1.0 Purpose:

1.1 The objective of the Hartford HealthCare Human Research Protection Program (HHC HRPP) Quality Assurance / Quality Improvement Plan is to measure and improve the program's effectiveness, quality, and compliance with organizational policies and procedures and applicable federal, state, and local laws on an ongoing basis.

1.2 The purpose of this policy, therefore, is to describe methods to assess the quality, efficiency, and effectiveness of the HRPP. These methods are aimed at identifying strengths and weaknesses of the HRPP.

2.0 Definitions:

2.1 N/A

3.0 Procedure:

3.1 The Quality Assurance / Quality Improvement Plan includes internal directed audits, random internal compliance reviews, review and assessment of "HRPP Satisfaction Surveys" submitted by the research community via the website, review and assessment of "IRB Self Assessments" completed by IRB Members, and a review of HRPP metrics as prescribed by AAHRPP.

3.2 The QA/QI Plan will be implemented by the HRPP Director. The HRPP Director may designate appropriate HRPP staff members to conduct such reviews, or may request external assistance where appropriate.

3.3 **IRB Operations (IRB Internal Compliance Reviews)**

3.3.1 The HRPP office will conduct activities at least every 6 months to assess IRB compliance with applicable federal, state, and local laws and institutional policies and procedures.

3.3.2 Activities may include but not be limited to the following:

3.3.2.1 Review the IRB minutes to determine that adequate documentation of the meeting discussion and required findings has occurred. This review will include assessing the documentation surrounding the discussion for protections of vulnerable populations as well as other risk/benefit ratio and consent issues that are included in the criteria for approval;

3.3.2.2 Assess the IRB minutes to assure that quorum was met and maintained, and that conflict of interest policies for IRB members was followed;

3.3.2.3 Assess the current adverse event reporting process;

3.3.2.4 Assess that privacy provisions, according to HIPAA, have been adequately reviewed, discussed and documented in the IRB minutes;

3.3.2.5 Evaluate the continuing review discussions to assure they are substantive and meaningful and that no lapse has occurred since the previous IRB review (or that if a lapse occurred, no research activities took place);

3.3.2.6 Observation of IRB meetings or other related activities;

3.3.2.7 Review IRB files to assure retention of appropriate documentation and consistent organization of the IRB file according to current policies and procedures;

3.3.2.8 Review the IRB database to assure all fields are completed accurately;

3.3.2.9 Verification of IRB approvals for collaborating institutions or external performance sites;

3.3.2.10 Other monitoring or auditing activities deemed appropriate by the IRB and HRPP.

3.3.3 The HRPP Director will review the results of internal IRB compliance reviews with the IRB Chair. If any deficiencies are noted in the review, a corrective action plan will be developed by the HRPP Director and IRB Chair and approved by the Institutional Official (IO). The HRPP Director will have responsibility for implementing the corrective action plan, the results of which will be evaluated by the Institutional Official.

3.4 **Research Community Feedback**

3.4.1 The “HRPP Satisfaction Survey” is available on the Research website. Researchers can submit feedback via the surveys anonymously.

3.4.2 The “HRPP Satisfaction Survey” is designed to assess content areas such as HRPP Staff service excellence and expertise, efficiency and timeliness of IRB reviews, website ease of use, and adequacy of educational offerings.

3.4.3 Feedback from surveys will be reviewed periodically, at least quarterly.

3.5 **IRB Member Self-Assessment Surveys**

3.5.1 IRB Chairs, members, and alternates who attended meetings during the evaluation period will complete an evaluation checklist once a year, which includes a self-evaluation section on their performance.

3.5.2 Other content areas on this “IRB Self-Assessment: IRB Members” include:
3.5.2.1 Conduct of IRB Meetings
3.5.2.2 Administrative staff
3.5.2.3 IRB Chairman
3.5.2.4 Committee Members
3.5.2.5 Meeting Environment
3.5.2.6 Institutional Support

3.5.2.7 Future Direction

3.5.3 These will be reviewed by the HRPP Director. Results, issues, and trends will be shared with the HRPP Staff, IRB Chair, Members, and the IO, as applicable.

3.5.4 Corrective measures will be taken as necessary. These may involve education or development and implementation of new processes.

3.6 **Assessment of "Metrics" and Volumes**

3.6.1 Metrics, as prescribed by the Association for the Accreditation of Human Research Protection Programs (AAHRPP), will be tracked, assessed, and reported yearly.

3.6.2 The following metrics will be measured:

3.6.2.1 Number of active protocols (exempt, expedited, full board)
3.6.2.2 Number of FTEs dedicated to IRB and HRPP functions
3.6.2.3 Dollars allocated to the HRPP and IRB
3.6.2.4 Numbers of investigators and research staff
3.6.2.5 Mean number of days from submission to review and approval for new studies for full board and expedited
3.6.2.6 Mean number of days from submission to exempt determination
3.6.2.7 Percentage of protocols disapproved by the IRB
3.6.2.8 Number of protocol deviations
3.6.2.9 Number of complaints from research participants received
3.6.2.10 Number of cases of alleged non-compliance investigated
3.6.2.11 Number of determinations of serious non-compliance
3.6.2.12 Number of determinations of continuing non-compliance
3.6.2.13 Number of unanticipated problems investigated
3.6.2.14 Number of unanticipated problems involving risks to participants or others
3.6.2.15 Number of "for cause" audits of investigator protocols
3.6.2.16 Number of random audits of investigator protocols
3.6.2.17 Number of "for cause" audits of IRB records conducted
3.6.2.18 Number of random audits of IRB records conducted
3.6.2.19 Number of FDA inspections of investigators or the IRB(s)

3.6.3 Several of these measures, "turnaround times" for example, will be assessed more frequently. They will be discussed at the monthly H3W meeting in conjunction with tracking of other Research Institute metrics.

3.6.4 Metrics will be used to assess the overall HRPP program to determine if the resources needed to implement the program and provide continuing education to investigators, research staff, and IRB members are adequate.

3.6.5 Examination of trends will be utilized to determine exactly where changes are needed or more education is in order.

3.6.6 The HRPP Director will complete Table 2 of the AAHRPP "Annual Report Form". This table allows for a comparison of performance on specific elements of the HRPP program between the current and previous year.

Changes are quantified as gradations of improvement, no change, and worsening.

3.6.7 The HRPP Director will utilize the annual "Metrics on Human Research Protection Programs Performance" released by AAHRPP to benchmark performance for the upcoming year.

3.7 The aggregate results of these assessments will be used to evaluate current practices, establish whether additional educational activities needed, and if resources are adequate.

3.8 Reports will be made periodically to the IO as needed.

4.0 Documentation:

4.1 All activities undertaken to assess HRPP program quality, efficiency, and effectiveness will be documented in writing, filed in a binder in the HRPP Director's office and retained for at least six (6) years.

5.0 References:

5.1 N/A

6.0 Revision History:

Rev #	Initials	Effective Date	Description of Change(s)
00	CLB	7/1/11	New Issue
01	CLB	3/15/20	General review

Element 1.5.B