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Office of Human Research Protection
Institutional Review Board

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Jefferson Office of Human Research Protection (JOHRP) Announcement

October 8, 2024

Re: JOHRP Policies and Procedures Manual Summary of Recent Changes for Version Dated 10/1/2024

To keep the research community informed of new and revised JOHRP policies, we are providing a summary of recent changes below.

Changes made throughout the manual:

- Manual moved to a new format
- Grammar and other minor changes for clarity
- References to OHR updated to JOHRP
- 'Subject' changed to 'participants'
- Pronouns and gender binary language updated to gender-neutral terms
- Common Abbreviations table added
- Additional references have been added
- References are linked to their source
- TJU and TJUH have been updated to Jefferson as appropriate
- Legacy Database, Portal, and OHR form references have been updated to the appropriate names corresponding with the current IRB e-system

- Office of Research Administration (ORA) updated to Office of Research Support Services (ORSS)

- Legal Office updated to Enterprise Office of Legal Affairs

- The Senior Compliance Officer's title has been updated to Associate Provost for Research Integrity, Conduct, & Compliance

- The term 'disapprove' has been updated to 'not approve' as appropriate

- For exempt studies and studies designated as no further continuing review (NFCR), an annual check-in form should be completed in the IRB e-system

The following policies were retired:

- Policy GA 108, *Patient Consent for Use of Database Information*

- Policy GA 111, *Reporting Adverse Events Associated with Gene Transfer Clinical Trials*

- Policy GA 117, *Resolution of Conflict Between the IRB and Sponsors*

- Policy GA 123, *Protection of the Confidentiality of Identifiable Data by the Investigator and the IRB*

- Policy SC 502, *Review of Cancer Trials Approved Under NCI Central IRB Independent Review Model*

- Guidance 602, *Reporting Adverse Events and Unanticipated Problems Involving Risks to Subjects or Others – Guidance for Problem Issues*

- Guidance G 617, *Ordering, Distributing, Storing and Inventory of Investigational Devices*

The following policies were re-designated as guidance:

- *Research Device Acquisition, Use, and Tracking*
    - Previously Policy GA 131, now Guidance G 622

- *Human Research Protection Program*

  - Previously Policy GA 132, now Guidance G 623

- *Enrollment of Women and Minorities as Participants in Research*
  - Previously Policy SC 507, now Guidance G 624

No significant changes other than those general changes listed above were noted for the following policies:

- Policy GA 103, *Maintenance of Policies, Procedures, and Internal Forms*
- Policy GA 115, *Management of Research Concerns*
- Policy GA 116, *Use of Students and Employees as Key Personnel and Participants in Clinical Trials*
- Policy GA 118, *Protocol Inclusion/Exclusion Waivers*
- Policy GA 121, *Jefferson Office of Human Research Protection and Institutional Review Board Document Management*
- Policy GA 125, *Investigator Responsibility and Delegation of Responsibility*
- Policy GA 126, *Sponsor Agreements*
- Policy GA 128, *Designation of the Institutional Official Responsible for the Human Research Protection Program*
- Policy OP 201, *Institutional Review Board Membership*
- Policy OP 203, *Institutional Review Board Consultants*
- Policy RR 402, *Continuing Review by Convened Institutional Review Board*
- Policy RR 403, *Exempt Studies*
- Policy RR 408, *Review of Amendments*
- Policy RR 413, *Review of Research Involving Investigational Drugs and Devices*
- Policy RR 414, *Institutional Conflicts of Interest*

- Policy SC 501, *Determining Whether a Device Study Involves a Significant Risk or Nonsignificant Risk*
- Policy SC 503, *Review and Approval of a Humanitarian Device Exemption*
- Guidance G 601, *Definition of Key Personnel in Human Subjects Research*
- Guidance G 616, *Independent Monitoring of Investigator-Initiated Clinical Trials*
- Policy IC 705, *Informed Consent – Non-English-Speaking Participants*

Please see the tables below for a summary of recent changes per individual policies.

Policy Number	Title
GA 101	The Authority and Purpose of the Institutional Review Board
Changes:	
• The statement regarding checking COI in the pre-review process was moved to Policy GA 106.	

Policy Number	Title
GA 102	Activities Requiring Institutional Review Board Approval
Changes:	
• Statement added that for the purposes of this policy 'approval' includes exempt determinations • For activities considered exempt from IRB review, the policy manual now refers to the FDA regulation for the research categories of exemption determination. • Additional statement that a PI can use available JOHRP checklists to determine if a research activity is not IRB-regulated, but consultation with JOHRP is encouraged if there is a question of edge cases • The following was removed from examples of human subjects research that may begin only after receiving IRB approval or exempt determination, "One time emergency uses of an investigational drug or device may proceed without prospective IRB review.	

Any subsequent use of the test article must have prior review by the full IRB. See OHR Policy GA 112."

- "Single-case emergency uses of an investigational drug or device may proceed without prospective IRB review. See OHR Policy GA 112, *Emergency Use of an Investigational Drug, Biologic, or Medical Device*" was added

- "The IRB e-system is configured to automatically generate reminder notifications of approaching study expiration. Notifications are sent to investigators and/or study staff. This is a courtesy reminder, and it is the PI's responsibility to submit renewal." was added

Policy Number	Title
GA 105	Use of a Single Institutional Review Board in Multi-Site Research Studies

Changes:

- References to NIH policies added in regard to which research must be reviewed under an sIRB

Policy Number	Title
GA 106	Conflicts of Interest

Changes:

- Reference to COI-SMART have been updated to the generic term of COI-reporting system

- Removal of the prohibition of 'employees in the Jefferson Office of Technology Transfer and Business Development' from serving as member of the IRB

- The statement regarding checking COI in the pre-review process was moved to this policy from Policy GA 101

- "Subcommittee reviewers will consider management plans as part of their review." was added

- "Individuals who will be performing IRB activities outside of a convened meeting must notify the Director/Associate Director, OHR of any COI." was removed

- Subcommittee reviewers have been added as those part of the IRB that will determine if a COI must be disclosed in the consent form
- Examples added for what is and isn't an IRB member COI
- This policy has been updated to state that this policy will be available to all IRB member on the JOHRP website in lieu of being distributed annually

Policy Number	Title
GA 109	Roles and Responsibilities of Study Personnel and Department Chairs

Changes:

- Department Chair designees have been added as responsible parties to this policy
- Delegated responsibilities should be documented in a delegation of authority log kept in the study binder was added
- The statement regarding a site of study performance that is not a part of Jefferson and its Divisions was removed
- Further explanation provided that at least one (1) Co-I is required for all interventional human subjects research 'to assume the responsibility for care of participants if PI is unavailable"
- Additional statement added that, in general, any interventional research and all greater than minimal risk studies require a free-standing written protocol
- Change in PI requires an amendment to the master application to be submitted
- Those responsible for reporting of noncompliance now include investigators, department chairs, and/or study staff
- "Investigators may not attend IRB meetings without a specific invitation" was added
- Definition of PI is updated to "the primary responsible agent for a research study"
- For the purposes of this policy, TJU faculty is defined as TJU employees, including those employed by a TJU controlled affiliate, that have a TJU faculty appointment, or individuals holding a TJU volunteer, adjunct, or emeritus appointment

- Jefferson employees of colleges and hospitals with appropriate training and expertise may serve as a PI
- In general, residents, clinical fellows, post-doctoral fellows, and students would not serve as PI
- Co-I now defined as, in general, someone who by licensure/degree can assume oversight of the study in the absence of the PI
- Definition of study coordinator has been removed

Policy Number	Title
GA 110	Signatory Authority

Changes:

- The Director of JOHRP may designate signatory authority to appropriate individuals as necessary
- Results of reviews and actions taken by the IRB no longer require signature of the Director or Associate Director of JOHRP or JOHRP administrative staff

Policy Number	Title
GA 112	Emergent Use of an Investigational Drug, Biologic, or Medical Device

Changes:

- The purpose of this policy now references the FDA's expanded access program
- Definition of Emergency Use updated to match regulations
- For the purposes of this policy emergency and emergent use are used interchangeably.
- Expanded Access definition added
- Definition of Life Threatening has been updated to match regulations

- Removal of the statement regarding HHS regulations regarding non-exempt human subjects research
- The physician or their designee should contact JOHRP as soon as possible when considering emergent use
- The term 'Emergency IND' has been updated to 'single patient IND (SPIND)'
- Removal of sentences regarding a manufacturer's requirement for an IRB approval letter before releasing a test article
- Statement added regarding FDA's stance on waiver of prospective IRB review for SPIND
- The statement regarding shipment of unapproved devices was removed
- The information required to be submitted to JOHRP and JOHRP's procedures to follow the emergent use of a test article clarified
- The statement regarding obtaining consent and exceptions to obtaining prior consent was added
- The statement regarding the restriction of use of additional doses of a test article was removed
- An alternate regulatory review route described for the recurrent use of a test article under emergent conditions

Policy Number	Title
GA 113	Institutional Review Board Reporting of Findings and Actions to Investigators
Changes:	
• Sections were added regarding Administrative Termination and Administrative Withdrawal of studies.	

Policy Number	Title
GA 120	Reporting and Reviewing Unanticipated Problems Involving Risks to Participants or Others

Changes:

- Quote in the purpose section from the regulations has been updated to match current relevant regulation language
- "Emergency room visits lasting more than 24 hours" was removed from the list of criteria that could make an AE serious
- Grade 3 AE defined to include severe or medically significant AEs
- 'Probably' added as a designation that is considered a related event
- An action that may be taken by JOHRP in response to SAEs and UAPs changed from 'monitoring' to 'auditing'
- "Often, the log of protocol deviations/violations is maintained separately from the other UAPS." was removed
- The clarification that generally external reports do not need to be submitted to the IRB in an expedited manner
- The table of Timeframes for AE, SAE, and UAP Reporting has been updated and information previously captured in the table is now captured in the text of the policy

Policy Number	Title
GA 124	Good Clinical Practice for Investigators

Changes:

- Text has been updated to match ICH E6 (R2)
- "While not required by GCP, per Jefferson policy, a written agreement (e.g. professional services agreement) between Jefferson and the external individual/party should be entered into that includes the services to be provided and the qualifications of the individual/party. Contact the Office of Research Support Services (ORSS) for assistance." was added
- "While not required by GCP, it is general good practice that if a participant withdraws from a trial, the investigator should take all reasonable steps to ensure the participant's safety such as appropriate discontinuation of study medications" was added

- "While not required by GCP, per Jefferson policy, the signed and dated informed consent form will be made part of the subject's electronic medical records along with any informed consent form updates and amendments" was added

- "While not required by GCP, documents should be retained to ensure researchers can validate findings and defend against any research misconduct allegations. See Jefferson Policy No. 110.02 Responding to Alleged Misconduct in Research discussing the six (6) year statute of limitations" was added

- Attachment A has been updated and reformatted

Policy Number	Title
GA 127	Participant Screening and Enrollment

Changes:

- Regarding Jefferson researchers contacting patients in the Jefferson EMR, the following statement was added, "The individual contacting the patient should use wording on the availability of the study rather than referring to the patient as having a particular diagnosis. Depending on the sensitivity of the research topic, it may benefit the researcher if they first contact the practice from which the patients are being drawn."

Policy Number	Title
GA 129	Protection of Privacy Interests of Research Participants and Confidentiality of Participant Data

Changes:

- The definition of confidentiality has been updated

- "Each research participant participating in human subjects research must be provided with a HIPAA Informed Consent Form or a study informed consent form that includes the HIPAA requirements." was added

- "Under the Privacy Rule, an investigator may: conduct chart or record reviews; acquire clinical data; analyze data; disclose/communicate data to co-investigator(s); report data to a multi-site data center; publish PHI" was removed

- The condition of information only collected in preparation to research for an investigator to be permitted to access, use, and disclose PHI for research purposes was removed

- "An IRB approval letter for the study will always be issued simultaneously with a HIPAA waiver letter." was removed

- "The criteria for waiver of authorization for recruiting purposes under the Privacy Rule are essentially the same as for waiver of informed consent under 45 CFR Part 46.116 (i.e., minimal risk to privacy compared to minimal risk to the subject). If a treating physician wishes to share PHI with an investigator for enrollment purposes, the Investigator must obtain an authorization from the patient or a waiver of authorization from the IRB." was removed

- Research staff should also obtain permission before searching medical records and/or databases to which they ordinarily would not have clinical access and a list from the FDA as to what to consider during the recruiting process was added

- "If an investigator wishes to view potential subjects' PHI in the course of preparing for research, s/he must provide the IRB with a Review Preparatory to Research Request Form (OHR-29)" was removed

- A DUA secured with the Enterprise Office of Legal Affairs is required for the use and disclosure of de-identified data outside of Jefferson

- "Research conducted exclusively with decedent data and/or tissue does not qualify as human subjects research and does not require IRB review." was added

- Section regarding collection of PHI from specimens and tissue samples was removed

- "Research staff must not search medical records to which they ordinarily would not have clinical access; this constitutes a breach of privacy as well as confidentiality of the patient's medical record. Similar concerns arise with any search of a database conducted to identify potential participants." was removed

- The list of what the IRB may consider for relevant privacy issues has been removed.

- The following sections were deleted: Privacy and Confidentiality Issues During Waiver of Documentation of Informed Consent; Confidentiality of Information During IRB Review; and Confidentiality Issues within OHR.

Policy Number	Title
GA 133	Human Subjects Research Training
Changes:	
• Suitability of non-CITI training will be determined by JOHRP staff.	

Policy Number	Title
OP 202	Recruiting, Appointing, and Performance Evaluation of Institutional Review Board Members, Chairs, and Vice Chairs
Changes:	
• Individual IRB member performance will be additionally assessed on oral presentation skills	

Policy Number	Title
OP 204	Institutional Review Board Review of Protocols
Changes:	
• "Jefferson has three (3) separate IRBs which for ease of reference are referred to throughout the policy manual as the IRB." was added • Relevant review documents will be available to IRB members in the IRB e-system or will be sent via email one (1) week prior.	

Policy Number	Title
OP 205	Institutional Review Board Member Responsibilities
Changes:	
• The preference that individuals remain IRB members for at least three (3) years has been removed	

Policy Number	Title
OP 206	Institutional Review Board Meeting Administration
Changes:	

- Copies of federal or other grant applications was removed from the list of additional items primary reviewers are to receive

- The section regarding Telephone Use for IRB meetings has been removed

Policy Number	Title
QA 301	Quality Assurance Program

Changes:

- The purpose of the QA program further expanded to include supporting study teams 'regarding policy, regulations, ethical principles, and GCP' and to 'ensure the rights of human subjects and data integrity are protected'

- Additional criteria for audit selection added, 'IND/IDE's held by Jefferson employees'

- The statement regarding For Cause Audits was updated to 'for cause audits are generated based on report or request reflecting significant concern regarding study activities, such as termination or suspensions, noncompliance, or UAPs'

- The report previously defined as a corrective action plan (CAP) will now be defined as an audit report

- "Audits are conducted by the Quality Assurance Program at the direction of legal counsel and should not be shared externally." was added

- A corrective and preventative action (CAPA) plan section was added

- Audits of IRB Processes and Documentation section was added

- The responsibilities of the Quality Assurance Program have been updated

Policy Number	Title
QA 303	Inspections or Audits by External Entities

Changes:

- "Sponsors or funding agencies of research may also have authority to audit research sites." was added

- "The principal investigator, Director, OHR, and the OHR administrative staff designated to participate in the audit are required to follow the following steps in preparing the site for an audit." was removed

- "Please notify JOHRP as soon as possible if there is advanced knowledge of an inspection." was added

- "Copies of the FDA 482 should be made for retention at the site and sent to JOHRP. For site audits, the research team should ensure that the consent form correctly identifies the auditing agency as a party that will have access to PHI." was added

- The statement regarding documents to be taken off-site by authorized personnel during an inspection/audit has been updated.

- "Daily audit/inspection updates should be sent to the Quality Assurance Program of JOHRP for all studies and to the Quality Assurance & Education group of SKCCC for oncology studies. These updates should include questions asked by the auditor/inspector, who was interviewed, which documents were requested, and any other pertinent information." was added

- "The Legal Reports of the audit, either verbal or written and directed to the operations of the IRBs should be addressed to the Director, OHR, as soon as possible. If the Principal Investigator is unsure whether a response is required or preferred, the Principal Investigator should contact the Director, OHR and the Legal Office. For an FDA audit the Director, OHR, should request a FDA form 483 from the auditor at the completion of the exit interview." was removed

- "All OAI reports should be submitted immediately to JOHRP for review prior to submitting response to the auditing agency." was added

Policy Number	Title
QA 304	Study Team Training

Changes:

- "The Investigator must ensure that all key personnel are knowledgeable about all protocol specific regulatory requirements for ongoing study protocols, study procedures and investigational products. Investigators and other key personnel should attend periodic workshops and seminars to acquire timely information about topics germane to the field of human subject investigations." was removed

- Regarding documentation of training, "the content of training should be maintained in the study records." was added

Policy Number	Title
QA 305	Verification by Outside Sources that No Material Changes have been made to an Institutional Review Board Approved Protocol

Changes:

- "Audits conducted by the Quality Assurance Program are at the direction of legal counsel and should not be shared externally." was added

Policy Number	Title
RR 401	Initial Review – Criteria for Institutional Review Board Review and Approval

Changes:

- The Criteria for Initial IRB Approval for Research has been updated.
- 'Impartial' has been added to witness for oral presentations of the consent using the short form process.
- The Criteria for what the IRB determines when the short form is used when following FDA regulations has been removed.
- "When a participant withdraws from a study, if any specimens are collected, the participant may have the option to request that specimens be destroyed on a per study basis." was added
- Additional statements have been added and the current statement has been updated in the Waiver or alteration of the consent process/parental permission section.
- The section regarding following HHS regulations has been removed.
- Statements regarding SKCCC processes have been removed.
- Additional statement and list regarding DoD supported research has been removed.

Policy Number	Title
RR 404	Expedited Review of New and Continuing Research
Changes:	
• "A research activity may be disapproved only after full board review." was added	

Policy Number	Title
RR 407	Suspension or Termination of Human Subjects Research
Changes:	
• Regarding notification of suspensions and terminations, the IRB will also communicate "any study-related processes that may continue" • "All termination or suspensions will be reported according to University Policy 110.15, Institutional Review Board of Noncompliance Issues." was removed	

Policy Number	Title
RR 409	Study Completion
Changes:	
• "For a completed chart or film review, the IRB requires a Final Report within 30 days of completion of the study." was removed	

Policy Number	Title
RR 410	Review of Advertisements
Changes:	
• When describing payment for participation in advertisements, examples for inappropriately emphasize payment for participant, "no money amounts, inappropriate words" was replaced with "inappropriate use of dollar symbols, large font, etc."	

Policy Number	Title
RR 412	Recruitment, Enrollment, and Participant Payment
Changes:	

- The Criteria Applicable to Recruiting Subjects from another Health Care Provider section has been removed.

- Addition of the following to the list of information advertisements should be limited to, 'Amount and frequency of payment' and 'appropriate graphics'

- "A subject may be provided with test article free of charge or continue to be provided with an effective test article after leaving the study, but this should not be considered as payment. Free or discounted test article should not steer a subject toward a specific test article, e.g. only be offered for one of the test articles under investigation. Free or discounted test article, once approved, should not be offered as this may imply that approval is guaranteed." was removed

- The section regarding Lotteries and Raffles has been added.

Policy Number	Title
RR 415	Undergraduate Research

Changes:

- The OHR-35, Checklist for Undergraduate Research Study, will act as a decision tool for faculty when determining whether the project will need formal IRB review.

Policy Number	Title
SC 504	Populations Requiring Special Consideration (Pregnant Persons, Prisoners, Children)

Changes:

- "Women of childbearing potential should not be included in a trial if teratogenicity (malformation of development) is likely, since the risk of malformation of the fetus far outweighs any societal benefit. The IRB should also review and consider any possible teratogenic effect on the fetus due to involvement of a male subject. The investigator's brochure will be reviewed for relevant reproductive risks from animal studies." was removed

- Consent requirements for studies of pregnant persons and fetuses, neonates, and children have been revised for brevity and clarity.

- Definitions regarding prisoners and parolees have been updated.

- IRB considerations for prisoner enrollment in a study not approved as a prisoner study has been removed.

- A link to the Subpart C Certification Form has been added and the criteria to be included in that form has been removed.

Policy Number	Title
SC 508	Pennsylvania and New Jersey Reporting Requirements
Changes:	
• New Jersey reporting requirements added	

Policy Number	Title
SC 509	International Research
Changes:	
• Jefferson cannot rely solely on a local IRB for federally funded international studies. • "Moreover, while Jefferson researchers should respect local custom, they must adhere to the principles of the Belmont Report and the Common Rule. If these standards cannot be met in the given circumstances, the participant should not be enrolled." was added	

Guidance Number	Title
G 607	Certificates of Confidentiality
Changes:	
• "Once a subject enrolled in a study in which a certificate of confidentiality is in place, the protection afforded by the certificate is permanent and information identifying that subject will never be disclosed unless it is volunteered by the subject or the investigator for certain urgent issues, or it expires." was removed	

Guidance Number	Title
G 608	Socio-Behavioral Research and Deception in Research

Changes:
• Pedagogy has been added as an area of socio-behavioral research • "And while socio-behavioral studies often do not benefit the participant, they may benefit society at large." was added • Harms and their associated risks have been organized into a table. • "(Deception is not specifically addressed in federal regulation.) Any research involving deception also must be approved by an IRB prior to initiation." Was added

Guidance Number	Title
G 610	Burden of Research Interventions
Changes:	
• 'Quality of Life Issues' updated to 'Burden of Research Interventions' • "Investigators may underestimate the impact of study assessments and procedures on participants." was added	

Guidance Number	Title
G 615	Institutional Review Board Fees
Changes:	
• IRB fees are not assessed for federally funded studies, 'unless Jefferson IRB serves as single IRB for funded, multi-site study'	

Guidance Number	Title
G 618	HIPAA and Activities Preparatory to Research
Changes:	
• Definition of 'covered entity' has been updated • References to IDX Custom Request Forms has been replaced with up-to-date information	

Guidance Number	Title
G 619	Radioactive Materials

Changes:

- Definitions added per 21 CFR 310.3(n) and 21 CFR 600.3(ee)
- New Jersey added as an 'Agreement State'
- "The regulatory authority in New Jersey for licensing and regulating byproduct, source, and certain special nuclear radioactive material users is the New Jersey Department of Environmental Protection, Bureau of Environmental Radiation." was added
- Criterion for RSC (or RSO) approval has been updated
- "As with employees and the general public, radiation dose to research subjects is required to be 'as low as reasonably achievable" (ALARA). Specifically, radiation doses administered should be the minimum necessary to achieve the desired research objectives. For imaging studies performed on human research subjects, as with patients, radiation doses should be optimized such that the lowest radiation dose necessary to produce adequate quality images is utilized." was removed
- Contact information for RSO has been removed.

Guidance Number	Title
G 620	Department of Defense Requirements for the Conduct of Human Subjects Research

Changes:

- This policy is being withheld from publications for further updating

Guidance Number	Title
G 621	Safeguarding and Protection of Children in Research Studies

Changes:

- "Research implemented by Jefferson will involve children, the consent form for the research will detail any potential risks to a child due to the study intervention. Furthermore, the consent, a copy of which will be given to the parents/guardians of

participating children, will include contact information for the Principal Investigator and the Office of Human Research (OHR) to facilitate the communication of child safety concerns." was removed

- Statement regarding ensuring CITI training is completed for those doing research on children was removed
- "Researchers should be aware that New Jersey state law includes different requirements. For both Pennsylvania and New Jersey, researchers should work with Jefferson Human Resources to ensure compliance" was added
- "All Jefferson researchers must adhere to HIPAA standards and applicable international standards when collecting and storing confidential research data" was removed
- "Researchers should request copies of any relevant court documents and include these documents in the research file(s)" was added
- Jefferson Alert Line information was updated
- The following statements were removed, "Any student, faculty, employees, or contracted personnel, consultants, contractors, or volunteers engaged in the research undertaken by Jefferson shall not have sexual relations involving anyone under the age of 18 years old who is involved in the research. Neither should such individuals associated with Jefferson engage in sexual relations with any young person that is 18 to 25 years of age and is connected with research involving Jefferson (with a rare exception being marriage to such an individual in this age group)" and "Students, faculty, employees or contracted personnel, consultants, contractors, or volunteers engaged in the research undertaken by Jefferson are always expected to behave in a manner consistent with a commitment to promoting the safety and well-being of children."

Policy Number	Title
IC 701	Informed Consent and HIPAA Authorization: General Requirements
Changes:	

- "The study team must ensure (e.g. by the use of version date/number) the version approved by the IRB is identical to the version given to the participants" was added

- The following statements have been removed, "Document that are not easily stamped or copied (e.g. electronic documents, laminated materials and booklets provided by the sponsor): If a paper version is made for submission purposes and approved, it will be stamped by the IRB. The actual versions given to the subjects will not be individually stamped. However, the study teams must ensure (e.g. by the use of version date/number) that the version approved by the IRB is identical to the version given to the subjects. The approval and expiration dates appear on the first page of the document. The expiration date appears on the signature page(s). Except where necessary to eliminate apparent immediate hazards to the human subjects, no research related activities may occur after midnight on the date of expiration."

- The following statement was added that informed consent is more than just obtaining proper signatures

- A statement involving exculpatory language was added

- The statement regarding inclusion of reasonably foreseeable risks or discomforts has been updated

- The statement regarding the description of any potential benefits has been further clarified. Note that the FDA prohibits the overstatement of benefit and identifying payments and reimbursements as benefits

- A statement has been added to the required element of consent that an explanation of whom to contact for answers to pertinent questions about the research

- A statement has been added to the element of consent regarding stating that participation is voluntary

Policy Number	Title
IC 702	Documentation, Waiver, and Alteration of Informed Consent
Changes:	
• "A witness, independent of the study, must be present for the entire consent discussion and must sign to verify the participant's consent." was added regarding participants physically unable to sign a consent form	

Policy Number	Title
IC 704	Child Assent and Parental Permission for Participation in Research

Changes:
• The definition of children under New Jersey law has been added • Additional information regarding the definition of a guardian has been added

Policy Number	Title
IC 706	Waiver and Alteration of Informed Consent and HIPAA Authorization
Changes:	
• A statement was added that while exempt studies are exempt from the Common Rule they still need determinations to be made regarding HIPAA	

Policy Number	Title
IC 707	Surrogate Consent
Changes:	
• Definitions of Types of LARs have been added. • The procedures sections has been amended to include the following: Adults are presumed competent to consent unless legally judged to be incompetent; minors are assumed to not be competent to consent for themselves; cognitively impaired individuals are considered a vulnerable population as their mental disability may compromise their decision making capacity and thus their capacity to provide their own informed consent for research; federal regulations and state laws permit the use of LARs via surrogate consents for those who are cognitively impaired under certain circumstances; please review the National Bioethics Advisory Commission report when considering research involving this vulnerable population; who can serve as a surrogate in the consent process can be found in the surrogate section of the informed consent template; PA and NJ law is cited for additional information regarding guardians and health care power of attorney. • "The circumstances surrounding the use of the surrogate and the surrogate's relationship to the participant should be thoroughly documented in the research record" was added	

Policy Number	Title

IC 708	Planned Research in Emergency Settings
Changes:	
• "If the IRB makes this determination and the Principal Investigator (PI) is the sponsor of the IND, the PI must promptly disclose this information to the FDA" was added	

Policy Number	Title
IC 709	Treatment and Cost of Research Related Injury
Changes:	
• "If the IRB makes this determination and the Principal Investigator (PI) is the sponsor of the IND, the PI must promptly disclose this information to the FDA" was added • Highlights of Sponsor responsibilities has been removed	