PURPOSE
It is the mission of the Pennington Biomedical Research Center to discover the triggers of chronic diseases through innovative research that improves human health across the lifespan. To achieve this goal, departments within the Center will participate in ongoing and systematic quality improvement (QI) efforts. This plan demonstrates the Center’s commitment to training, monitoring, and improving the quality of the research we conduct. The QI plan outlines the goals and strategies for the Center to improve the quality of the research it performs.

AUTHORITY
The Executive Director is ultimately responsible for assuring that high quality research is performed at the Center. The Executive Director may delegate the implementation of this plan to the Executive Committee, the Policy Committee, and/or the Quality Improvement Committee.

SCOPE
To achieve the goal of performing high quality research, all departments are given the responsibility and authority to participate in the quality improvement program in accordance with the quality plan guidelines as developed by the Quality Improvement Committee, and approved by the Executive Director (for specific guidelines see the QI Program Guidelines).

QUALITY IMPROVEMENT COMMITTEE
The Quality Improvement committee provides ongoing operational leadership of quality improvement activities at the Center. The committee meets at least quarterly and consists of representatives from appropriate departments in order to meet the goals of the QI Committee’s needs.

The responsibilities of the committee include:
1. Developing and approving the QI Plan
2. Ensuring that measurable objectives are established for improving the quality of clinical research services
3. Overseeing the establishment of specific quality improvement initiatives
4. Reporting to the Executive Director on quality improvement activities

QUALITY IMPROVEMENT PROCESSES AND METHODS
The QI Plan provides a framework of organized, ongoing, and systematic measurement, assessment and performance improvement activities.

One example of an acceptable QI Plan is the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) 10-step process for the monitoring and evaluation of the quality and appropriateness of patient care.

The steps are listed below:
1. Assign Responsibility
2. Define scope of services
3. Identify important aspects of care  
4. Develop key indicators  
5. Establish thresholds for evaluation  
6. Collect and organize data  
7. Evaluate data  
8. Take actions to improve patient care  
9. Assess effects of actions  
10. Communicate pertinent information via QIP

Other acceptable plans include but are not limited to Shewhart’s PDCA Cycle, Juran’s Journey, HCA’s FOCUS-PDCA Process, Joiner’s Process, and ODI’s F-A-D-E Process.

DEPARTMENTAL RESPONSIBILITY
Each department within the Center is responsible for implementing quality improvement activities.

   Departmental responsibilities include:
   1. Establishing measurable quality improvement objectives specific to their unit or lab.
   2. Developing quality indicators on a priority basis
   3. Assessing quality indicator data and taking needed actions to solve problems and pursue opportunities to improve quality on a regular basis
   4. Ensuring that employees are aware of the departmental QI plan, and their responsibilities related to QI.
   5. Reporting QI activities to the Quality Improvement Committee

ANNUAL EVALUATION
The QI Plan will be evaluated on an annual basis for effectiveness in achieving the goal of assuring high quality research. A summary of activities, improvements made, projects in progress, and recommendations for changes to this plan will be compiled and forwarded to the Executive Director for action.
Pennington Biomedical Research Center
QI Committee Quality Improvement Plan Guidelines and Forms

<table>
<thead>
<tr>
<th>Pennington Biomedical Research Center</th>
<th>March 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>QI Committee</td>
<td>2012</td>
</tr>
<tr>
<td>Quality Improvement</td>
<td></td>
</tr>
<tr>
<td>Plan</td>
<td></td>
</tr>
<tr>
<td>Guidelines and Forms</td>
<td></td>
</tr>
</tbody>
</table>
1. What is a Quality Improvement Plan?
   a. Is a plan that is used to assess overall quality of services
   b. This plan is meant to identify problems and improve services provided

2. Who needs a Quality Improvement Plan?
   a. Anyone that has contact with research subjects, even animals
   b. Anyone that could be audited by the FDA

3. How do I create a Quality Improvement Plan?
   a. You need to establish a QI committee
   b. You need to figure out What services you provide, What are the important aspects of those services.
      i. This is where you will need KEY/ QUALITY Indicators
      ii. A key indicator is a quantifiable measurement that is created to reflect what is necessary for
          the success of the unit and the overall mission of the Center.
   c. Then you need to decide how you will evaluate/analyze those services, this needs to be measurable
   d. Finally, you need to evaluate the plan annually and modify as needed. This plan will always need to
      be evaluated and changed.

4. Quality Improvement Framework
   a. A major decision in implementing an ongoing quality surveillance program is selection of an
      appropriate improvement process. Choose the improvement process that is most appropriate for
      the quality management resources of your department. (Shewhart’s PDCA Cycle, JCAHO’s Ten-Step
      Process, Juran’s Journey, HCA’s FOCUS-PDCA Process, Joiner’s Process, ODI’s F-A-D-E Process, etc.)
   b. We encourage the implementation of either:
      **Please note that it is not mandatory to use the JCAHO plan, but all of the examples are based on
      that program.**
      The JCAHO’s Ten-Step process:
      • Assign responsibility
      • Define the scope of services
      • Identify important aspects of care
      • Develop key indicators
      • Establish thresholds for evaluation
      • Collect and organize data
      • Evaluate data
      • Take actions to improve patient care
      • Assess effects of actions
      • Communicate pertinent information via quality improvement process

      Or
      Shewhart’s PDCA Cycle:
      • Plan
      • Do
      • Check
• Act

c. To implement any of these processes, the department should generally do the following:
   • Establish prioritized surveillance objectives with measurable quality indicators; these objectives
     and indicators must match the department’s quality management resources.
   • Collect appropriate data for prioritized objectives and indicators.
   • Evaluate the data
   • Determine appropriate action
   • Assess the effectiveness of that action and provide appropriate follow-up recommendations until
     the level of desired improvement is reached.

5. How do I report my findings?
   a. You can create a report, spreadsheet, data base to track all findings.
   b. You will report a summary of findings each December to the PBRC QI Committee.
   c. You will monitor the findings to your own group and make changes throughout the year.

6. What do I do with my findings?
   a. Make changes or improvements if needed.
   b. As stated above, you will provide a yearly summary of all findings to the QI Committee.

7. How do I get help with my plan?
   a. You can contact the QI Committee or any committee members at any time.
   b. See attached examples and templates.

8. What is required of me after my initial Quality plan is developed?
   a. The plan will need to be evaluated annually by the department.
   b. A QI evaluation will need to be created to evaluate the plan and key indicators. (see example)
   c. The key indicators will possibly need to be changed if all goals were met.
   d. New goals may need to be created for the upcoming year.

9. What ongoing processes will I follow?
   a. An annual review of the QI plan.
   b. An annual evaluation of the plan, submitted to the QI committee.
   c. New goals for the upcoming year, submitted to the QI committee.
   d. Make sure your department has Standard Operating Procedures (SOPs) to support your plan.
**This is an example template only, please note that this format is not mandatory**

**Purpose**

The purpose of the *your unit* Quality Improvement Plan is to achieve continuous quality improvement and customer satisfaction through a systematic process of monitoring key indicators of quality and implementing specific strategies to improve important operational procedures on a prioritized basis.

**Quality Improvement Plan**

A major decision in implementing an ongoing quality surveillance program is selection of an appropriate improvement process. Various formats range from the simpler concepts of Shewhart’s PDCA cycle to the more familiar Joint commission on Accreditation of Healthcare Organization’s Ten-Step Process.

Choose the improvement process that is most appropriate for the quality management resources of your department.

- Shewhart’s PDCA Cycle
- JCAHO’s Ten-Step Process
- Juran’s Journey
- HCA’s FOCUS-PDCA Process
- Joiner’s Process
- ODI’s F-A-D-E Process

To implement any of these processes, the department should generally do the following:

- Establish prioritized surveillance objectives with measurable quality indicators; these objectives and indicators must match the department’s quality management resources.
- Collect appropriate data for prioritized objectives and indicators.
- Evaluate the data
- Determine appropriate action
- Assess the effectiveness of that action and provide appropriate follow-up recommendations until the level of desired improvement is reached.
The remainder of this template is based on JCAHO's Ten-Step Process

The Quality Improvement Plan utilizes the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Ten-Step Process for monitoring and evaluating quality and appropriateness of important operational procedures.

The ten steps are:

- assign responsibility
- define scope of services
- identify important aspects of care
- develop key indicators
- establish thresholds for evaluation
- collect and organize data
- evaluate data
- take actions to improve patient care
- assess effects of actions
- communicate pertinent information via QIP

As an on-going quality surveillance program the Quality Improvement Plan is:

- Designed to identify and resolve process performance as evidenced by objective QI surveillance data exceeding their predetermined thresholds. *(symptomatic problems)*
- Designed to identify and improve processes that are important in satisfying a prioritized need even though there is no overt problem as evidenced by objective surveillance data. *(asymptomatic problems)*
- Coordinated with other programs at Pennington Biomedical Research Center (PBRC).

**Responsibility**

The *your unit director, manager* is responsible for:

- Approving the design of the Quality Improvement Plan.
- Implementation of the Quality Improvement Plan as designed.

The *your unit director, and/or manager, and/or designee* is responsible for:

- quality assurance activities that provide adequate confidence that requirements of quality will be met.
- Ensuring that all employees have sufficient education, training, quality management resources, and participation in the quality improvement process
- Fulfilling the role of QI Coordinator and coordinating the Quality Improvement Plan with other programs at PBRC
- Establishing prioritized surveillance objectives and measurable, key indicators
that match the department’s quality management resources.

- Evaluating data
- Recommending actions to be taken and assigning responsibility
- Assessing effects of actions taken

All **your unit staff** are responsible for:

- Following the department’s approved operational procedures and policies.
- Quality Control - operational techniques and activities that are used to fulfill requirements for quality.
- Collecting and organizing data
- Appropriate communication of information pertinent to the quality improvement process.
- Implementing actions to be taken based on evaluation of data collected

**Scope of Services**

To provide high quality **whatever care your unit provides** in a safe and efficient manner to participants undergoing research procedures in the **unit** and adhering to Good Clinical Practice Guidelines. Services provided may include but are not limited to:

- List the services that your unit provides here
- ...

**Important Aspects of Care**

The **unit** monitors multiple aspects of care delivered in the unit. These include but are not limited to:

- List the important aspects that determine the quality of the services that your unit provides
- ...

**Key Indicators**

Key indicators of quality (what will be measured and how it will be measured) are developed based on important aspects of care and are monitored and evaluated to detect real or potential problems and opportunities for quality improvement. These indicators reflect services that:

- Are critical to participant safety
Indicator Thresholds

Indicator Thresholds will be established based on Good Clinical Practice Guidelines and professional experience. Indicators are monitored and a compliance percentage is documented. If the compliance is less than the designated threshold value the indicator is reevaluated, a plan for improvement developed and implemented and compliance is reevaluated. Thresholds should meet a minimum goal of 95% (could change this percentage) or better.

Collect and organize data

The QI unit representative in conjunction with other staff will select one or more areas to assess as a QI project. QI projects can evolve from a review of important aspects of care for opportunities to improve services, in response to a problem or complaint (occurrence reports), clinical quality or safety, or as requested by unit director/staff member.

Any deviation from standards of care, complaints, or medication errors will be documented on an occurrence report. This report will be submitted to the unit director who in turn tracks the reports looking for potential areas to improve.

Once a QI project is identified the QI representative will collaborate with other team members to determine what the actual or potential problem is, identify what important aspect of care does the problem affect, identify key indicators, develop data collection tool to evaluate the key indicators, set minimum thresholds the indicators should meet, and collect the data.

Data will be collected utilizing patient surveys, phone calls, occurrence reports, chart reviews, calibration and quality controls of equipment, quality surveys and any other method deemed appropriate by the unit director. (This is where you can determine how you will collect your data using measurable identifiers) The unit QI coordinator will coordinate the collection of the data and then organize the data utilizing spreadsheets, charts or other means to report the data in an organized fashion.

The Quality Improvement Plan includes review of errors, complaints, and incidents at defined intervals to identify trends and/or shifts and initiate corrective/preventive actions as appropriate.

Evaluation of data

Quality Improvement projects are evaluated to determine if a problem or an area for improvement exists. This is accomplished by determining if the indicators meet the predetermined thresholds. If the thresholds
are not met targets for improvement are set and implemented to include a plan for reassessment. The unit
director is responsible for reviewing data, defining acceptable compliance, reviewing present compliance,
and initiating corrective action as indicated. Actions to improve problems/concerns are taken when
opportunities are identified.

**Actions to Improve**

When a key indicator does not meet threshold or an area to improve is identify a specific work plan is
developed that will lead to improvement in performance and/or outcomes. Actions to improve may include
education, communication, change in policy or procedure or any other activity that will lead to improvement
in performance and/or outcomes. The plan is approved or modified as necessary and implemented.

**Assessment of Actions**

After an appropriate time period, new data may be gathered to assess the success of the plan for
improvement or data may be gathered at regular intervals on an ongoing basis for continuous assessment
of performance. Based on the analysis of the data a decision is made regarding the next step:

- Continue the process as is with the same indicators/data monitoring
- Continue the process with modifications (i.e. implement additional interventions )
- Add new monitors/quality indicators
- Stop monitoring

**Communication of Data**

Data will be presented to team members at regular staff meetings eliciting input from the team. A report
will be compiled by the unit QI Coordinator to present to the PBRC Quality Improvement Committee for
evaluation, suggestions, and further actions to be taken.

The Quality Improvement Committee meets monthly to evaluate data collected and recommend actions to
be taken if required. The Quality Improvement Plan is reviewed annually and an appraisal of effectiveness
is reported to the PBRC Quality Improvement Committee.

**Referenced documents, SOPs and forms**

**Review**

This document will be reviewed annually and revised as required.

Prepared: *date* By: *Name* Approved By: ___________________________

*your unit director, manager*
**This is an example template only, please note that this format is not mandatory**

Specific Unit

Process Improvement Evaluation

RESPONSIBILITY

- Those involved

SCOPE OF SERVICES for 2011

- What will you look at for the current year?

IMPORTANT ASPECTS OF CARE

- What have you looked at for the past year?
** Continue with all key indicators until review all of them

**EVALUATION OF DATA**
- What did your unit do with the evaluation of the data?

**ACTIONS TO IMPROVE**
- What did your unit do to improve?

**ASSESSMENT OF ACTIONS**
- How will your unit assess the outcomes on a continuous basis?

**COMMUNICATION OF DATA**
- What will you do with findings?
Purpose

To describe the procedure for writing and formatting a SOP

Responsibility

Each department is responsible for the development and revision of all SOP’s that describe the clinical research procedures related to that department.

Procedure Steps

A. Summary of the specific SOP procedure should be outlined here, using letters to designate each separate step. You should never have only an “A”.
B.
C.
D.
E.

Procedure Steps in Detail

A. Describe in detail each step of the procedure
B.
C.
D.
E.

Referenced Documents
Policy Committee Secretary’s Attestation

Date of Policy Committee Meeting: N/A Expedited Approval by Email initiated 4/2/2012

Policy 107.00: Quality Improvement Plan Policy

Date of Approval: 4/3/2012 subject to minor edits (completed on 4/11/2012)

Publication Date: 04/2/2012

Effective Date: 04/12/12

Anne Duke, Policy Committee Secretary

[Signature]

4/11/12

Date