## 1 PURPOSE

1.1 This procedure establishes the process to conduct quality improvement activities in the Office of IRB administration (OIA) that periodically assess the quality, efficiency, and/or effectiveness of the OIA.

1.2 The process begins when the OIA director or designee initiates a new review period.

1.3 The process ends when all evaluations have been completed and if needed, acted upon.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 None

## 3 REQUIREMENTS

3.1 The goal of the quality improvement plan is to achieve and maintain compliance and to attain targeted levels of quality, efficiency, and effectiveness of the OIA.

3.2 Objectives of the quality improvement program are to:

3.2.1 Assess and continuously improve quality and efficiency of reviews conducted by OIA staff acting as designated reviewers.

3.2.2 Assess and continuously improve regulatory compliance of IRB minutes.

3.2.3 Increase efficiency of recording and finalizing minutes.

3.2.4 Assess and continuously improve quality of the assistance provided to investigators and research staff through the OIA online assistance request system, or equivalent.

3.3 The measures of the quality improvement program are defined in:

3.3.1 *OIA-335 WORKSHEET: Minutes Quality Improvement Assessment*, or equivalent.

3.3.2 *OIA-430 CHECKLIST: Staff Quality Improvement Assessment*, or equivalent.

3.3.3 *OIA-602 DATABASE: Investigator Assistance Improvement Assessment,* or equivalent.

## 4 RESPONSIBILITIES

4.1 The OIA director or designee initiates this process.

4.2 The OIA staff ensure completion of these procedures.

## 5 PROCEDURE

5.1 Complete *OIA-430 CHECKLIST: Staff Quality Improvement Assessment*, or equivalent.

5.1.1 At least five work-products from all individuals from each of the functional groups of OIA staff (i.e., non-committee review team or committee team) who regularly function as a designated reviewer should be selected for assessment each review period.

5.1.2 Select at least five pieces of work-product which were reviewed and approved by the selected individual in the time period for assessment selected by the OIA director or designee.

5.1.3 Track compliance and examine submissions for trends.

5.1.4 Send the results to the OIA staff member's supervisor and OIA director.

5.1.5 If the results of any evaluations demonstrate high variability or do not meet any established performance targets, work with the OIA director, institutional official, or designee to implement an improvement plan.

5.2 Complete *OIA-335 WORKSHEET: Minutes Quality Improvement Assessment*, or equivalent, on a representative sample of the minutes within the time period for assessment selected by the OIA director or designee, typically the previous three months.

5.2.1 Track compliance and the number of days required to complete minutes and examine for trends.

5.2.2 Send the results to the OIA director and assistant director.

5.2.3 If the results of any evaluations demonstrate high variability, do not meet any established performance targets, or do not conform to the requirements of *OIA-043 SOP: IRB Meeting Minutes*, work with the OIA director, institutional official, or designee to implement an improvement plan.

5.3 Complete *OIA-602 DATABASE: Investigator Assistance Improvement Assessment*, or equivalent, on the online assistance request system from the time period for assessment selected by the OIA director or designee.

5.3.1     Track days required to close tickets and review scores for helpfulness, quality, and timeliness and examine for trends.

5.3.2     Track suggested improvements from research community and examine for trends.

5.3.3     Send the results to the OIA director and OIA leadership team.

5.3.4     If the results demonstrate high variability or do not meet any established performance targets, work with the OIA director, <u>institutional official,</u> or designee to implement an improvement plan.

5.3.5     If there is an identified need for a change, improvement, or other action from the suggested improvements, work with the OIA director, <u>institutional official,</u> or designee to consider an appropriate response.

## 6   MATERIALS

6.1    *OIA-001 SOP: Definitions*

6.2    *OIA-043 SOP: IRB Meeting Minutes*

6.3    *OIA-335 WORKSHEET: Minutes Quality Improvement Assessment*

6.4    *OIA-430 CHECKLIST: Staff Quality Improvement Assessment*

6.5    *OIA-602 DATABASE: Investigator Assistance Improvement Assessment*

## 7   REFERENCES

7.1    None