Wayne State University Human Investigation Committee	
Subject	Quality Improvement Program
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Approvals	Administrative Approval 9/30/10

Background

Research involving human subjects is essential for the progress of scientific knowledge. Wayne State University has long been committed to maximizing the safety of all volunteers who participate in these important studies. The University's mission is to create an institutional culture that values integrity in the conduct of research as well as the pursuit of knowledge and innovation that provide human benefit.

All proposed human research is subject to the policies and procedures of the human research protection program (HRPP) at WSU and is carefully reviewed by one of the Institutional Review Boards. In accordance with its dedication to the highest levels of research integrity, all research at WSU is conducted in compliance with the principles of the Belmont Report and other ethical codes of conduct for research, such as the Declaration of Helsinki and the Nuremberg Code, as well as federal regulations, state and local laws and statutes.

To strengthen the HRPP at WSU, the Human Investigation Committee has established a Quality Improvement Program (QIP) to demonstrate our commitment to continuous improvement in research compliance.

Scope

Implementation of the QIP to evaluate human research protections provides a means to assess WSU's level of compliance with federal, state, and institutional regulations, and Good Clinical Practice (GCP) guidance. Varying levels of review take place to: (1) evaluate compliance with organizational policies and procedures and applicable laws, regulations, codes, and guidance; (2) assess effectiveness of the HRPP by identifying strengths and weaknesses and make improvements necessary to increase the quality, efficiency and effectiveness of the program.

HIC Quality Improvement Program

A Senior Research Compliance Specialist (RCS) has been appointed to oversee the QIP. This individual will conduct:

- On-site reviews of research, when directed by HIC Administration, due to allegations or concerns that have been brought to the IRB's attention about a research study.
- Random reviews of IRB approved research to ensure that the studies are being carried out in accordance with the approved protocol. The review will ensure adherence to University and regulatory policies and that research participants have been clearly informed of what to expect as a participant in the study to which they have enrolled. Thus, approval of a research study by an IRB is just the beginning of an ongoing process to ensure compliance and that protection of research participants is maintained.
- Administrative assessment reviews, when directed by HIC Administration, to include a thorough examination of any IRB records for improvement of management or to evaluate the procedures applied or issues addressed by the HRPP and the IRB for protection of human subjects in research.
- Assessment reviews focusing on maintenance of applicable documentation representing current policy and procedures, utilization of the AAHRPP Self-Evaluation Instrument, and evaluation of current HRPP practices to ensure appropriate fulfillment of AAHRPP accreditation standards.

Compliance QIP – Audits of approved protocols

Key elements involved in monitoring adherence to IRB approved human subject research protocols include:

- Review of the informed consent(s). The review will check to see that the most current approved informed consent is in use, and has been appropriately signed and witnessed. Confidentiality of the research data is assessed to determine if there are appropriate measures in place to ensure confidentiality of the data.
- Performance of safety monitoring is evaluated to assess level of monitoring, documentation of safety monitoring, and how identified safety issues (adverse events) are reported.
- Recruitment of research participants is reviewed, looking at the number (if any) of participants who have withdrawn from the study and the reasons given for that withdrawal. A review of the recorded reasons for participant withdrawal is done to determine if the reasons suggest any safety issues.
- Data collected for a study are evaluated, including inclusion/exclusion criteria for eligibility, performance of the specific intervention or observation, and outcome measures, in order to evaluate adherence to the protocol.

What to expect during a for-cause audit

For-cause audits are conducted when there are concerns about whether or not the rights and welfare of participants enrolled in a particular research study are adequately protected. When a for-cause audit is to be scheduled, a memo will be sent to the principal investigator that will outline the reason for the audit, whether a "hold" has been placed on the conduct of the research, items that will be reviewed, interviews that will be conducted, and any other planned activities. (See HIC Policy/Procedure, "For-cause Audits".)

Upon completion of the audit, collected data will be analyzed and a report generated detailing findings, and outlining required corrections and/or recommended remedial actions. The principal investigator will have an opportunity to respond to the audit report. Final actions will be determined by the IRB of record followed by an administrative review by the AVPR. A final notice will be sent to the PI with any additional requirements. A written report will then be generated and sent to all applicable federal regulatory agencies, the study sponsor, and any appropriate institutional or departmental officials.

What to expect during a random QIP audit

Studies to be reviewed are chosen at random. The review is meant to be a collaborative process in which the RCS assesses compliance and assists the investigator in resolving and/or correcting any identified discrepancies and makes recommendations for process improvement.

The QIP review may take one or more visits to the research site to complete. Initially, the RCS will communicate with the principal investigator (PI) and designated study staff to explain the QIP process (i.e., what to expect) and to address any questions or concerns. A date will then be set for the full review—the review will usually take a full day.

The QIP review will include assessment of the following:

- Documentation to ensure that the PI and his/her research team are following the approved protocol and study procedures, including:
    - Study-related documents
        - Signed consent forms
        - Participant files
        - Inclusion/exclusion checklists for eligibility
        - Drug/device accountability (if applicable)
    - Adverse events (AE's and SAE's), regulatory binder, IRB files and correspondence, sponsor and FDA correspondence.
    - Source documentation (including the medical record)
    - Additional documentation/information may be requested.

<u>The PI's responsibility for a random QIP audit</u>

- Ensure adequate space is available for the reviewer to inspect documents.
- The PI and/or study coordinator should be available for questions. Although the PI may not need to be present for the entire time of the review, a staff member should be assigned to be available to provide necessary documents, files, binders, etc., and answer any questions or to contact the PI if needed.
- Prior to the review, files should be reviewed to ensure that they are all in order – consent forms, drug/device accountability, regulatory binder and IRB correspondence, etc.

<u>What to expect at the end of a QIP audit</u>

Once the review is completed, a report will be generated and sent to the PI. The report will identify any findings that need to be addressed, and specify corrective or preventive actions, if applicable, as well as a time frame in which to complete the request. When all items have been addressed to the satisfaction of the

RCS, a summary letter will be sent. If serious or continuing noncompliance is found during the review, the RCS will discuss this immediately with the PI and a plan will be established to resolve the issue(s). Serious or continuing noncompliance will be reported to the IRB of record for further action.

Compliance QIP – Internal Audits of HIC Operations

In order to evaluate efficiency and effectiveness of the QIP of the HRPP on a regular basis, the following procedures will take place:

- The RCS will audit at least one set of minutes per month on a rotating basis so that each IRB has at least 2 sets of minutes audited per year. The audit will involve a checklist that is based on the pertinent federal regulations and relevant HIC policies. Feedback will be provided to the staff members associated with the generation of minutes, and findings will be reported to IRB administration as well as to the AVPR. Corrective actions such as re-training of the staff will occur both individually and at the monthly meetings of the research compliance administrators and the IRB administration.
- The AVPR and/or the Director, RCR, will conduct administrative reviews of minutes as well as reviews of any associated audits of these minutes that were conducted by the RCS. These reviews will include at least one set of minutes from each IRB committee each year. These administrative reviews of the minutes will also involve verification that the IRB membership listed on the minutes for a given IRB meeting is accurate according to the master list maintained by the IRB administration as well as the roster provided to OHRP. Any necessary corrective actions will be addressed with the appropriate HIC staff persons.
- The RCS and/or the HIC Education Coordinator will attend every convened meeting of the IRBs in order to answer regulatory questions for the members and to advise on policy issues. In their absence, the Director, RCR, or one of the Associate Directors will perform this function.
- In addition to the Research Compliance Administrator (RCA) who is assigned to a specific IRB for its convened meetings, a second staff person will attend every meeting in order to record presence and absence of members; to assure that quorum is met and maintained; and to count and record votes. This additional staff support will help ensure the accuracy of the record of the IRB's activities that will be reflected in the minutes from each meeting.
- Assessment of IRB chairs and members will be conducted annually. The AVPR will meet with each IRB chair to assess the constitution of the committee as well as members' performance and need for additional training.

Measurement of QIP Outcomes

One means of monitoring the overall quality, efficiency and effectiveness of WSU's HRPP is to monitor the time from submission to full approval of HIC protocol submissions. This will be calculated twice each year and reported to the Director, Responsible Conduct of Research. He/she will review the findings and the trends over time with the AVPR in order to identify additional opportunities for quality improvement of the program.

Summary

The goal of the QIP is to provide a program that serves to focus on educating the research community at Wayne State University on the mechanisms by which human subjects are protected. The QIP will allow researchers, IRB members, and HIC staff an opportunity to improve performance in human research protection.