Evaluation and quality improvement (QI) are complementary processes that assess and provide feedback regarding the functioning of the Michigan State University (MSU) Human Research Protection Program (HRPP). Evaluation processes collect information about the program and QI uses the information collected to implement changes in policies and procedures to improve the functioning of the program. The goal and mission of the QI program is to protect human research subjects through a quality HRPP that achieves and maintains compliance using efficient and effective processes. Periodic assessment and evaluation of the HRPP are necessary to measure and make systematic improvements to the program.

Evaluation and QI of the MSU HRPP is a shared responsibility. It involves multiple stakeholders such as the Vice President for Research and Graduate Studies (VPRGS), the Office of Regulatory Affairs, the HRPP, the Institutional Review Board (IRB) staff, IRB chairs, IRB members, the Human Research Liaison (HRL) office, investigators, research staff, sponsors, and subjects. This shared responsibility is implemented by multiple mechanisms to acquire and evaluate information regarding the compliance, quality, efficiency, and effectiveness of the HRPP. While each of these areas (i.e. compliance, quality, efficiency, and effectiveness) are described separately in this policy, they are highly dependent upon one another. For example, a review that is highly efficient but deviates seriously from IRB requirements would not be acceptable.

Stakeholder input assists the HRPP in conducting evaluation and QI activities and is encouraged (e.g. wide publication of HRPP contact information to obtain answers to questions, express concerns, and convey suggestions regarding the HRPP). See HRPP Manual 5-6 “Contact Information” for a description of how stakeholders can provide input.

**Evaluation and QI Methods**

This section describes multiple methods utilized for evaluation and QI of the HRPP. These methods provide both internal controls and external assessments. Internal evaluation controls provide regular improvements to the program and include stakeholders such as the principal investigator (PI), IRB administrators, HRPP managers, Human Research Liaisons, and IRB members. External assessments provide a check on the internal controls. The evaluations provide feedback into the QI assessment plan.
PI
PIs are responsible for the conduct and oversight of their research study, including oversight of personnel. See HRPP Manual 4-6, “Responsibilities of Investigators.” Oversight includes the responsibility of providing proper training to the investigators and research staff to assure that the research is conducted in accordance with the IRB approved protocol. Oversight also includes assuring that procedures are being properly conducted throughout the research study (e.g., consent process is being appropriately conducted and documented, records are appropriately maintained). PIs are encouraged to utilize the “Investigator Self-Audit” checklist available on the HRPP website to evaluate their research studies.

IRB Office
IRB staff are responsible for assuring that IRB applications are processed in accordance with MSU HRPP policies and procedures and that proper documentation is maintained in the IRB record. The IRB manager provides an internal control on approved IRB applications and may provide specific corrective actions (e.g. with a particular IRB administrator on a specific research study). The HRPP manager reviews all federally funded full review research studies and may review a sample of other research studies. The HRPP manager may also identify systematic improvements (e.g. identification of a recurrent issue) and address through changes in process, targeted education, suggested policy changes, and other corrective actions as necessary.

IRB administrator IIIIs are responsible for generating IRB minutes for their respective meetings. The HRPP manager will review all IRB minutes and may provide specific feedback. The HRPP manager may also identify areas of concern (e.g. identification of a recurrent issue) and address through changes in process, targeted education, suggested policy changes, and other corrective actions as necessary.

IRB staff are also evaluated on an annual basis following MSU Human Resource guidelines.

IRB Members
IRB members are responsible for assuring that IRB applications are approved in accordance with federal, state, and local regulations as well as with the MSU HRPP policies and procedures and that proper documentation is completed. IRB members may utilize applicable checklists (e.g. initial review) to assure that approval criteria have been met. IRB staff provides an internal control to assure that the proper documentation has been completed and is maintained in the IRB record. Potential issues should be brought to the IRB chair for discussion with IRB members as appropriate.

Input will be provided to the VPRGS or his/her designee on the participation of IRB members. This input may include but is not limited to their attendance at scheduled meetings, the number and types of reviews conducted, the timeliness of reviews, participation in workshops, etc.

IRB Committee
A mechanism to assess the composition of the IRB is a review of metrics. The volume of submissions, stratified by college and department, will be reviewed to determine representation and areas of expertise needed by the committee. Composition will also be considered by the IRB chair and recommended as needed (e.g. particular areas of expertise).

**Human Research Liaison (HRL)**
The HRL provides a check on these internal controls. See HRPP Manual 5-2-B, “Human Research Liaison” for a description of the responsibilities of the HRL. The HRL site visits provide information to identify areas for QI.

The HRLs:
1. Maintain adequate training and proficiency in human subject requirements
2. Exercise independent judgment and professional care in a respectful manner
3. Plan and supervise the site visit
4. Study and evaluate existing internal controls (systems, policies, and procedures)
5. Gather sufficient information to draw a conclusion
6. Provide a report from site visit findings

The HRL may review a sample of IRB transactions. Such a review may include assessments of types of applications (e.g. initial, renewals, revisions, closures) and also research studies that involve certain subject populations or types of actions (e.g. waivers, research involving pregnant women, fetuses, or neonates, prisoners, children, individuals with diminished capacity, less than one year approval, engaged sites, previous noncompliance, engaged sites). The HRL will review all full review initial applications with subjects enrolled and a sample of other research studies. Directed site visits may also be requested and can be limited to a particular area of concern or may encompass the entire research study. See HRPP Manual 8-10 “Research Site Visits” for detailed procedures. An expanded number of research studies may be reviewed as part of the site visit if the site visit findings indicate a need.

The HRL will evaluate research studies for compliance with applicable federal regulations (e.g. 45 CFR 46, 21 CFR 50, 21 CFR 56) and/or agency specific requirements, state or local laws, and MSU policies and procedures. The review will encompass the IRB records. Site visit findings are provided to the Principal Investigator and others as appropriate. The HRL may also provide recommendations for system-wide improvements.

**HRPP Director**
The HRPP director provides information on an annual basis or more frequently as requested to the assistant vice president for the Office of Regulatory Affairs (AVP ORA). This information will include an assessment and evaluation of physical space, staff resources, funding, and committee activities. The AVP ORA reviews the information in order to develop plans for the coming fiscal year and follows the overall university budget planning cycle. When funds are allocated, the AVP ORA reviews and allocates funds to its units, including HRPP. Special budgetary requests may be made as needed.
by the HRPP director to the AVP ORA during the current fiscal year after resource allocation.

**Institutional Official (IO)**
The IO is provided with regular updates on the HRPP, including workload and metrics. Such updates include the following information:

- Number of studies submitted by review type (initial review, amendments, continuing review) and review level (full, expedited, exempt);
- Turnaround time; and
- Copies of the meeting minutes for each IRB.

The HRPP director and IO meet quarterly for programmatic discussion and review of the HRPP. This may include review of workload issues such as the timeliness of IRB reviews, the number, types and complexity of IRB submissions and any perceived deficiencies, such as the number of IRBs or IRB members, necessary reviewer expertise, resources or HRPP staff allocations.

**Internal QI Group**
An internal QI group will meet regularly to discuss findings. The internal QI group will review findings of the QI program to assess and develop system-wide improvements. Representatives for this group may include the AVP ORA or their designee, HRPP director, IRB manager, HRL manager, and IRB chairs. In addition to reviewing site visit findings, this group will also perform QI assessments on other initiatives. The internal QI group will review HRPP policies and procedures as part of the QI process. Evaluation of the program may include changes to processes or procedures to improve metrics or the program. Trends observed in the site visits will be tracked and evaluated for improvement. The internal QI group will also evaluate written policies and procedures and determine whether changes are needed. Any individuals may recommend a policy to the group for review. Policies may also be reviewed in response to site visit findings.

**Human Research Protection Program (HRPP) Working Group**
An HRPP Working Group consists of representatives of different HRPP components. These include the Office of Sponsored Programs, Research Integrity, Conflict of Interest, Environmental Health and Safety, Clinical and Translational Sciences Institute / Office of Clinical Research, Office of the General Counsel, Graduate School, Pharmacy, Research Privacy Board, MSU Technologies, and the Internal QI group. The HRPP Working Group was established to strengthen communication among the units involved in the protection of humans in research.

**Compliance**
The goal of compliance is to assure that research studies are reviewed, approved, and conducted in accordance with federal, state, and local regulations, university policies, and ethical principles.

The measures of compliance may include but are not limited to:

- Number of directed site visits
• Type and frequency of serious and / or continuing noncompliance

Methods of compliance review are described in the section above (Evaluation and QI Methods) and include reviews of internal IRB operations, including protocols and IRB minutes, post approval monitoring visits, etc.

**Efficiency**
The goal of efficiency is to complete IRB reviews in a timely manner in compliance with federal, state, and local regulations, university policies, and ethical principles. Efficiency is typically calculated by the turnaround time for approval (i.e., from the date of a complete submission to the IRB office to the date of approval). Components of this time may be examined to determine where targeted process improvements may occur.

The measures of efficiency may include but are not limited to:
- Number of submissions, type, etc.
- Turnaround time (submission to notification of approval, including components of this total time)

A monthly report will provide the volume and average approval turnaround time by submission type (e.g. initial, renewal, revision) stratified by committee and review level. The average turnaround times will be compared with the goals for turnaround. Turnaround time is defined as the difference between the date the application is approved and the date the application is submitted to the IRB and is complete (e.g. all necessary supporting documents). The monthly reports are provided regularly to the HRPP director, AVP ORA, IRB chairs, and the IO. Each month will be compared to the target. Such reports will also be regularly provided to the internal QI group.

The goals for turnaround time are: (application is submitted and complete to approval)
- 45 CFR 46.118: 2 days [range 1-3 days]
  - Initial
    - Exempt: 8 days [range 7-9 days]
    - Expedited: 21 days [range 2-4 weeks]
    - Full Review: 28 days [range 3-5 weeks]
  - Renewals
    - Expedited: 10 days [range 1-2 weeks]
    - Full Review: 21 days [range 2-4 weeks]
  - Revisions
    - Expedited: 10 days [range 1-2 weeks]
    - Full Review: 21 days [range 2-4 weeks]

The HRPP manager may also review protocols that considerably deviate from the maximum turnaround time goals to determine the cause. Summary reports of these reviews will be provided to the HRPP director and as appropriate, the internal QI group to evaluate and determine whether system-wide improvements are needed. The HRPP manager will identify significant deviations and determine from the sample whether
components should be targeted for QI, such as process changes, education, training, etc.

The goals for components of the IRB turnaround time are:

- **Staff**:
  - Processing applications: 2 days [range 1-3 days]
  - Processing comments: 2 days [range 1-3 days]

- **Reviewers**:
  - Reviews 7 days
  - Responding to comments: 2 days [range 1-3 days]

The turnaround goals of the HRPP will be evaluated minimally every year to determine if the goals should be modified.

**Quality**

The goal for quality is to maintain a high quality HRPP that protects human research subjects involved in research and continually seeks to improve its program.

The measures of quality may include but are not limited to:

- Assessment of compliance mechanisms (e.g. reduction in noncompliance reduces the potential risk to human subjects)
- Serious and/or continuing noncompliance
- Investigator satisfaction with the overall program
- Subject protection
- Trained IRB staff, IRB members, and researchers (e.g. assessment of the education and training program)

Surveys may be made available to a sample of current investigators to collect information that will be used for QI in the IRB application and review process or in the research site visit process. The information collected will be reviewed by the HRPP manager to determine whether immediate action or targeted improvements are needed and by the internal QI group to evaluate systematic improvements. The response rate will be periodically assessed to determine the effectiveness of the satisfaction survey.

A feedback document is provided on the HRPP website as a tool to encourage individuals (e.g. subjects, researchers) to provide feedback to the IRB.

**Effectiveness**

The goal for effectiveness is to achieve an HRPP that protects human subjects in research while maintaining compliance with federal, state, and local regulations, university policies, and ethical principles and achieves its goals in a timely manner.

The measures of effectiveness may include but are not limited to:

- Reduced instances of noncompliance
- Reduced severity of noncompliance
- Improved investigator satisfaction with the HRPP
• Positive responses from subjects
• Improved investigator, staff, member, and subject understanding of the HRPP
• Greater human subject research protections (e.g. unanticipated problems, complaints)

Such indicators taken together will measure the effectiveness of the HRPP. The internal QI group will review the information gathered with various evaluation mechanisms and review in their totality to determine the effectiveness of the program.