WAYNE STATE UNIVERSITY

HIC Policy/ Procedure/ Guidance

Wayne State University Human Investigation Committee	
SUBJECT	Use of the National Cancer Institute's Central Institutional Review Board Initiative
Section	
Form Date	09/01/09
Approvals	Administrative, 9/22/2009

Background

The Wayne State University Human Research Protection Program ensures the safe and ethical conduct of all human participant research conducted at Wayne State University and its affiliated institutions. The HRPP designates the Human Investigation Committee as the Institutional Review Board required by federal regulations to review and approve human participant research.

WSU has recently enrolled in the National Cancer Institute Central Institutional Review Board (CIRB) Initiative, designed to partner the central and local IRBs' efforts to provide human participant protection for clinical cancer research in national, multi-centered, federally sponsored Cooperative Group treatment trials, and to create a more efficient and streamlined review, approval and monitoring process. The impact of this should be to improve access to trials for potential study participants and their physicians, as well as to reduce the administrative burden on the HIC and research staff. The CIRB's primary responsibility is initial and continuing review of these research studies. The local IRB's primary responsibility is consideration of their local context and oversight of their local performance.

The FDA and OHRP, the primary regulatory bodies overseeing human subject protection programs, have supported the CIRB's model of central and local cooperative review and both the CIRB and the WSU's HIC are committed to maintaining the rigorous requirements of their regulations.

This document sets out WSU policies for the use of the CIRB Initiative and summarizes the HIC responsibilities within the Initiative. The document also gives details of the HIC's process for meeting its responsibilities in reviewing WSU Investigators' requests to use CIRB approved studies and in monitoring the performance of these studies at WSU. Investigators and Coordinators are invited to give constructive feedback on the operation of this process in the interests of continuing improvement.

Policy

- The HIC may authorize the use of NCI-sponsored Cooperative Group research studies approved through the NCI CIRB in which WSU and its affiliated institutions wish to participate.

  Research studies currently reviewed and approved by the Central IRB are Phase 3 adult trials coordinated by the NCI Clinical Trials Cooperative Groups (ACOSOG, CALGB, ECOG, GOG, NCCTG, NCIC, NSABP, RTOG, and SWOG), as well as any other Phase 3 studies opened in the Cancer Trials Support Unit (CTSU), together with pediatric COG Phase 2, Phase 3, and Pilot Studies.

- The HIC will conduct a Facilitated Review of CIRB reviewed and approved studies and will decide on a study-by-study basis whether to authorize the CIRB review and approval or to require Full Board review by the HIC.

- Once HIC has accepted Facilitated Review for a study, the HIC will recognize the CIRB as the IRB of Record for the research study conducted at WSU and its affiliated institutions.

- All the responsibilities identified for local IRBs in the CIRB initiative will be met and duplication of effort between the HIC and the CIRB will be eliminated as far as is consistent with comprehensive protection of human participant safety and welfare.

- The HIC will retain certain responsibilities for local oversight and review of the research in order to comply with WSU requirements, and all pertinent federal, state and local laws and regulations.

- Standard WSU policies will apply for disclosing significant financial conflicts of interest. Regulatory review and approval will also be conducted by the WSU Bio-safety Officer and Radiation Safety Officer as necessary.

- The HIC reserves the right to withdraw, suspend or restrict its acceptance of Facilitated Review for a CIRB reviewed and approved research study being conducted at WSU and its affiliated institutions.

WSU HIC responsibilities

The CIRB defines the prime responsibility of the HIC as the local institution in this partnership as ‘ensuring the safe and appropriate performance of the research at WSU and its affiliated institutions. This includes, but is not limited to,

- monitoring protocol compliance
- managing any major protocol violations
- managing any serious adverse events occurring at the institution
- ensuring qualifications of research staff
- providing a mechanism by which complaints about the research can be made by local study participants or others’.

The HIC also has a number of administrative responsibilities such as developing procedures, maintaining records and providing contact information. The HIC will continue to maintain its regulatory responsibilities to the OHRP and FDA, as well as to ensure compliance with Michigan, local and institutional requirements.

The CIRB also provides information on a number of specific responsibilities of the local institution in relation to HIPAA, Informed Consent and Assent, and the reporting of unanticipated problems and serious adverse events, as well as participation by prisoners and individuals with impaired decision making capacity. These have been incorporated into the HIC Facilitated Review process and procedures described below, and the guidelines which follow.

The HIC Facilitated Review Process

The HIC Facilitated Review process is designed to simplify and streamline local review and approval of CIRB approved research studies, to minimize the administrative burden on researchers and the HIC and to expedite implementation of research studies at WSU and its affiliated institutions.

It is also HIC's intention to simplify the post-approval processes of amendments, changes to key personnel, continuations, reporting unexpected problems and serious adverse events, and closures, to reflect the division of responsibilities between the CIRB and the HIC and to ensure that these dovetail with each other.

Procedures

1 Initial Submission

The following documents should be completed and sent by e-mail to the CIRB@wayne.edu.

- HIC CIRB Protocol Summary Form
- HIC CIRB Key Study Personnel Form
- HIPAA Summary Form (standard HIC form)
- The locally modified CIRB approved written informed consent, including HIPAA Authorization
- Assent documentation for local child participants or information sheet if appropriate
- Any other materials modified for local use (for example, advertisements, survey tools, letters)
- DMC/KCI Authorization, as appropriate, for the conduct of human research at these sites.

No documentation relating to the CIRB Approved Study posted on the CIRB website needs to be submitted to the HIC, but references may be made to relevant items where appropriate.

There are no deadlines for submission of CIRB Studies for Facilitated Review.

2 Facilitated Review

The submission materials, together with all appropriate documents relating to the CIRB Study on their website, will be reviewed by an IRB Chair and/or designee and appropriate HIC staff.

The main focus of the review will be local context considerations, such as the targeted population and related cultural issues, Michigan and local laws, WSU regulations and policies, as well as local investigator credentials.

Review will be as efficient as consistent with thoroughness. Any questions, concerns, or revisions will be resolved by email or telephone.

Should the HIC consider Facilitated Review inappropriate for the CIRB Study, for example, for reasons of risk, the PI will be advised and may submit the study for Full Board Review, using appropriate CIRB approved materials.

Full Board Review will always be required if Investigators wish to enroll prisoners on any of these trials, as the CIRB is not constituted to review studies for participation by prisoners.

3 Approval or Disapproval

HIC Facilitated Review approval can only be issued once the CIRB has reviewed and approved the study. Formal notice of HIC Facilitated Review approval will be issued to the PI and Research/Study Coordinator, with the approved and date stamped modified Informed Consent/Assent and any other materials for use with local participants. The HIC Expiration Date will coincide with the CIRB Expiration Date for its approval of the Study.

Simultaneously, HIC will notify the CIRB electronically of its Acceptance of Facilitated Review and a copy will be sent to the PI with the HIC approval notice.

In the event of Disapproval, a formal notice will include the reasons for the HIC decision.

Post Approval Procedures

1 Amendments

Amendments made to the Study and approved by the CIRB may require revisions to the HIC approved Informed Consent/Assent and other materials already approved for local participants.

The following documents should be completed and sent by e-mail to the CIRB@wayne.edu:

- HIC CIRB Amendment Form
- Revised version of the local Informed Consent/Assent and other materials as appropriate.

No documentation relating to the CIRB Approved Amendment posted on the CIRB website needs to be submitted to the HIC.

Note that if the Amendment relates to significant increases in risk for local participants, Full-Board review may be required. This should not normally affect the Facilitated Review status accepted by the HIC for the Study.

Formal notice of Amendment Approval will be issued to the PI and Research/Study Coordinator, with the approval and date stamped revised local Informed Consent/Assent and materials as appropriate. The HIC Expiration Date will coincide with the CIRB Expiration Date for its Amendment Approval.

2 Additions and Deletions of Key Study Personnel

The HIC CIRB Amendment Form is not required. Page 2 of the HIC CIRB Key Study Personnel Form should be completed and sent by e-mail to the CIRB@wayne.edu. Changes to Key Study Personnel will be acknowledged by the HIC. Formal approval will not be issued.

3 Reporting Unexpected Problems/ Adverse Events

Unexpected problems, which may or may not be Adverse Events, and which occur locally at WSU/DMC/KCI, must be reported to the HIC within 5 working days, using the UP/AE form and procedures on the HIC website. Only Serious Adverse Events locally and/or serious study deviations/violations locally should be reported to the HIC: those which do not involve study participants here should not be reported to the HIC.

PIs should also report local Serious Adverse Events to the Coordinating Group as per their guidelines. They should not be reported to the CIRB. The CIRB will review unexpected incidents, events or outcomes identified by the Cooperative Group which impact the trial nationally, and will report them to the appropriate agency (OHRP/FDA).

4 Continuations

Procedures and documentation are under development to ensure that there is no unnecessary duplication by the HIC and local PIs of the CIRB Continuation review. While the CIRB does have primary responsibility for Continuation review, the HIC regards a local review as an essential element in meeting its responsibility to oversee the safe and appropriate performance of the research at WSU and its affiliated institutions and to ensure that the study is progressing in a manner which is consistent with the original submission and with federal and university regulations and policies.

5 Withdrawing a Study from the CIRB

If the HIC wishes to withdraw a facilitated review for any reason and there are study participants enrolled here, the study must first be given Full-Board review and approval, in order to ensure that there are no gaps in HIC coverage for the protection of these participants.

6 Closures

The PI must notify the HIC when the study is closed locally by completing the Closure form on the HIC website.

Guidance

CIRB Website

The comprehensive CIRB Website for all documentation relating to the CIRB reviewed and approved study should be checked regularly at two-weekly intervals to monitor for all recent actions, such as amendments and continuations, which may need consequent action locally, including HIC submission and approval.

Key Study Personnel Form

The Key Study Personnel Form submitted for each new study may be copied from previous studies, with just a change to the protocol title and reference numbers, where there are no changes of personnel. However, always check that personnel have no new conflicts of interest with the new study (see attached guidance: CIRB Protocols: Endorsements and Financial Conflict of Interest Disclosure.)

Signatures may be scanned originals or, once the procedures are in place, electronic.

Modifying Informed Consent Documents

The CIRB approved Informed Consent documents should be used for this: there is no requirement to use the format of the HIC template.

However, for HIC Facilitated Review, the documents must be modified to include the following, completed as appropriate and using the wording required by WSU and the HIC:

- Heading, Research Related Injuries and Questions: Local PI details
- 'The estimated number of study participants to be enrolled at WSU/DMC/KCI is about…'
- Risks: if appropriate, include standard language on reporting certain information to the authorities, in accordance with Michigan law
- Research Related Injuries: 'No reimbursement, compensation, or free medical care is offered by Wayne State University, the Detroit Medical Centre or Karmanos Cancer Institute' (as appropriate)
- Confidentiality: 'The Human Investigation Committee (HIC) at Wayne State University may review your records'
- Voluntary Participation/Withdrawal: 'Your decisions will not change any present or future relationship with Wayne State University, DMC or KCI, or other services you ('or your child', if appropriate) are entitled to receive'

- Questions: HIC contact phone number for participant questions, concerns or complaints

- Any specifically local information on study costs and compensation.

Additional modifications may be made to wording in the interests of readability, but must not change the meaning of the CIRB approved document in any way. The text may not be otherwise deleted or contradicted.

The modified Informed Consent must include the HIC HIPAA Authorization, using the HIC template on the website and matching the PHI Use and Disclosure information with the HIPAA Summary Form information. The HIPAA Authorization should immediately follow the main body of the Informed Consent. Attachments such as Certificate of Confidentiality information should be included after the HIPAA Authorization.

Assent and Information Sheet

Assent may or may not be required by the CIRB, but they do not prescribe the form it should take. The HIC requires that assent should be sought of all child participants over the age of 7, providing that they are capable of providing it.

The HIC template for documenting the assent of adolescents ages 13-17 should be used; an oral script for children ages 7-12 is usually appropriate. For further guidance on HIC Policy and Procedure, and instructions on using the assent template, see www.hic.wayne.edu.

An information sheet may be appropriate where the criteria for waiving written informed consent are met.

Guidance on Endorsements and Financial Conflict of Interest Disclosure

The same requirement for disclosure of endorsements and financial conflict of interest applies to CIRB protocols as to all research protocols at Wayne State University.

For full details, see HIC Policy/ Procedure: Conflict of Interest: Principal Investigator/Key Personnel and WSU Research Policy: Individual and Institutional Financial Conflict of Interest and Commitment.

With CIRB protocols, financial conflicts of interest are most likely to be with the pharmaceutical companies sponsoring the Cooperative Group's research studies by providing resources, including the supply of drugs, to local sites.

Examples of relevant relationships for potential conflict of interest include but are not limited to:

(1) receiving past, current, or expecting future income in the form of salary, stock or stock options/warranties, equity, dividends, royalties, profit sharing, capital gain, forbearance or forgiveness of a loan, interest in real or personal property, or involvement in a legal partnership with the sponsor

(2) receiving past, current, or expecting future income in the form of consulting fees, honoraria, gifts, gifts to the University, or payments resulting from seminars, lectures, or teaching engagements, or service on a non-federal advisory committee or review panel
(3) serving in a corporate or for-profit leadership position, such as executive officer, board member, fundraising officer, agent, member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee, regardless of compensation
(4) inventor on a patent or copyright involving technology/processes/products licensed or expected to be licensed to the sponsor.

The HIC maintains objectivity in the conduct of research by having all individuals involved in research design, development, or data evaluation/analysis disclose any potential and/or real financial conflict of interest.

The Principal Investigator and Department Chair or senior official authorizing the research must respond to the Conflict of Interest question on the first page of the Protocol Summary Form, and all staff involved with the research should make an entry in the Conflict of Interest column of the Key Study Personnel Form. This should reflect not only their own Conflict of Interest, but also any that their immediate family may have.

If any Conflict Of Interest response on these forms is 'yes', there must be a Financial Conflict of Interest Detailed Disclosure Form submitted directly to the Financial Conflict of Interest Committee at the time of this protocol submission and then annually or when changes occur. If this form is not submitted, the protocol cannot be approved. The form is available at: www.research.wayne.edu/coi.

For additional information please contact the Conflict of Interest Coordinator, 5057 Woodward, Suite 6305, Detroit, MI 48202, Telephone 313-577-9064, Fax 313-577-2159.