and data retention requirements.

Federal Regulations

Investigational New Drug (IND) Applications: Research records for studies that involve INDs must be retained by the investigator during the study and “for a period of 2 years following the date a marketing application is approved for the drug for the indication of which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.” (21 CFR 312.57)


Investigational Device Exemptions (IDE): Research records for studies that involve IDEs must be retained by the investigator during the study and “for

two years after the latter of the following two dates: the date on which the investigation is terminated or completed, or the date that the records are no longer required for supporting a premarket approval application or a notice of completion of a product development protocol.” (21 CFR 812.140(d)).

The Department of Health and Human Services (DHHS) protection of human subjects regulations (Common Rule) require retention of research records for at least three years after completion of the research (45 CFR 46.115(b)).

Sponsors


Sponsors may require investigators to maintain study records for a specified length of time in the sponsor’s agreement.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 116.01	Title: Informed Consent Process	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB will review the proposed consent process associated with all studies that involve an interaction or intervention with a human subject. Investigators must seek consent under such circumstances that provide the prospective participant with sufficient time and opportunity to consider whether or not to participate. The IRB's evaluation of the investigator's proposed participant selection/recruitment process and informed consent process will include:

- Consideration of the capacity of the participant to make an independent and voluntary informed decision whether or not to participate in a study;
- Review of who will obtain consent, the human subjects research training of that person, and under what circumstances consent will be obtained;
- Determination of how the investigator will assess the understanding of the participant, if appropriate; and
- Deciding whether consent will be documented.


The information to be presented to a potential participant, in a written or oral form, must be understandable to the participant or the participant's legally authorized representative. The informed consent may not include any language which waives, or appears to waive, any of the participant's legal rights, or releases or appears to release the parties to the research from liability for negligence.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status Approved	Revision Date
Policy No. 116.02	Title: Informed Consent Documentation	Date of Approval 10/3/08	Approved By Janet DiPietro

JHSPH investigators may enroll participants in human subjects research activities only after the IRB has approved the study, and when required by the IRB, the investigator obtains the participant's legally effective informed consent. The JHSPH will review both the proposed informed consent process, and the documentation associated with that process.

JHSPH investigators must comply with the informed consent requirements of 45 CFR 46.116 (for DHHS regulated studies) and 21 CFR 50.20 (for FDA regulated studies). Documentation of informed consent will be required, with all the required elements of informed consent and all appropriate additional elements, unless the research activity and it meets the criteria for waiver or alteration of the elements of informed consent. For these studies, the IRB may waive consent entirely or may waive certain of the required elements of consent from the consent document, depending upon what may be required to obtain "legally effective" informed consent from the study population. The IRB may also waive documentation of informed consent under 45 CFR 46.117(c), or 21 CFR 56.109(c) for FDA regulated studies, and permit an oral consent process in appropriate cases.

The JHSPH IRB will post Consent Form Templates with all the required elements of informed consent and will post guidance for investigators explain what is required for research applications. The consent forms used to enroll participants must be marked with a current IRB stamp or logo, unless waived by the IRB

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 116.4	Title: Informed Consent from non-English Speakers	Date of Approval 12/1/08	Approved By Janet DiPietro

Federal regulations require that consent be obtained in a language understandable to the subject. The consent process, and documentation (if applicable), must satisfy this requirement.

Documentation of Informed Consent

If non-English speaking subjects are the target of the research or are expected to be included in a study and informed consent will be documented, the English version of the consent document(s) must be submitted with the research application for review and approval by the JHSPH IRB. When the project is approved, it will be approved “with administrative changes”; the approved English version of the consent will be given to the investigator for translation and for review by the local IRB (if there is one). The local language translation of the consent document, and a Certificate of Translation (see below) must then be submitted to the IRB for administrative review and final approval. Any substantive changes to the English version required by the local IRB must go back to the IRB for review.

A Certificate of Translation (available on the JHSPH IRB website) must be provided to the JHSPH IRB, along with a copy of the local language consent document(s), to attest to the accuracy of the translation of the consent document. The investigator(s) conducting the research may not certify the translation. For international research, the local IRB can certify the translation. Alternatively, a translator fluent in English and the local language may certify the translation.

Study activity may not begin until the JHSPH IRB has formally approved both the English and local language versions of the consent, and has received the Certificate of Translation.

Short Form Documentation of Informed Consent


The short form process and documentation may be used when a non-English speaking individual who meets eligibility criteria wishes to join the study and no consent form has been translated into that person’s native language. Generic short forms are available in Korean, Vietnamese, Arabic, Polish, Chinese, Portuguese, Haitian, Russian, Italian and Spanish on the Johns Hopkins School of Medicine IRB website

(<http://irb.jhmi.edu/Forms/ShortFormTranslation.html>). They may be used for JHSPH research projects.

Oral presentation of consent information should be used together with the *short form consent document*, both of which must be in a language understandable to the subject. The English version of the consent form approved by JHSPH IRB should be used as the script for the consent designee to summarize the study. The short form should confirm that all the elements of informed consent have been presented orally to the subject. The consent process should be witnessed by someone who is fluent in both English and the subject's native language; if the person obtaining consent is assisted by a translator, the translator may serve as the witness. A copy of the short form consent document must be given to each research subject after the consent process is complete.


Oral Consent

If the IRB does not require a signature on a consent document and approves an oral consent process, the PI must submit an Oral Consent Script written in the language that will be used to describe the study to the potential participants. The oral consent script should include all the required elements of consent, as appropriate, and any of the additional elements that are applicable. Signature of the participant and the consent designee are not required, but the PI is responsible for maintaining appropriate study records reflecting enrollment of subjects.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. 116.05	Title: Use of Research Data in Cases of Questionable Consent Documentation	Date of Approval 12/1/08	Approved By Janet DiPietro

Research projects that are conducted over a period of many years may experience problems with study documentation. Changes in study personnel, including change in the PI, may result in confusion about where original consent forms are filed or stored. The JHSPH IRB periodically receives requests from PIs to use data in cases where consent documentation is in question. The JHSPH IRB may consider use of data in these cases only as follows:


1. When data continues to be collected through interaction with participants, or the PI has existing data he/she wishes to use and knows the patient/subject population is still available for contact, the PI must re-consent the participants before continuing to use the existing data or collect additional data. Data from any individuals who do not re-consent when approached must be discarded. Contact with the subjects to ask for re-consent must be through use of an IRB approved document.
2. When data exists and interaction with participants is not possible (either due to relocation of the participants, or participant is lost to follow-up or is deceased), data may be used only if the research record (or the medical record) contains a note that a research consent was obtained and in the case of biospecimens, the IRB approved consent form did not contain an opt out provision for subjects to indicate they did not wish their samples to be used for research purposes. The note in the record must specify who obtained the research consent and the date on which it was obtained. If a note exists in the record, but the consent form approved by the IRB contains an opt-out provision, the data must be discarded, as one could not determine that a subject had or had not restricted future use of their data. If the research record or medical record does not contain a note attesting to consent having been obtained, data must be discarded.
3. Samples and data from pediatric populations represent a unique case. If the consent form is not available to indicate parental permission was granted in writing to obtain a sample/data for research purposes, data/specimens may not be used in the research.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status DRAFT	Revision Date
Policy No. 117.01	Title: Signing the Consent/Assent Document	Date of Approval 12/1/08	Approved By Janet DiPietro


The JHSPH requires that participants must sign and date a research consent form before study intervention or procedures begin unless the reviewing IRB approves and documents exceptions meeting federal regulations. The person obtaining informed consent (consent designee) must sign and date the form at the time and on the date that the participant signs it, unless the consent process approved by the IRB indicates otherwise. The JHSPH IRB does not require a witness signature line, but may allow use of consent forms that have a witness signature line.

For research involving pediatric participants, the IRB must determine whether to require an assent form or assent statement within the parent/guardian consent document. If the IRB determines that a child is old enough and mature enough to sign the consent form as documentation of assent, an assent signature line must be provided on the signature page of the parent/guardian form. For research approved under 45 CFR 46.406, 21 CFR 50.53, 45 CFR 46.407, and 21 CFR 50.54, both parents (when applicable according to the regulations) must sign and date the consent form, and the consent form must have signature lines for each parent. For research approved under 45 CFR 46.404, 21 CFR 50.51, 45 CFR 46.405 or 21 CFR 50.53, the IRB will determine whether the signature of both parents is required or whether the signature of one parent is sufficient. The proper number of signature lines must be provided in accordance with IRB review and approval.

For research involving adults lacking capacity to consent for themselves, the consent form must provide a signature line for the legally authorized representative who will sign and date the consent form on behalf of the adult subject.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. B203	Title: Research Involving Pregnant Women, Human Fetuses, and/or Neonates as Participants	Date of Approval 9/30/08	Approved By Janet DiPietro

The JHSPH will adhere to DHHS regulations regarding additional protections required for research involving pregnant women, fetuses, and neonates. In addition to the other responsibilities assigned to the JHSPH IRB under 45 CFR Part 46 Subpart A, the IRB will determine whether pregnant women may or may not be included in research (45 CFR 46 Subpart B, 46.203), and if so, whether all appropriate safeguards are in place. The required regulatory findings must be documented on a review sheet when the IRB knows that pregnant women or neonates may be included in the research population, the research requires convened review, and the IRB determines that the research procedures are more than minimal risk. The IRB will not make the regulatory findings for minimal risk studies that qualify for review by an expedited process except for studies that specifically target pregnant women. For research that will involve neonates, the IRB must make required regulatory findings and document the determinations on a separate review sheet.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. C304	Title: Research Involving Prisoners as Participants	Date of Approval 12/1/08	Approved By Janet DiPietro

JHSPH, and the JHSPH PI, are “engaged” in research involving prisoners under the following conditions:

1. The JHSPH investigator obtains data through intervention or interaction with a prisoner, or identifiable private information about a prisoner; AND
2. The investigator knows that one or more of the data subjects is a person whose circumstances meets the regulatory definition of “prisoner” under [45 CFR 46.303\(c\)](#).

For the research to “involve” prisoners, the investigator must have actual knowledge of circumstances that would cause a data subject to meet the regulatory definition of “prisoner” under 45 CFR 46.303(c). Investigators are not required to determine prospectively whether each potential subject is, or may become, a prisoner.

For example, if an investigator proposes to perform a chart review of patients who have been treated for a particular disease, it is unlikely that the investigator will know or discover as a result of reviewing charts that one or more of the patients in the cohort is a prisoner. The investigator is not required to seek information about subjects’ prisoner status if such information is not necessary to answer the research question. If, however, the investigator should happen to learn that one or more subjects is actually a prisoner, the protections and requirements of Subpart C will then apply to the research.

For all research involving prisoners, an IRB member who qualifies as a prisoner representative must be present during the presentation, discussion, and vote of any study which involves individuals who meet the regulatory definition of prisoner. For the purposes of human subject research, this definition includes any person who enrolls in a research study, and then becomes a prisoner while in the study. The additional responsibilities for IRB review of prisoner research under 45 CFR 46 Subpart C must be fulfilled. The Subpart C criteria will be considered for all research involving prisoners, regardless of funding source. The JHSPH IRB must make the required determinations when reviewing an application involving prisoner research and will document the determinations required by the regulations noted below along with protocol specific findings justifying those determinations:

1. Whether the research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2);


2. Whether the advantages of participating in this research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such magnitude to impair the participant's ability to weigh the risks of the research against the value of such advantages in the limited choice environment;
3. Whether the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
4. Whether the procedures for the selection of participants within the prison (or other institution) are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners;
5. Whether the information is presented in language that is understandable to the participant population;
6. Whether the JHSPH IRB has adequate assurance that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
7. If the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

If a study is reviewed and approved by the IRB without prisoners as participants, and a participant becomes a prisoner during the study, the PI must inform the JHSPH IRB when the PI becomes aware of the change in status of the participant. The PI must inform the IRB:

- If it is in the subject's best interests to continue on the study as a prisoner, and whether the subject's status as prisoner affects the risks of participation in the study or the potential benefits that might accrue from continued participation;
- If the subject wishes to continue as a study participant, and what the re-consent process will be;
- If there are practical complications of subject continuation in the study,
- If there is any other factor that is important for the JHSPH IRB to consider when determining whether the subject should continue as a participant in the study.

The JHSPH IRB must make the final determination as to whether the subject may continue as a participant. If the Board determines that the participant may continue in the study, the IRB must review the study under the criteria on research involving prisoners, above.

If the IRB approves a study involving prisoners, and it is funded by a federal agency, the protocol will be submitted to the Secretary of the Department of Health and Human Services as required under [45 CFR 46.306](#).

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. D403	Title: Research Involving Children as Participants	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB will follow federal regulations regarding the additional responsibilities assigned to the IRB under DHHS regulations ([45 CFR 46 Subpart D](#)) and FDA regulations ([21 CFR 50 Subpart D](#)), as applicable. These regulations provide additional protections for children who participate in research. For the purpose of applying Subpart D of the federal regulations, children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, and who do not fall within any of the legal exceptions under the applicable law of the jurisdiction in which the research will be conducted..

The JHSPH IRB must review all research covered by Subpart D, and will approve only research that satisfies the conditions of all applicable sections of Subpart D. The IRB must determine that whenever Subpart D applies, consent will be obtained in accordance to the requirements of Subpart D; e.g., from each child subject’s parents or guardians as required, in addition to the child’s assent (when applicable). These findings will be documented on a checklist and in the Minutes for the meeting.

Under DHHS regulations, “guardian” means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care; and under FDA regulations “guardian” means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes of subpart D of this part, a guardian also means an individual who is authorized by law to consent on behalf of a child to participate in research.

The JHSPH IRB may approve research applications that may enroll children in foster care. The IRB and investigators shall follow the procedures developed with the State of Maryland and other local authorities, such as the Baltimore City Department of Social Services, and General Counsels of JHHS and JHU to determine the type of guardianship order that would be required to obtain legally authorized consent for such a child who may be eligible for enrollment. The procedures provide a template for investigators who wish to enroll a child who is considered in foster care in another jurisdiction. The JHSPH will follow the regulatory criteria found in DHHS 45 CFR 46.409 Subpart D and in FDA 21 CFR 50 Subpart D, section 50.56, “Wards.” The IRB is authorized to approve research involving foster children (or wards of the state) that meet the regulatory criteria for involving children in research found at 45 CFR 46.[404](#),

[405](#), and [406](#); as well as 21 CFR 50.[51](#), [52](#), and [53](#). When an IRB determines that a project may be approved under 45 CFR 46.406 and/or 21 CFR 50.53, the IRB may “appoint an advocate for each child who is a ward, in addition to any other individual or entity acting on behalf of the child as guardian or in loco parentis” as a condition of approval in accord with federal regulations.

Under Maryland law, individuals younger than 18 years of age are considered “children” as defined in Federal regulations, unless one of the exceptions listed below applies. In other words, under Maryland law, Subpart D applies to all individuals under 18 years of age, unless the one of following exceptions apply:

A) A person under the age of 18 is married;

B) A person under the age of 18 is the parent of a child; or

C) A person under the age of 18 seeks treatment for one of the following conditions (provided that the research is directly related to one of these conditions and involves minimal risk or involves more than minimal risk and offers the prospect of direct benefit to the subject from the specific treatment):

1. Drug abuse;
2. Alcoholism;
3. Mental or emotional disorder (if age 16 or older);
4. Venereal disease;
5. Pregnancy;
6. Contraception other than sterilization;
7. Physical examination and treatment of injuries from an alleged rape or sexual offense;
8. Physical examination to obtain evidence of an alleged rape or sexual offense; or
9. Initial medical screening and physical examination on and after admission of the person into a detention center.

When research is conducted outside of the State of Maryland, the IRB will consult with the General Counsels for a legal determination about the local jurisdiction’s definition of “children” and “legal guardians.”

Requirements for Assent by Children

“Assent” means agreement – specifically, in this context, a child’s agreement to participate in research. Assent, like consent, is a process that must be documented.

Under [45 CFR 46.408\(a\)](#), if the IRB determines that children are capable of providing assent, the IRB must determine that adequate provisions are made for soliciting their assent. The IRB will additionally consider how assent will be solicited, obtained and documented. In determining whether children are capable of assenting, the IRB takes

into account their ages, maturity, and psychological state. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, then the IRB may determine assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the participants are capable of assenting, the IRB still may waive the assent requirement in accord with [45 CFR 46.116](#).


Documentation of Assent

Under [45 CFR 46.408\(e\)](#), when the IRB determines that assent is required, it shall also determine whether and how assent must be documented. Assent forms are designed similarly to consent forms and should include the purpose, procedures, risks and benefits of participating in a particular research study. The assent should be written at the age level of the children, with jargon and technical terms explained or removed.


For children aged approximately seven and under, the IRB may determine written documentation is not required, but that Investigators must verbally explain the study to the child, including its purpose, procedures, and potential risks and benefits (if appropriate, depending on the child's age, maturity and development). For children ages eight through 17 years, the IRB may require separate written assent from the child, or may allow an affirmative statement in the parental permission form to provide documentation of assent, as follows:

“This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.”

Depending on the study, its procedures, risk and benefits, the IRB may determine that an oral assent process may be conducted and written documentation made in the record that an assent discussion occurred. Assent (written and oral) should be obtained in the presence of a parent or legal guardian.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. FDA 312/812	Title: Clinical Investigations with FDA Test Articles	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB has the authority to review and approve studies involving FDA regulated “test articles.” Test articles may include drugs, botanicals, biologics, gene therapy, and medical devices, as defined under FDA regulations on protection of human subjects ([21 CFR 50](#) and [21 CFR 56](#)), and the Investigational New Drug (IND) and Investigational Device Exemption (IDE) regulations ([21 CFR 312](#) and [21 CFR 812](#)).

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. FDA 50.1	Title: In Vitro Diagnostic Device Research	Date of Approval 12/1/08	Approved By Janet DiPietro

The JHSPH IRB may review studies involving FDA test articles. An IVD study will be reviewed by the JHSPH IRB and not by WIRB, regardless of whether the study has a commercial sponsor, if the study meets the criteria (listed below) for exemption from FDA’s IDE regulations.

In Vitro Diagnostics (IVDs) are reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, to cure, mitigate, treat, or prevent disease. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.

IVDs that are being tested for possible future marketing are devices, and may also be biological products. They are test articles under Food and Drug Administration regulations and are subject to FDA regulations governing investigational devices (IDE regulations). When IVDs are used in research involving human subjects (or human samples), FDA’s regulations for the protection of human subjects (informed consent and IRB review) generally also apply.

IDE Exempt Studies

Studies may be exempt from FDA’s IDE regulations when the research meets all of the following criteria:

- The sponsor has labeled the device properly;
- The testing is non-invasive;
- The testing does not require an invasive sampling procedure that presents significant risk;
- The testing does not by design or intention introduce energy into a participant; and
- The testing is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically-established diagnostic product or procedure.

*Investigators should also be aware that IVD testing performed in the laboratory setting is subject to the requirements of the Clinical Laboratories Improvement Act (“CLIA”). If

an investigator intends to share results of an IVD test with research subjects or their care providers, the IRB must be informed of this fact.

IRB Review

Unlike DHHS regulations, FDA regulations do not provide for exemption from IRB review when research involves existing specimens and the investigator records information without identifiers or linking codes. Nor do FDA regulations define “human subjects” with reference to the identifiability of the subject or of the subject’s private information (i.e., the donors of specimens/samples remain “human subjects” even when the specimens/samples are de-identified). Current FDA guidance indicates that IRB review is required for any IVD study involving human specimens/samples, even when the research involves no identifiers and the biological materials cannot be linked to any identifying information.

Informed Consent

With a few narrow exceptions (emergency and some DOD research), FDA regulations do not permit waiver of consent, even when studies are minimal risk and would meet criteria for waiver of consent under DHHS regulations. Under FDA regulations, informed consent is required for IVD studies involving samples that are identifiable (i.e., are labeled with identifiers or accompanied by the patient’s identifiable clinical information), as well as for studies in which the samples are not identifiable but are coded or linked to identifiable information.

Current FDA guidance (4/25/06), however, indicates that under some circumstances, when samples taken from excess clinical or research specimens cannot be identified (e.g., all linking codes and identifiers have been removed, or the investigator has no access to the code keys or identifying information), the agency will exercise “enforcement discretion” and permit the IRB to approve the study without requiring informed consent of the sample sources.

To be eligible for approval without a requirement for informed consent, FDA indicates that IVD research must meet the following criteria:

- The research must be conducted under an IRB-approved protocol;
- The research must meet criteria for an IDE exemption (see above) [\[1\]](#) ;
- The research must use specimens left over from clinical care, specimen repositories, or other research (i.e., the specimens may not be collected specifically for the proposed research, and no additional specimen may be collected for the purpose of research);
- Individuals caring for the patients are different from and do not share information about the patient with those conducting the investigation*;
- The specimens are provided for research without identifiers (codes are permissible only if neither the investigator nor anyone associated with the study


has access to the code key or can identify the person who was the source of the specimen);

- Any clinical information supplied with the specimen must not be individually identifiable.
- No test results from the research may be reported to any subject or that subject's health care provider; and
- The supplier of the specimens must have established policies and procedures to prevent the release of identifying information.

FDA recommends that the IRB review the policies and procedures that are in place to determine (1) that identifiers will not be released to investigators, and (2) whether there is the potential for test results to be needed for clinical patient management (e.g., FDA suggests that if the research involves a public health threat such as anthrax, it may be necessary to report positive results; therefore informed consent might be required).

*We do not interpret this criterion to exclude investigators who also perform clinical services, provided that the research meets the other criteria established by FDA.

[1] If an IDE is required for an IVD study, informed consent must be obtained unless the study involves planned emergency research and the sponsor has successfully completed the entire regulatory review and community consultation process. See Office of the Commissioner, FDA, "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (DRAFT)" (Sept., 2006).

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. SL1	Title: Adherence to the Hubbard Act	Date of Approval 12/1/08	Approved By Janet DiPietro

The Johns Hopkins University (JHU) acknowledges its obligation to comply with Maryland House Bill No. 917, concerning human participants research and institutional review board (IRB) approval of such research. Therefore, the requester will be able to access minutes for meetings held on and after October 1, 2002.

Individuals who wish to inspect minutes from JHU and Johns Hopkins Health System (JHHS) IRB convened meetings after 10/1/2002 may submit a written request outlining the specific minutes to be inspected. The JHM and JHU interpretation by General Counsels is that the Act is prospective in application and does not apply retrospectively to IRB minutes that existed prior to October 1, 2002. The written request should be submitted as follows:

Johns Hopkins School of Medicine (JHUSOM) and Johns Hopkins Health System (JHHS) IRB Minutes:

JHUSOM and JHHS IRB requests should be submitted to the Assistant Dean for Human Subjects Research Compliance, Reed Hall B-130.


Johns Hopkins School of Public Health IRB Minutes:

JHSPH IRB system requests should be submitted to the Director of the JHSPH IRB Office, E1100 Wolfe Street Building, with a copy to the Associate Dean for Graduate Education and Research, E1152 Wolfe Street Building.

Johns Hopkins University – Homewood Campus IRB Minutes:

Homewood campus IRB system requests should be submitted to the Vice Provost for Research, 265 Garland.

Access for inspection of minutes will be provided within thirty (30) days after receipt of a written request. The Act (under 13-1603 (B)) allows the IRB to redact confidential or privileged information from the minutes; therefore, the individual who requests inspection of minutes will be provided access to only a redacted set. The Act in section 13-1605 states that the minutes maintained by an IRB shall be open to public inspection in the Institution during business hours. Therefore, individuals who inspect the minutes will be allowed to do so in one of the IRB offices during normal business hours. The individual will not be provided with a copy of the minutes, although notes may be produced during inspection. Once the inspection is complete, the individual must return the minutes to the IRB staff. The IRB staff will track requests for inspection of minutes.

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH		JHSPH IRB Policies	
		Document Status FINAL	Revision Date
Policy No. SL2	Title: State of Maryland Mandatory Reporting Requirements	Date of Approval 12/1/08	Approved By Janet DiPietro

JHSPH investigators who collect information about reportable diseases, or who may learn about abuse or neglect of a child or vulnerable adult, must address in their research applications and consent documents their obligation to report to legal authorities. The JHSPH IRB may require disclosure in the consent form of other reports that an investigator may voluntarily choose to make.

I. Reportable Diseases and Conditions

The JHSPH will comply with the State of Maryland mandatory reporting regulations. The list of reportable diseases and conditions is updated periodically and may be found at the Maryland Department of Health and Mental Hygiene (DHMH) web site. The Maryland Epidemiology Disease Control website may be found at <http://edcp.org>. The JHSPH IRB will determine in the review process when compliance is required in association with the conduct of a protocol.

The JHSPH IRB and its PIs must adhere to the requirements associated with Certificates of Confidentiality, when applicable. Information is available at http://grants1.nih.gov/grants/policy/coc/cd_policy.htm for options for addressing local reporting requirements in studies for which a Certificate of Confidentiality is granted.

II. Child or Elder Abuse or Neglect

Under Maryland law, any person, whether or not a “health care provider”, is required to report suspected child abuse or neglect. Health care providers must make these reports in specific oral and written forms. Although licensed providers are obligated to report suspected neglect or abuse of a vulnerable adult, non-provider investigators, who are permitted but not obligated to make such reports for adults, may be precluded from doing so if the reporting involves disclosure of protected health information (HIPAA may restrict disclosure of PHI to reports of adult abuse or neglect to those circumstances under which the report is required by law or the circumstances constitute an emergency.)

III. Threats of Harm

Investigators who are mental health providers licensed under the Health Occupations Article have a statutory duty to warn of a patient’s threats to inflict imminent physical

harm upon specific victims. This duty may be discharged by “reasonable and timely” efforts to inform law enforcement and the identified victims. The statutory language implies but does not specifically require a patient-provider relationship, so it is possible that the duty to warn might be found to extend to certain research settings involving investigators who are mental health providers.