Quality Improvement in Research: A Demonstration of an On-Site Review

Kathleen Wessman, Director-OHSP QI

Jennifer Dolan, Associate-OHSP QI

09APR15

Objectives

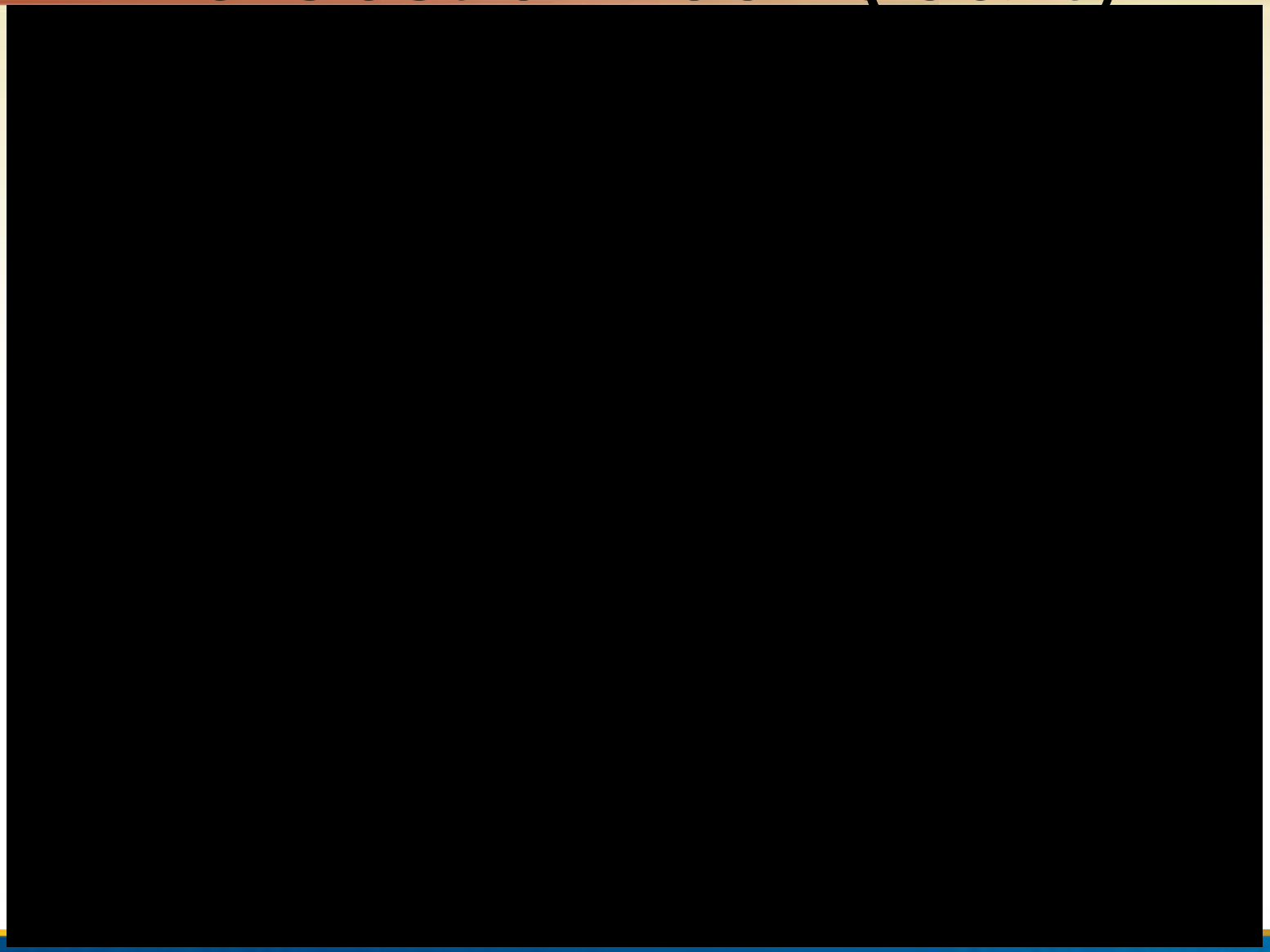
To understand:

- Why and how the OHSP Quality Improvement program works
- Why each study team member is an important part of the UR research quality improvement program
- What the processes are behind the OHSP-QI program

Why do Research QI Reviews exist?

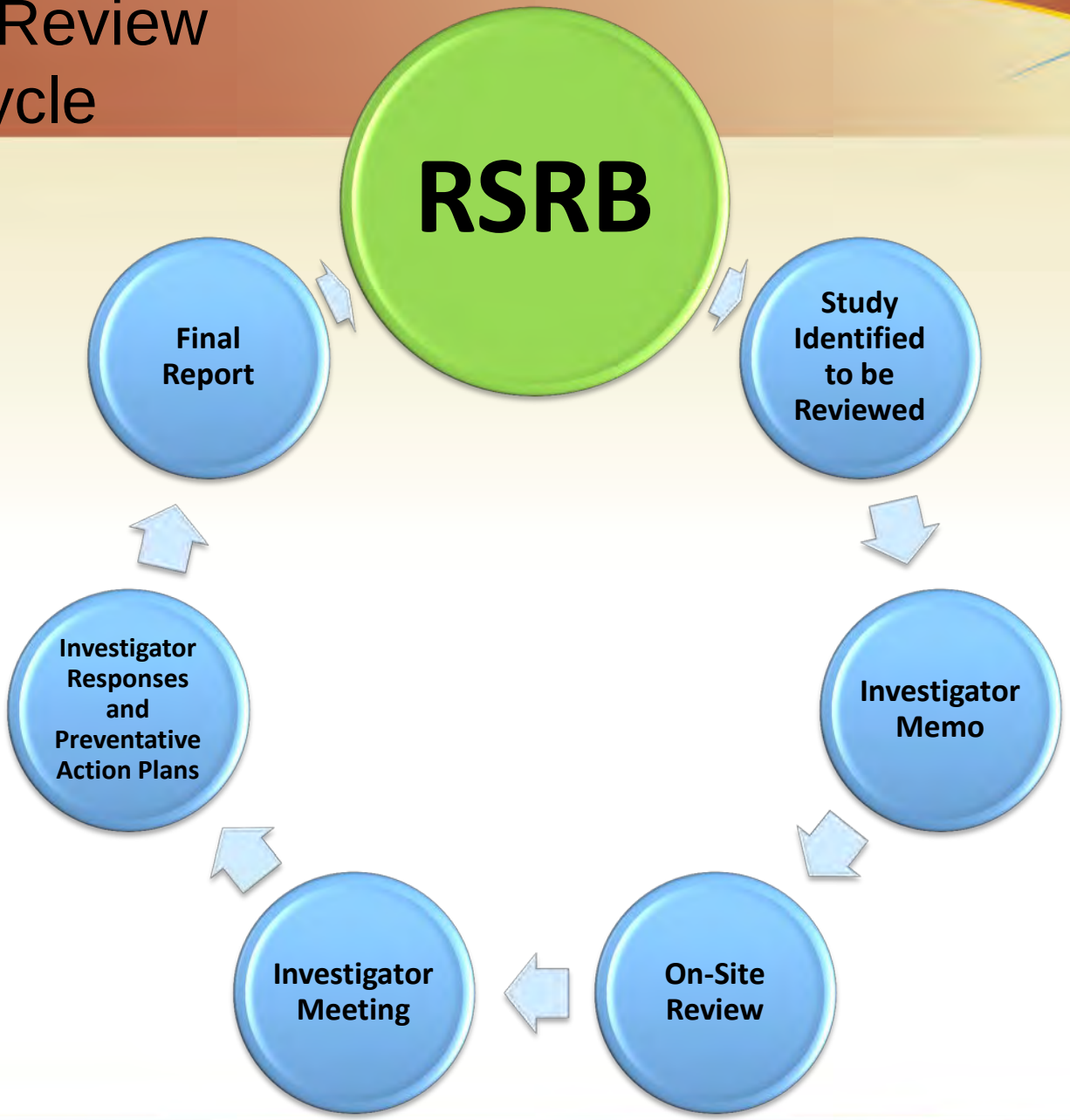
- To ensure the rights and well-being of human subjects are protected by assessing compliance to approval requirements
- To educate researchers about how to improve study conduct
- To provide resources to the Research Community

The Cost of Poor Quality



OHSP-QI Review Life Cycle

OHSP-QI Review Life Cycle



Investigator's Responsibility

How do Investigators know their responsibilities and what regulations apply?

- In general… OHSP ***Policy 901*** with associated summary pages
- By study…information will be on each **approval letter**

OFFICE FOR HUMAN SUBJECT PROTECTION

Research Subjects Review Board

UNIVERSITY of ROCHESTER

Letter of Initial Approval

RSRB: RSRB00012345 **Principal Investigator**: Dr. Ray Lyte

Study Title: Observing the Effect of Sunshine on Mood in Adults

Initial Approval: March 31, 2015

Approval Expires: March 23, 2016

Length of Review: 1 year

Level of Risk:

- Minimal Risk - Adults

Devices:
- XYZ

Non-significant Risk Device - NSR device studies must follow all the IDE regulations at 21 CRF 812.2(b)

Review Level: Full Board Meeting 3/24/2015

Expedite at next review - Category 9 - ***The research involves no greater than minimal risk and no additional risks have been identified at the meeting where the research is reviewed.***

Regulatory Findings Regarding Consent and HIPAA:

- There should be no documentation about this study in each subject's eRecord chart

List of Materials Approved by the RSRB: Protocol modified date 3/18/2015; consent form dated 3/18/2015; recruitment flyer modified date 3/30/2015; letter to patients modified date 3/30/2015

This study was reviewed and approved under the OHSP and UR policies, and in accordance with Federal regulations 45 CFR 46 under the University's Federalwide Assurance ([illegible]) and the Food and Drug Administration ([illegible]).

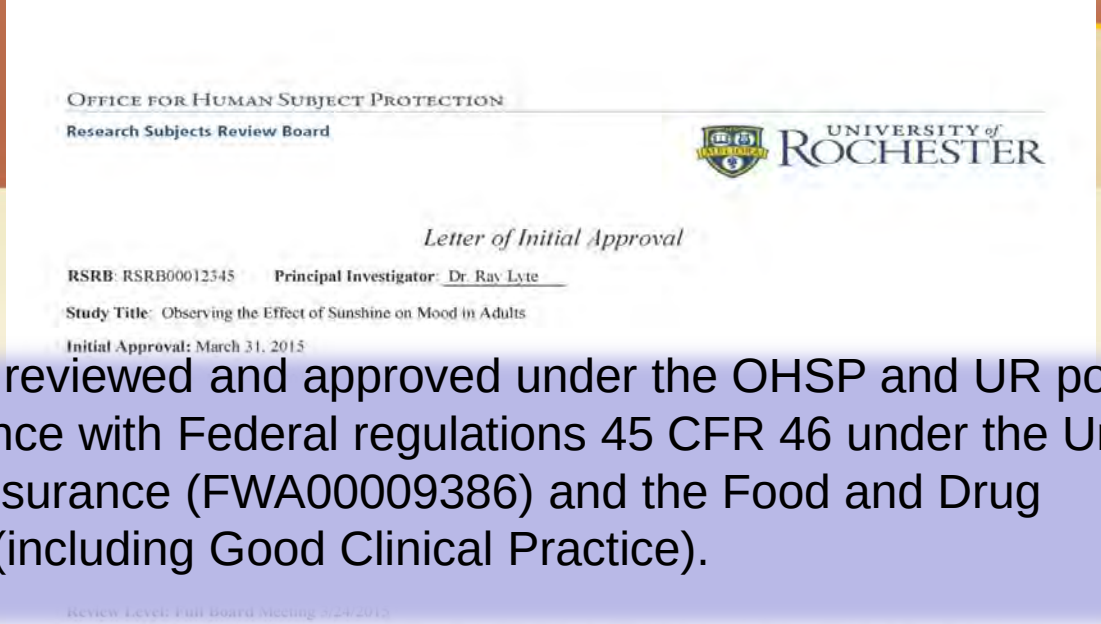
This approval is contingent upon the research being conducted in compliance with the approved study protocol including all requirements and/or determinations of the RSRB. Consent must be obtained and documented in the manner approved by the RSRB (unless a waiver of consent is specified above). Only the most currently approved version of consent forms and recruitment materials bearing an RSRB approved watermark may be used when obtaining consent and recruiting subjects. Consent forms/recruitment letters must be printed on department letterhead.

As the Principal Investigator, you are responsible for ensuring compliance with Policy 901 Investigator Responsibilities. Click here for the Summary of Responsibilities for Investigators. [illegible] unanticipated problems involving risks to subjects or others (including unexpected deaths, hospitalizations or serious injuries, breach of confidentiality, loss of privacy) must be reported according to Policy 801 Reporting Research Events.

All study documentation, including RSRB approved materials, should be maintained as required by applicable regulatory requirement(s). This includes all [illegible] signed consent form for at least three years after the research is completed (six years if protected health information was collected as part of the research), or for a longer term if required by FDA regulations or other contractual agreements.

Name, RSRB Chair March 31, 2015

Saunders Research Building - 265 Crittenden Blvd, Suite 1.250 - Box CU420628 - Rochester, NY 14642-0628
585.273.4127 - 585.273.1174 fax



OFFICE FOR HUMAN SUBJECT PROTECTION

Research Subjects Review Board

UNIVERSITY of ROCHESTER

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RSRB: RSRB00012345 **Principal Investigator**: Dr. Ray Lyte

Study Title: Observing the Effect of Sunshine on Mood in Adults

Initial Approval: March 31, 2015

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Regulatory Findings Regarding Consent and HIPAA:

- There should be no documentation about this study in each subject's eRecord chart

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This study was reviewed and approved under the OHSP and UR policies, and in accordance with Federal regulations 45 CFR 46 under the University's Federalwide Assurance (FWA00009386) and the Food and Drug Administration (including Good Clinical Practice).

As the Principal Investigator, you are responsible for ensuring compliance with Policy 901 Investigator Responsibilities. Click here for the Summary of Responsibilities for Investigators Conducting FDA Regulated Research. Also, any unanticipated problems involving risks to subjects or others (including unexpected deaths, hospitalizations or serious injuries, breach of confidentiality, loss of privacy) must be reported according to Policy 801 Reporting Research Events.

Notification Memo

OFFICE FOR HUMAN SUBJECT PROTECTION

UNIVERSITY of ROCHESTER

MEMORANDUM

TO: XXXXX, MD, PhD
Principal Investigator

FROM: Kelley O'Donoghue, MPH, CIP
Director, Office for Human Subject Protection

DATE: XXXXX

SUBJECT: Routine Internal Quality Improvement Review, RSRB #XXXXX

As part of its responsibilities under the University of Rochester's Human Subject Protection Program, the Office for Human Subject Protection (OHSP) has a quality improvement program that conducts routine on-site review of approved research. The intent is to provide an assessment of compliance with applicable regulations and requirements. Your study, RSRB #*XXXXX; TITLE*, has been selected for a routine review.

Studies are randomly selected from a sampling of research across the University. The studies selected may involve use of novel techniques, research without external monitoring systems, high subject enrollment or risk-based research or vulnerable populations. The intent of the review is to be cooperative and educational.

The study will be reviewed under the following regulations and/or guidelines:

- RSRB approved protocol/amendment(s),
- RSRB requirements,
- Good Clinical Practice,
- UR Policy,
- In accordance with applicable federal regulations, the Food and Drug Administration (FDA), and under the University's Federal Wide Assurance (45 CFR 46).

Kathleen Wessman and/or Jennifer Dolan will conduct this review and will contact you in the near future by email to schedule. You do not need to be present during the records review; you may delegate an individual (e.g., study coordinator or assistant) to provide access to the study documentation. However, if you do delegate this task, please note that as PI of the study, you must ensure that any and all necessary information and documents are provided in a timely fashion. If you have any questions, please contact Kathleen at 273-2118/Jennifer at 276-5709.

The intent of this on-site review is to replicate, in part, the types of reviews that could be conducted by a federal regulator or a study sponsor. Many of our investigators have found the process to be quite informative, either to confirm that appropriate study practices and procedures are being followed or to allow for the early detection and correction of problems or concerns when necessary.

Final Report

Final Quality Improvement Report - RSRB #XXXXX

This report is confidential. Please do not copy. If copies are required, please provide requests in writing. Controlled copies will be provided and then subsequently recovered at the end of their useful period for secured archival.

Executive Summary:
This greater than minimal/minimal risk study was selected for routine review under the Office for Human Subject Protection (OHSP) policy and guidelines. Funding is provided through the XXXXX via grant XXXXX. Vulnerable Populations included: XXX.

In accordance with OHSP Policy 1001, "Quality Improvement Program," the review findings for this site result in a rating[1] of:
[Utilize Ratings as defined by Policy 1001, as appropriate; remove this text]

- ☐ Commendable
- ☐ Acceptable
- ☐ Acceptable with Follow-Up
- ☐ Unacceptable

Findings are shared with the RSRB, who may take further action.

Brief Protocol Summary:
The purpose of this study is to evaluate XXXXX. This is a randomized controlled study involving XXXXX. Subjects are assigned randomly to XXXX and participate for XX months/years.

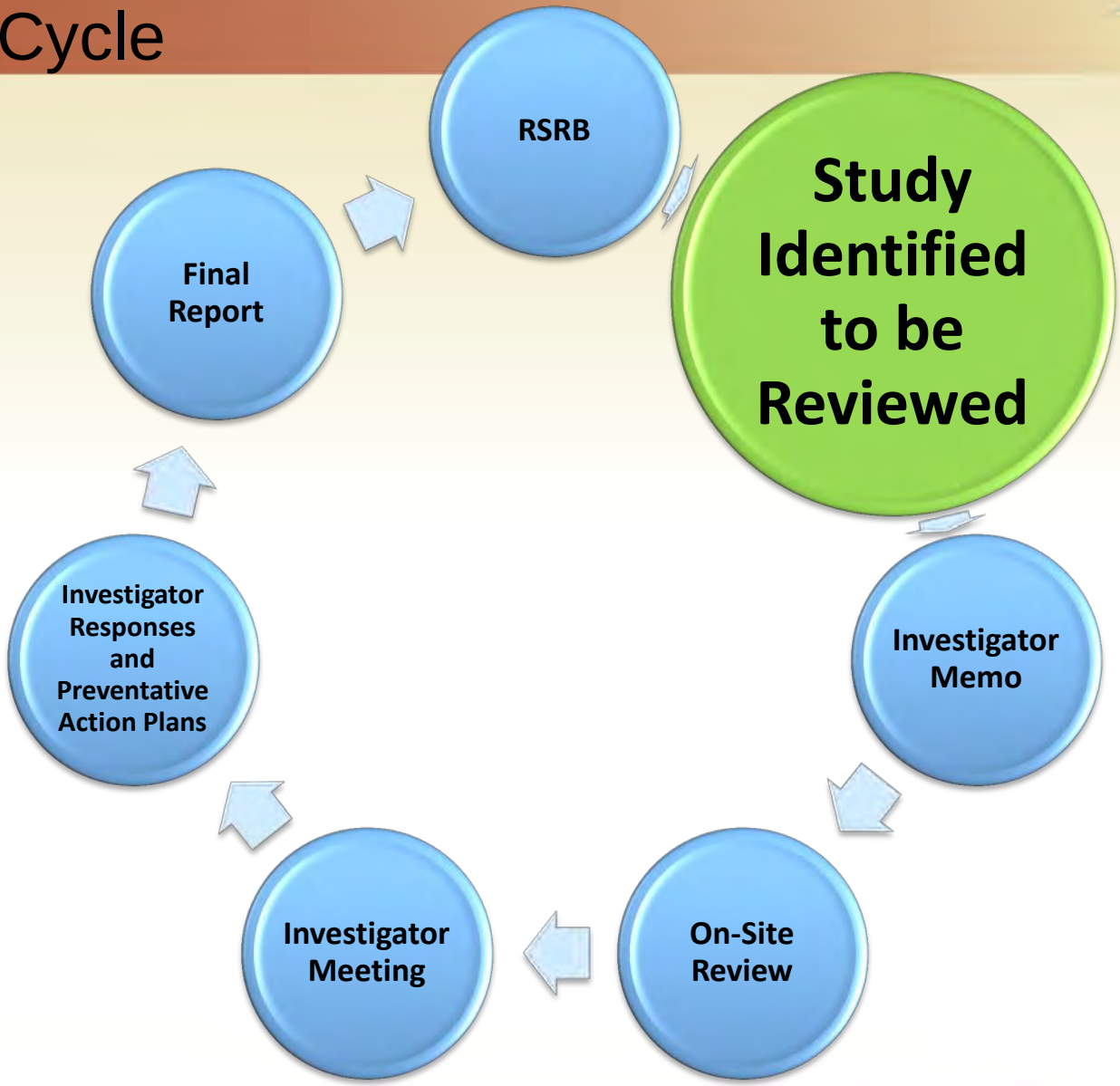
Scope:
The study was reviewed under the following regulations or guidelines:

- RSRB approved protocol/amendment(s),
- RSRB requirements,
- Good Clinical Practice,
- UR Policy,
- In accordance with applicable federal regulations, the Food and Drug Administration (FDA), and under the University's Federal Wide Assurance (45 CFR 46).

During the post-review meeting with the Principal Investigator (Investigator), the following topics were discussed:

1. OHSP Department structure, the selection and review process, and QI goals
2. Identification, reporting, and management of potential conflicts of interest
3. Investigator oversight of study activities
4. Documentation of compliance to the protocol and consent process
5. RSRB requirements of documentation of written consent
6. OHSP educational resources to support research

OHSP-QI Review Life Cycle



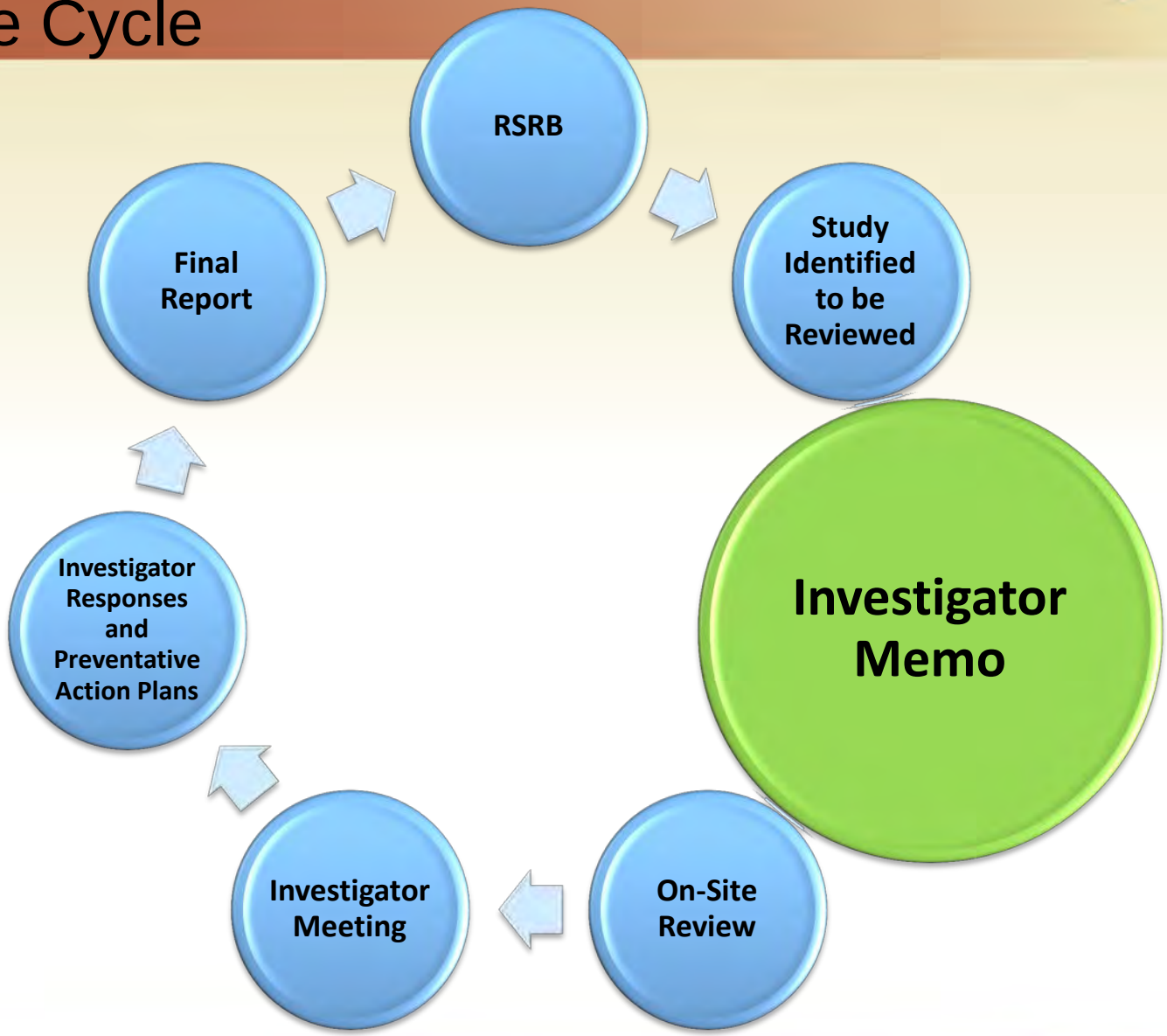
How Reviews are Identified

- **Routine (Random):**
  - Based on risk factors.
  - Approximately 80 annually.

- **Directed (For-Cause):**
  - Identified by the RSRB.
  - Approximately 15 annually.

- **Requested and Other:**
  - Requested by a member of the research team.
  - To meet grant or institutional requirements.
  - FDA/Sponsor audit preparation.
  - Related to our Federal Wide Assurance.
  - Approximately 6 annually.

OHSP-QI Review Life Cycle



Routine Review Letter to Investigator

OFFICE FOR HUMAN SUBJECT PROTECTION

UNIVERSITY of ROCHESTER

MEMORANDUM

TO: XXXXX, MD, PhD
Principal Investigator

FROM: Kelley O'Donoghue, MPH, CIP
Director, Office for Human Subject Protection

DATE: XXXXX

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The intent of this on-site review is to replicate, in part, the types of reviews that could be conducted by a federal regulator or a study sponsor. Many of our investigators have found the process to be quite informative, either to confirm that appropriate study practices and procedures are being followed or to allow for the early detection and correction of problems or concerns when necessary.

We urge you to participate fully in this review, and to promptly implement any recommendations contained in the final report when approved by the Board. The results of the review are treated by OHSP as confidential and, unless a report to internal/external offices is required, they are shared only with the parties listed below. You will be notified if others who may have a need to know receive copies.

Thank you in advance for your cooperation and support of the University's program for human subject protection.

For a description of the OHSP Internal Quality Improvement program, visit the website link:
http://www.rochester.edu/ohsp/quality/index.html

PI rights and responsibilities during the QI process:

You have the right to be present during the review and to transparency during the review process. You are encouraged to contact the reviewer with any questions you may have during the process. After reviewing the study documentation, a meeting with the reviewer is held at your convenience. During this meeting, study-specific processes at your site will be discussed and all potential findings will be shared. In addition, options to address any findings can be discussed. Shortly after this meeting, draft findings will be provided to you. Your written response and, if applicable, preventative action plan will be requested within a stated time frame.

You are responsible to provide timely written responses during the review process. Failure to do so may result in an unsatisfactory review. Because all QI Reports are reviewed by the RSRB, unsatisfactory site reviews may lead to actions on the part of the RSRB and/or the University. Per federal guidelines, some of these actions may require mandated reporting to federal agencies and study sponsors.

In the unlikely event that circumstances are identified that appear to put human subjects at risk, you will be notified promptly. I will also be notified immediately for a further assessment of risk. Immediate notification to and action by the RSRB may be required to prevent risk to human subjects.

cc: Kathleen Wessman, RN, MPA, CCRC - Director, Quality Improvement, OHSP
Jennifer Dolan, MS, LMT, CCRC - Associate, Quality Improvement, OHSP
Tiffany Gommel, MS, CIM, CIP - Executive Director, RSRB
XXXX - RSRB Chair
XXXX, CIP - RSRB Specialist
[X], MD, PhD - [Dept Chair/Chief/Director]

QI's Preparation

- Schedule the review with Investigator and site staff.
- Create a timeline of study from initial approval to current.
- Read and highlight important aspects of RSRB/WIRB application, protocol, consent forms, other study documents.
- Each review preparation takes about 2 hours.

How Should Site Staff Prepare?

- Select a time that works well for your site personnel.
- Gather all study documents (study-specific regulatory files including lab manual(s), investigational product files, and all subject research charts (including screen failures).
- Have Standard Operating Procedures available.
- Arrange for a work space for the Reviewer(s).
- You do not need to arrange access to eRecord.
- Don’t print anything stored electronically.

BUT…

- Be prepared to show any electronically stored items.

QI-2015 Plan

Goal

80 routine reviews

85% Medical Center

15% Campus

Risk Based Approach

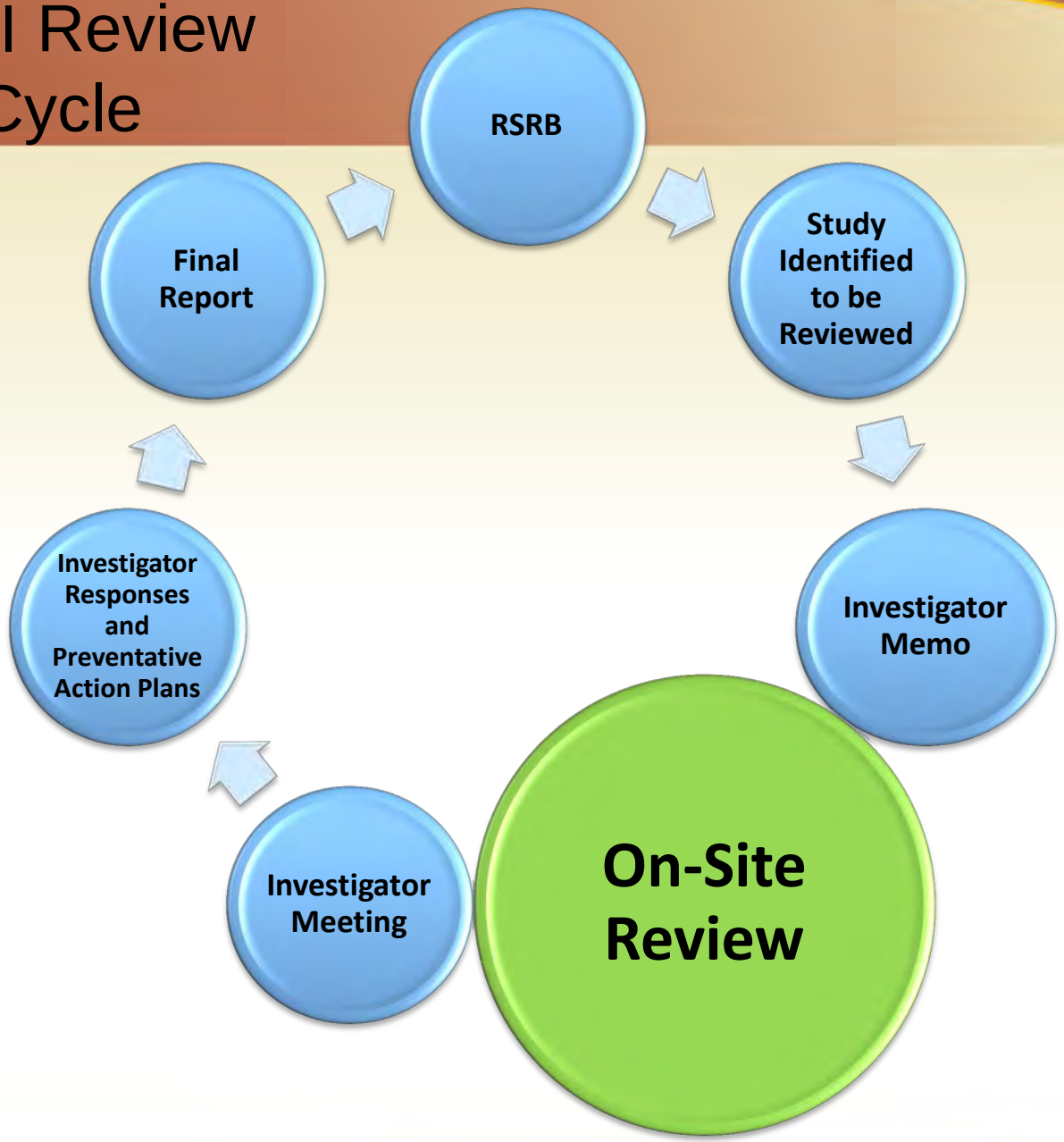
Primary Focus

- Phase 1 trials
- Investigator-initiated trials
- Investigators new to research
- Student Projects
- Electronic health record

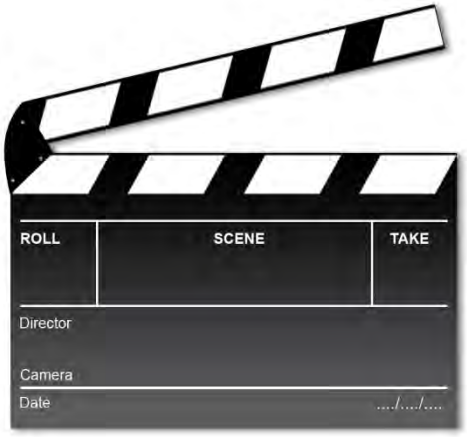
Secondary Focus

- Sites not previously reviewed
- UR Investigator-held INDs
- Vulnerable Populations
- No study coordinator
- Newly approved studies

OHSP-QI Review Life Cycle



Mock Review



What happens at an On-Site Review?

Actresses – in order of appearance

OHSP-QI Reviewer:	*Jennifer Dolan*
Study Coordinator:	*Margaret McGrath*, playing the role of 'Harmony Smith, RN'
Investigator:	*Kelly Unsworth*, playing the role of 'RayEllen Lyte, MD'

Regulatory File Review

Quality Improvement - Study Timeline

(OHSP Policy 901 Investigator Responsibilities:)

RSRB #: 54321 **PI:** Ray Lyte, MD

		Date Approved	In File	Protocol Change with date or version #	In File	Consent Form(s) with watermark date(s)	In File	Recruitment Material(s) with watermark date(s)	In File	Personnel (1.4-1.8, 85.1 of each ROSS Application)	Notes (need for reconsent, adds/deletions, Invest. Brochure, withdrawn amendments)
Initial Approval		15-Jan-10	✘	Protocol dated 1/2/2010	✘	Consent Form dated 1/2/2010 (WM cj)	✘	Recruitment Flyer (WM cj)		Ray Lyte (I), Harmony Smith (SC)	There should be no documentation about this study in each subject's eRecord chart.
Amendment	1	15-Feb-10	✘	Protocol dated 2/11/2010	✘	Consent Form dated 2/11/2010 (WM jd 2/15/10)	✘	iPod Flyer Cutout (WM jd 2/15/10)	✘	SS Jones (SC)	Revised study personnel; compensation; procedures; and recruitment. Editorial changes.
Amendment	2	19-Oct-10	✘							Sara Tonin (Pharm)	Added study personnel
Continuing Review	1	11-Jan-11	✘			Consent Form dated 11/18/2010 (WM jd 1/11/11)	✘				

DATE

Name
Address

The University of Rochester in Rochester, N.Y. is conducting a study entitled, Observing the Effect of Sunshine on Mood in Adults. This study is being conducted by Dr. Ray Lite, MD, PhD who is director of the Sunshine Research Center located at the University of Rochester. Dr. Lite is seeking individuals with great moods to participate in this study. According to our files, you may be eligible to participate. A description of the study is attached to this letter. If you are interested in this study, or if you would like more information, please contact Harmony Smith, the research study coordinator. You may reach me by telephone at 585-555-5555.

Thank you for your continued support of our research!
Sincerely,
Harmony Smith, BA
Study Coordinator

The protocol-specified Data Safety Monitoring Committee will meet yearly from initial approval until present.

Expected Data Safety Monitoring Committee Meeting Letters:

2010 ✗

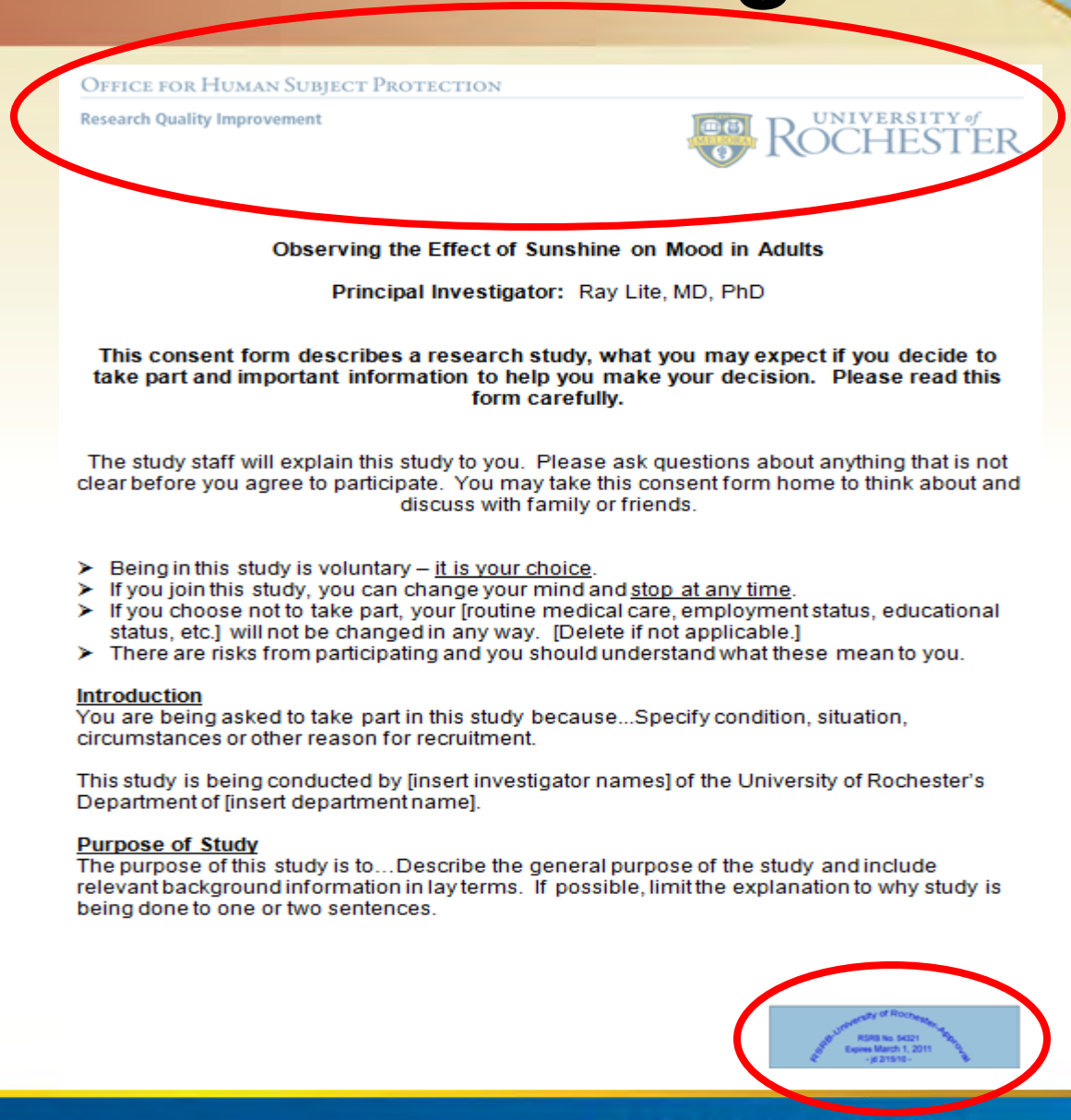
2011 ✗

2012 _____

2013 ✗

Consent Form Finding

Watermark/Letterhead?



OFFICE FOR HUMAN SUBJECT PROTECTION

Research Quality Improvement

UNIVERSITY of ROCHESTER

Observing the Effect of Sunshine on Mood in Adults

Principal Investigator: Ray Lite, MD, PhD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your [routine medical care, employment status, educational status, etc.] will not be changed in any way. [Delete if not applicable.]
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because...Specify condition, situation, circumstances or other reason for recruitment.

This study is being conducted by [insert investigator names] of the University of Rochester's Department of [insert department name].

Purpose of Study

The purpose of this study is to...Describe the general purpose of the study and include relevant background information in lay terms. If possible, limit the explanation to why study is being done to one or two sentences.

Consent Form Finding

Watermark/Letterhead?

Dates congruent? ✗

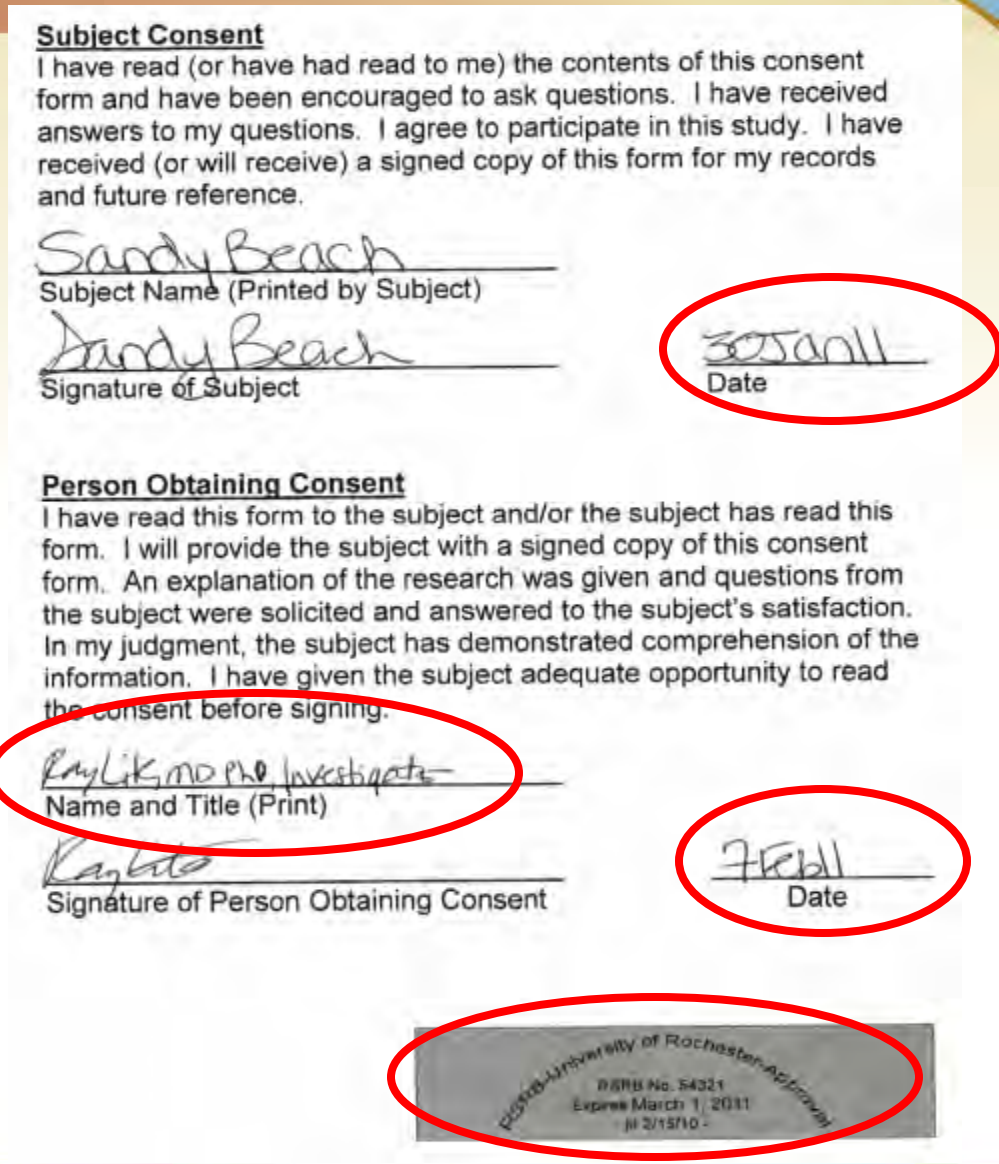
Original signatures in indelible ink?

Staff RSRB-approved?

Watermark valid?

Version correct? ✗

Options complete?



Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Sandy Beach
Subject Name (Printed by Subject)

Sandy Beach
Signature of Subject

30 Jan 11
Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

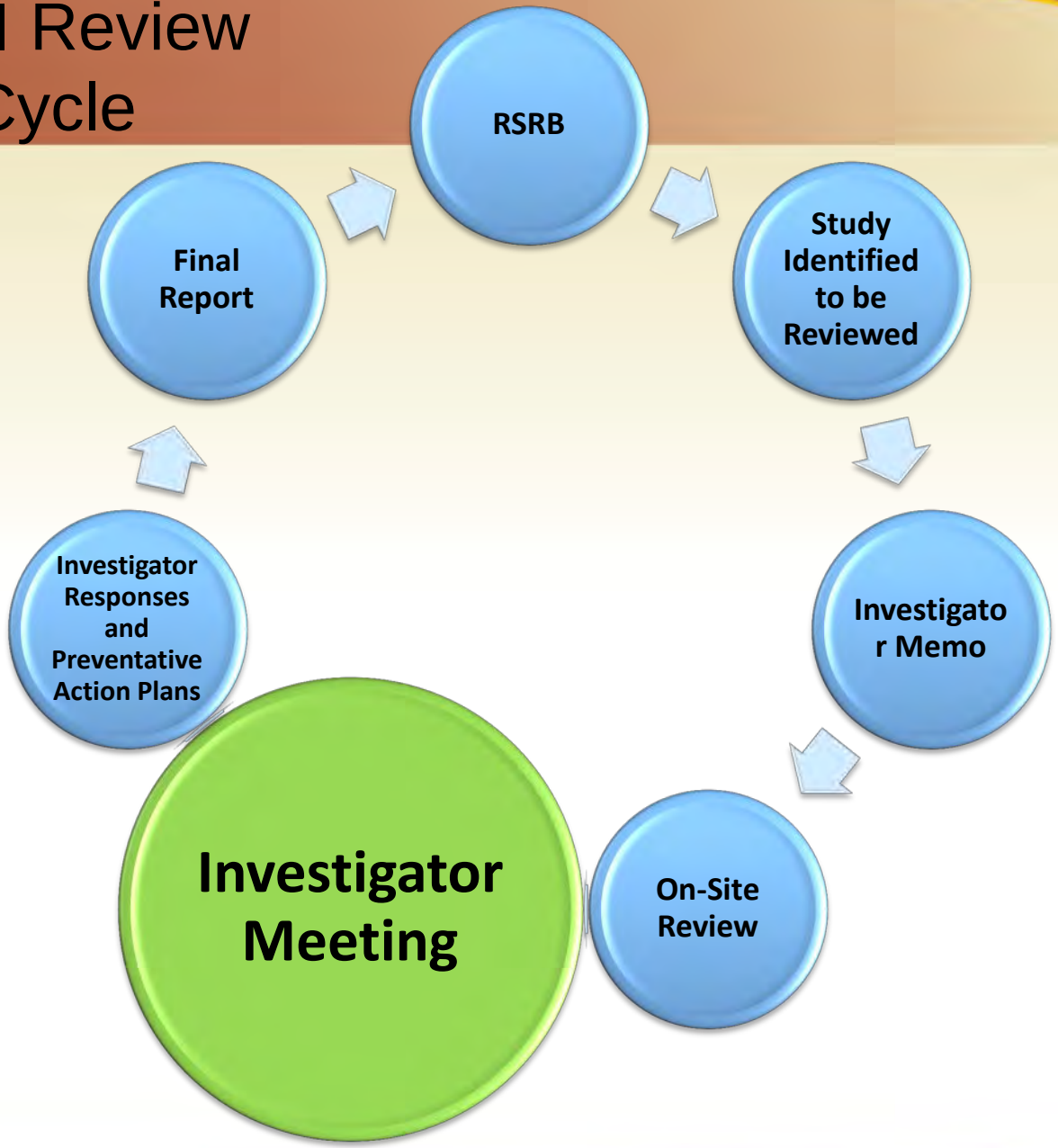
Ray Liu MD PhD Investigator
Name and Title (Print)

Ray Liu
Signature of Person Obtaining Consent

7 Feb 11
Date

RSRB-University of Rochester-Approved
RSRB No. 54321
Expires March 1, 2011
jn 2/15/10

OHSP-QI Review Life Cycle



Investigator's Meeting

In addition to the Review Findings, the following items are discussed during the post-review debriefing meeting with the Investigator.

- OHSP Department structure, the selection and review process, and QI goals
- Identification, reporting, and management of potential conflicts of interest
- Investigator oversight of study activities
- Documentation of compliance to the protocol and consent process
- RSRB requirements of documentation of written consent
- OHSP educational resources to support research

Review Findings Are:

1. The following item was not present in the Regulatory File:
   - Recruitment Flyer, Initial approval (15JAN10)

2. Documentation of the Data Safety Monitoring Committee meeting for 2012 was not present in the Regulatory File.

Review Findings Are: (continued)

3. a. The date of the subject's signature on the consent form (30JAN11) and the date of the person obtaining consent's signature (07FEB11) are not congruent. The RSRB-approved consent process indicates consent will be obtained by study staff in person on the same day and before study procedures begin, therefore it is expected that the dates would be the same.

b. The signed consent form was the incorrect version; there were administrative differences between the two consents.

Common OHSP-QI Findings

Regulatory Items: 71%

Consent Form Errors: 42%

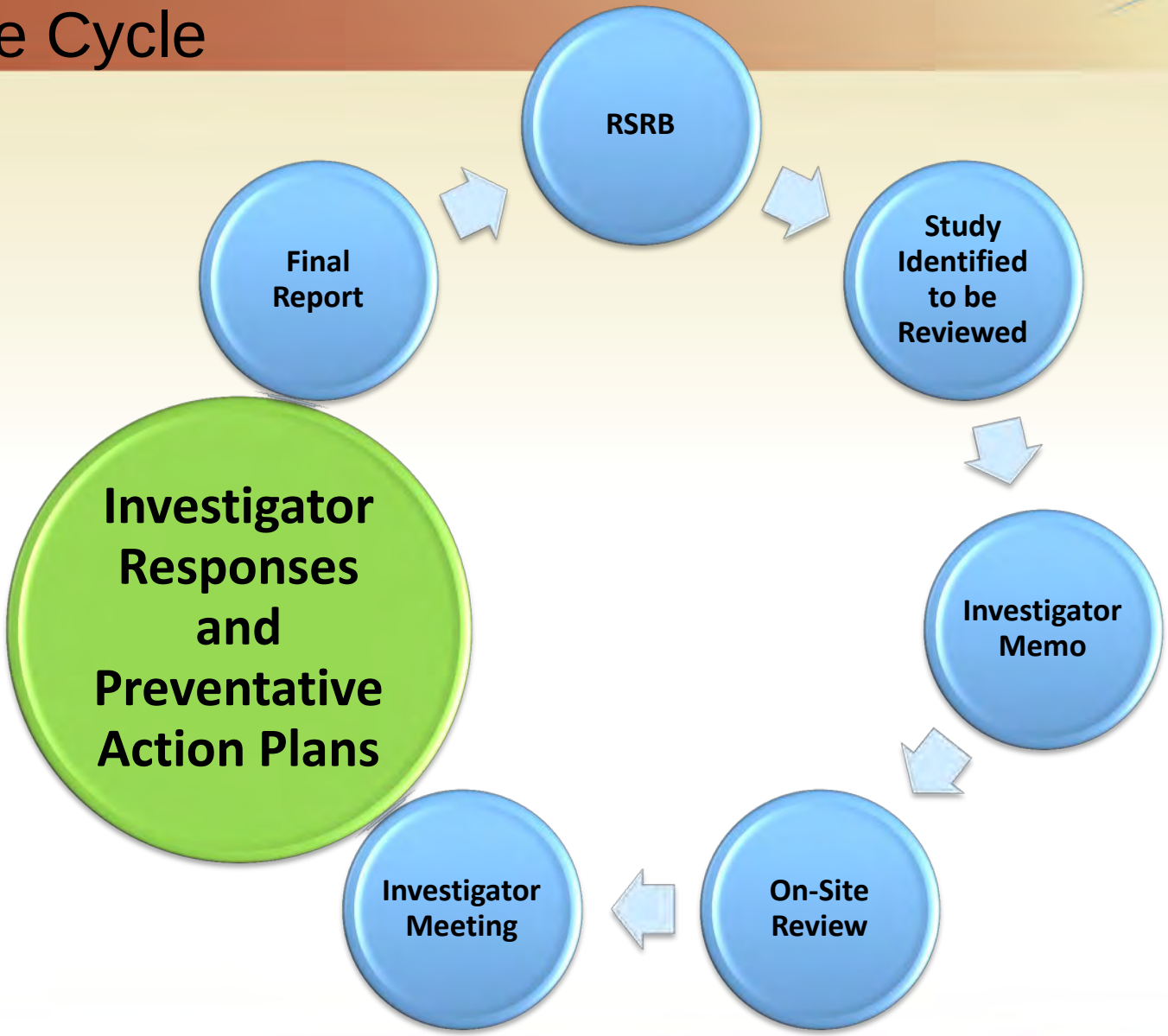
Adverse Event/Data Safety Monitoring Plan (GMR only): 32%

Protocol Adherence: 18%

Drug/Randomization: 8%

Source Documentation: 8%

OHSP-QI Review Life Cycle



Tips for Investigator Response Completion:

Investigator's response: Explain specifically why a finding occurred – what was the root cause?

For example, Missing Data: Explain exactly why the data is missing – data management error, subject refused to answer, subject inadvertently missed the questions, etc.

Investigator's preventative action plan: Be specific – use a simple, measurable solution to address the root cause.

Training is/can be a portion of your plan but not the only aspect.

How will you and your staff prevent reoccurrence?

For example, Regulatory File document(s) missing: "A Study Coordinator from another study will cross-check regulatory files annually."

This 'blue' section is not a part of your final report and will be removed by QI staff upon completion of the finding section.

Tips for Completion:

Investigator's response: Please explain specifically why a finding occurred – what was the root cause? For example, Missing Data: Explain exactly why the data is missing – data management error, subject refused to answer, subject inadvertently missed the questions, etc.

Investigator's preventative action plan: Again, please be specific – use a simple, measurable solution to address the root cause. Training is/can be a portion of your plan but not the only aspect. How will you and your staff prevent reoccurrence? For example, Regulatory File document(s) missing: "A Study Coordinator from another study will cross-check regulatory files annually."

For more guidance and information related to preparing corrective and preventative action (CAPA) plans, refer to the following OHSP seminar entitled "CAPA Plans: Solutions, not Blame" dated 2/25/2014, which includes a video recording.

This information is available on the OHSP website under Seminar Materials at:
www.rochester.edu/ohsp/education/seminars/seminarMaterialsDownload.html

Draft Findings, RSRB #XXXXX

The study was reviewed under the following regulations and/or guidelines:

- RSRB approved protocol/amendment(s),
- RSRB requirements,
- Good Clinical Practice,
- UR Policy,
- in accordance with applicable federal regulations, the Food and Drug Administration (FDA), and under the University's Federal Wide Assurance (45 CFR 46).

Review Findings:

Below is a list of findings identified during the review, and the Investigator's responses and corrective and preventative plans.

Preferred wording: Please refer to QI Finding Index file.

I. General Comments:

1. The Regulatory File was comprehensively reviewed.
2. Enrollment continues for this study. OR Enrollment is complete for this study.
3. The site reported XX subjects consented to participate in the study; XX subjects are in active treatment, XX subjects completed, XX withdrew consent, XX failed screening, and XX subject was lost to follow-up.
4. A comprehensive research chart review was completed for a random sample of XXXX subjects.
5. A sample of XX subjects underwent full review/consent form review. A total of XX consent forms were signed by the XX subjects and reviewed.
6. Site documentation was in accordance with RSRB requirements in the reviewed research charts. / Consent documentation is not in accordance with RSRB requirements in the reviewed consent forms (see Specific Subject Research Chart Findings below).
   - Consent was obtained prior to study procedure initiation.
   - Current and approved consent forms were used for each subject reviewed.
7. The protocol-specified Data Safety Monitoring Plan requirements were met and were fully documented. / The Data Safety Monitoring Plan did not meet the protocol-specific expectations of the PI performing a cumulative review of Adverse Events and XXX.
8. Adverse events were assessed for all reviewed subjects, as demonstrated by documentation. / There is no documentation to indicate assessment of adverse events for any subject.

II. Regulatory File Findings:

1. Consider findings related to the Regulatory binder, general consent process, study personnel, enrollment during a lapse etc:

Investigator's response:
Investigator's preventative action plan:

2. XX

Investigator's response:
Investigator's preventative action plan:

III. General Subject Research Chart Findings:

1. XX

Investigator's response:
Investigator's preventative action plan:

IV. Specific Subject Research Chart Findings:

1. Subject # / initials (consented on: XXX): XX

Investigator's response:
Investigator's preventative action plan:

2. Subject # / initials (consented on: XXX): XX

Investigator's response:
Investigator's preventative action plan:

3. Subject # / initials (consented on: XXX): XX
   a. XX
   b. XX

Investigator's response:
Investigator's preventative action plan:

Regulatory File Finding

Investigator's response: The recruitment flyer was inadvertently left out of the regulatory file.

Investigator's preventative action plan: The study coordinator has been educated as to what should be included in the regulatory binder. At the time of continuing review, the regulatory coordinator will review the binder for completeness. The Investigator will also review the documentation twice per year.

Data Safety Monitoring Committee Finding

Investigator's response: The meeting letter was inadvertently left out of the regulatory file.

Investigator's preventative action plan: An internal audit was conducted by the Investigator and study coordinator to ensure all Data Safety Monitoring Committee letters are present. The study coordinator will be responsible for documenting the yearly DSMC reviews and quarterly internal audits.

Consent Form Finding

Investigator's response: The wrong version of the consent form was an oversight. The incongruent dates is a result of the consent form being mailed to the subject and then brought in during the next clinic visit.

Investigator's preventative action plan: When a new consent form is approved, the study coordinator will collect and destroy all other blank copies at the clinic. If a consent form is mailed to the subject and they inadvertently sign the copy, we will re-consent the subject on the day of the clinic visit.

Helpful Hints for Completing Corrective Actions

- Step back and look at the ‘Big Picture’.
- Does your Response/CAPA make sense?
- Be realistic.
- Commit to what you can do.
- **Document** what you said you would do.

‘Does the punishment fit the crime?’

UR Lawyer quote:

“Defense against a claim is documentation”

“Strive for 10”

It is summed up well by observing that we are all striving for that perfect ‘10’.

However:

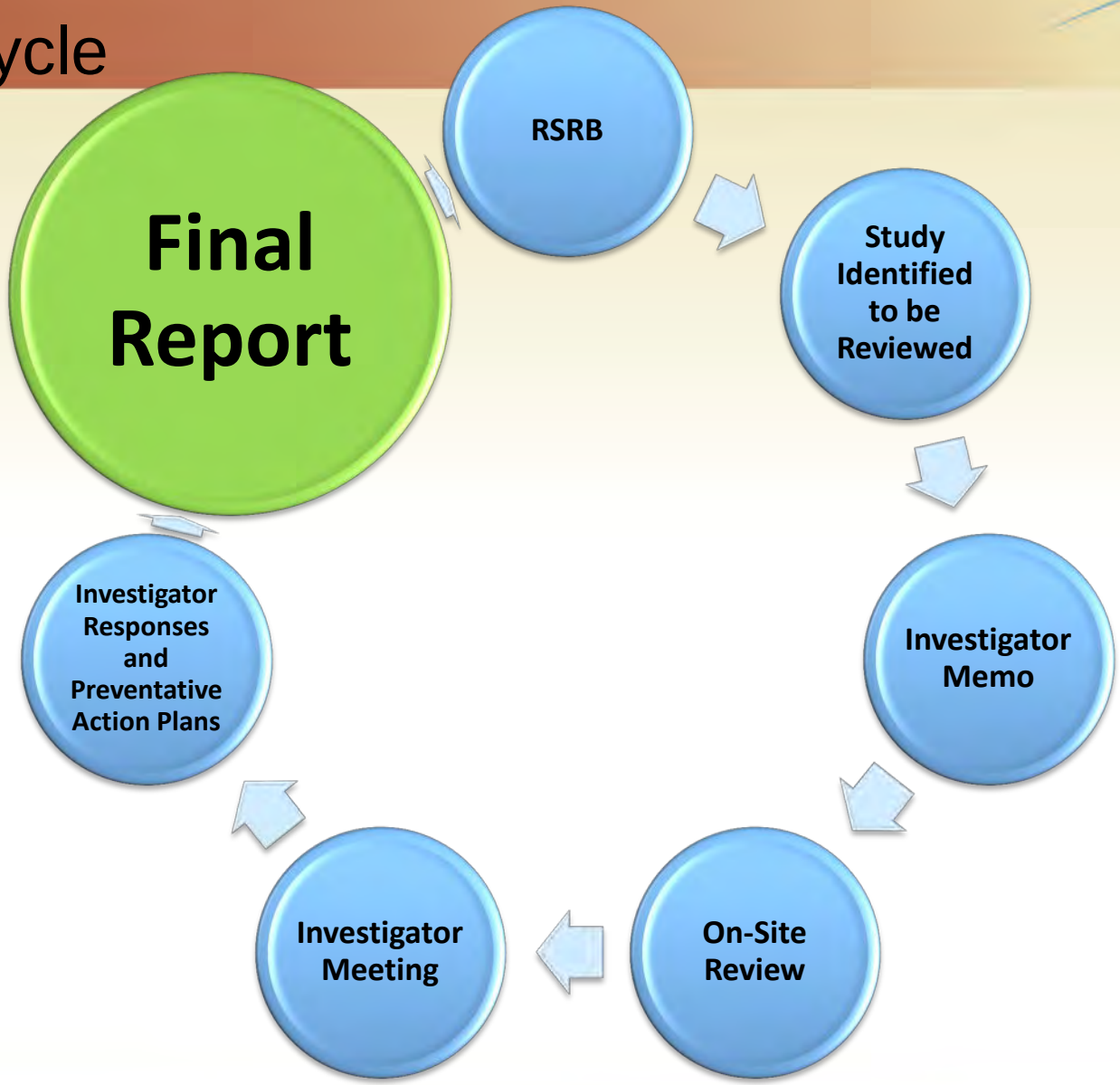
6+4=10

7+3=10

5+5=10

Bottom line, there are many ways to demonstrate compliance to that level of ‘10’.

OHSP-QI Review Life Cycle



UNIVERSITY of ROCHESTER

Report Finalized and sent to RSRB On: XXXXX

Final Quality Improvement Review Report **CONFIDENTIAL**

Review of: RSRB #XXXXX

Protocol Title: XXXXX

Issued to: XXXXX, MD, PhD (Principal Investigator)

Notification of Review Sent On: XXXXX
Review Conducted On: XXXXX
Investigator Exit Discussion: XXXXX
Draft Findings to Investigator: XXXXX
Investigator Response Received On: XXXXX

Research Site Staff Physically Present During Review: XXXXX
XXXXX
XXXXX
Research Site Staff involved in Exit Interview: XXXXX
XXXXX
XXXXX

Review Conducted By:

Kathleen Wessman RN

Jennifer Dolan

Kathleen Wessman, RN, MPA, RQAP-GCP, CCRC
Director, Research Quality Improvement
Office for Human Subject Protection

Jennifer Dolan, MS, LMT, CCRC
Associate, Research Quality Improvement
Office for Human Subject Protection

Saunders Research Building • 265 Crittenden Blvd • Box CU420628 • Rochester NY, 14642 • 585.275.2388

This report is confidential. Please do not copy. If copies are required, please provide requests in writing. Controlled copies will be provided and then subsequently recovered at the end of their useful period for secured archival.

Executive Summary:
This greater than minimal/minimal risk study was selected for routine review under the Office for Human Subject Protection (OHSP) policy and guidelines. Funding is provided through the XXXXX via grant XXXXX. Vulnerable Populations included: XXX.

In accordance with OHSP Policy 1001, "Quality Improvement Program," the review findings for this site result in a rating[i] of:
[Utilize Ratings as defined by Policy 1001, as appropriate; remove this text]

- ☐ Commendable
- ☐ Acceptable
- ☐ Acceptable with Follow-Up
- ☐ Unacceptable

Findings are shared with the RSRB, who may take further action.

Brief Protocol Summary:
The purpose of this study is to evaluate XXXXX. This is a randomized controlled study involving XXXXX. Subjects are assigned randomly to XXXX and participate for XX months/years.

Scope:
The study was reviewed under the following regulations or guidelines:

- RSRB approved protocol/amendment(s),
- RSRB requirements,
- Good Clinical Practice,
- UR Policy,
- In accordance with applicable federal regulations, the Food and Drug Administration (FDA), and under the University's Federal Wide Assurance (45 CFR 46).

During the post-review meeting with the Principal Investigator (Investigator), the following topics were discussed:

1. OHSP Department structure, the selection and review process, and QI goals
2. Identification, reporting, and management of potential conflicts of interest
3. Investigator oversight of study activities
4. Documentation of compliance to the protocol and consent process
5. RSRB requirements of documentation of written consent
6. OHSP educational resources to support research

Review Findings and Findings:
Below is a list of findings identified during the review, and the Investigator's responses and planned preventative actions.

[INSERT INVESTIGATOR'S COMPLETED FINDINGS/RESPONSES; remove this text.]

Follow-up:
This review found the findings noted above, which did not reveal an increased risk to human subjects. The Investigator's responses were determined to be adequate, and no further follow-up is planned for quality improvement purposes.

The Investigator is responsible for implementation of preventative actions for the findings and findings as stated. The Investigator is also responsible for continued adherence to protocol, regulations, and good clinical practice.

Upon review of this report, the RSRB will make the final determination regarding any corrective measures.

Attachments: Appendix A: XXXX

cc: Kelley O'Donoghue, MPH, CIP - Director, OHSP
Tiffany Gommel, MS, CIM, CIP - Executive Director, RSRB
Kathleen Wessman, RN, MPA, RQAP-GCP, CCRC - Director, Quality Improvement, OHSP
Jennifer Dolan, MS, LMT, CCRC - Associate, Quality Improvement, OHSP
[X] - RSRB Chair
[X], CIP - RSRB Specialist
[X], MD, PhD - [Dept Chair/Chief/Director]

[Utilize Ratings as defined by Policy 1001 as appropriate; update table and remove this text]

[i]

Commendable	• No deficiencies identified in a study with consent requirements and with enrolled subjects.
Acceptable	• Lesser deficiencies are identified that do not appear to involve risk to subjects. • No deficiencies and no local accrual however, accrual is possible.
Acceptable with follow-up	• Multiple lesser deficiencies are identified. • Any deficiency in which potential risk to subjects needs further consideration. • Self-reported deficiencies identified to the RSRB and being addressed prior to the conclusion of the review.
Unacceptable	• No response from the Investigator during the review process after a reasonable effort has been made by the reviewer. • Major deficiencies are identified. • A single major deficiency which impacts human subject safety/welfare is identified.

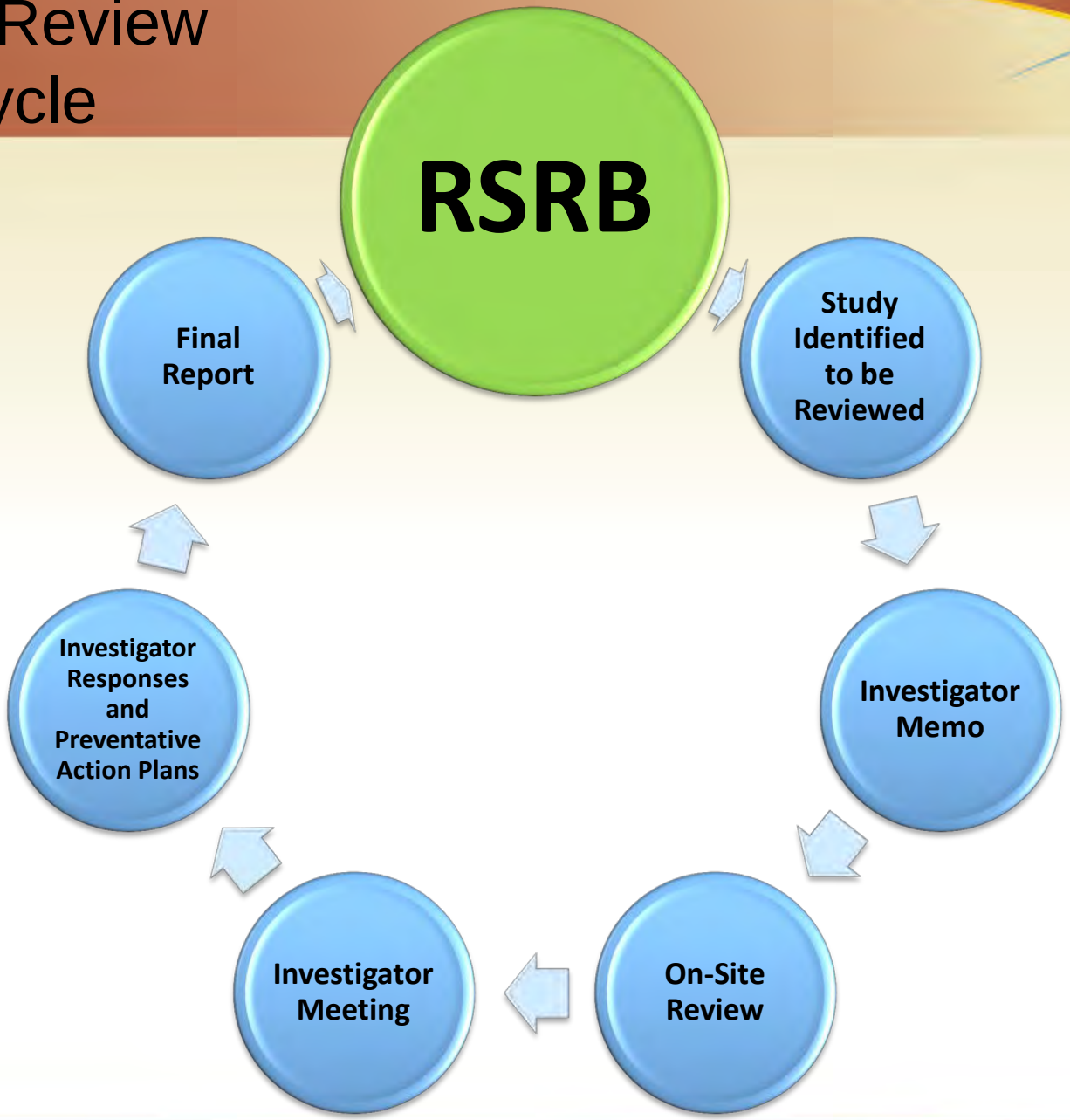
QI Review Report – Ratings

Commendable	• No deficiencies identified in a study with consent requirements and with enrolled subjects.
Acceptable	• Lesser deficiencies are identified that do not appear to involve risk to subjects. • No deficiencies and no local accrual however, accrual is possible. • No deficiencies identified in a study without consent requirements.
Acceptable with follow-up	• Multiple lesser deficiencies are identified. • Any deficiency in which potential risk to subjects needs further consideration. • Self-reported deficiencies identified to the IRB and being addressed prior to the conclusion of the review.
Unacceptable	• No response from the Investigator during the review process after a reasonable effort has been made by the reviewer. • Major deficiencies are identified. • A single major deficiency which impacts human subject safety/welfare is identified. • One or more missing consent form(s).

Each Review cycle takes OHSP-QI approximately…

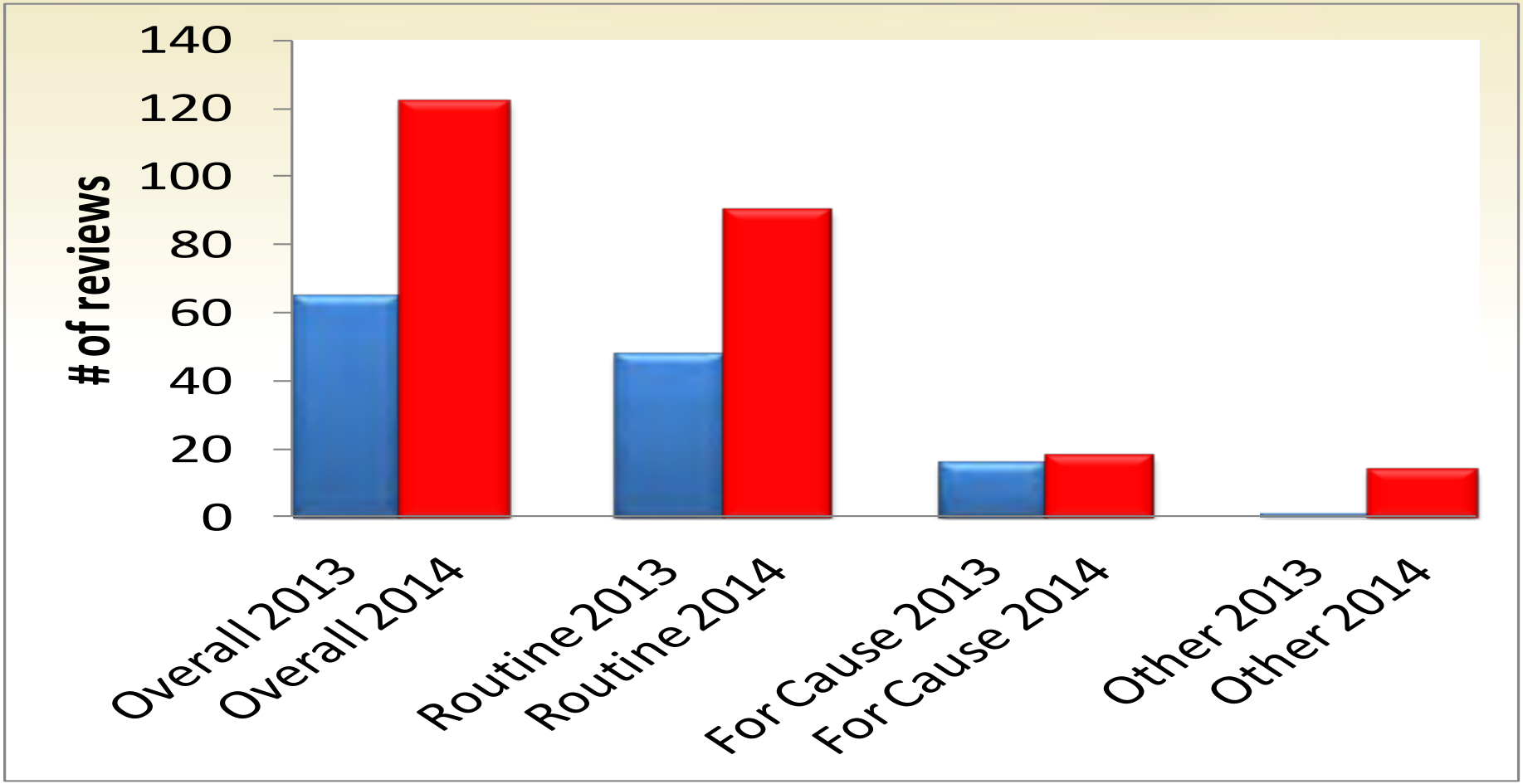
….20 hours to complete.

OHSP-QI Review Life Cycle

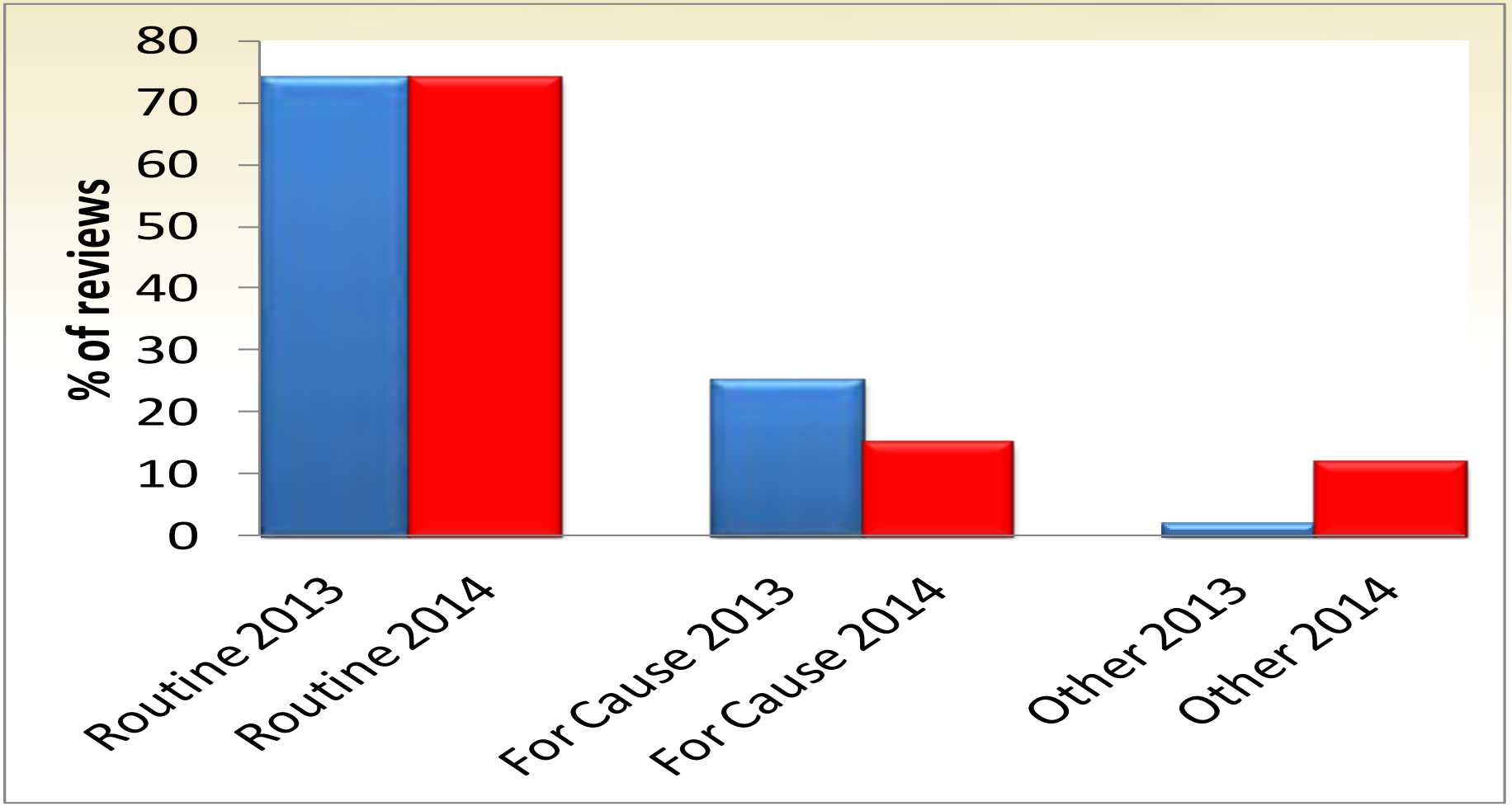


OHSP-QI Review Life Cycle

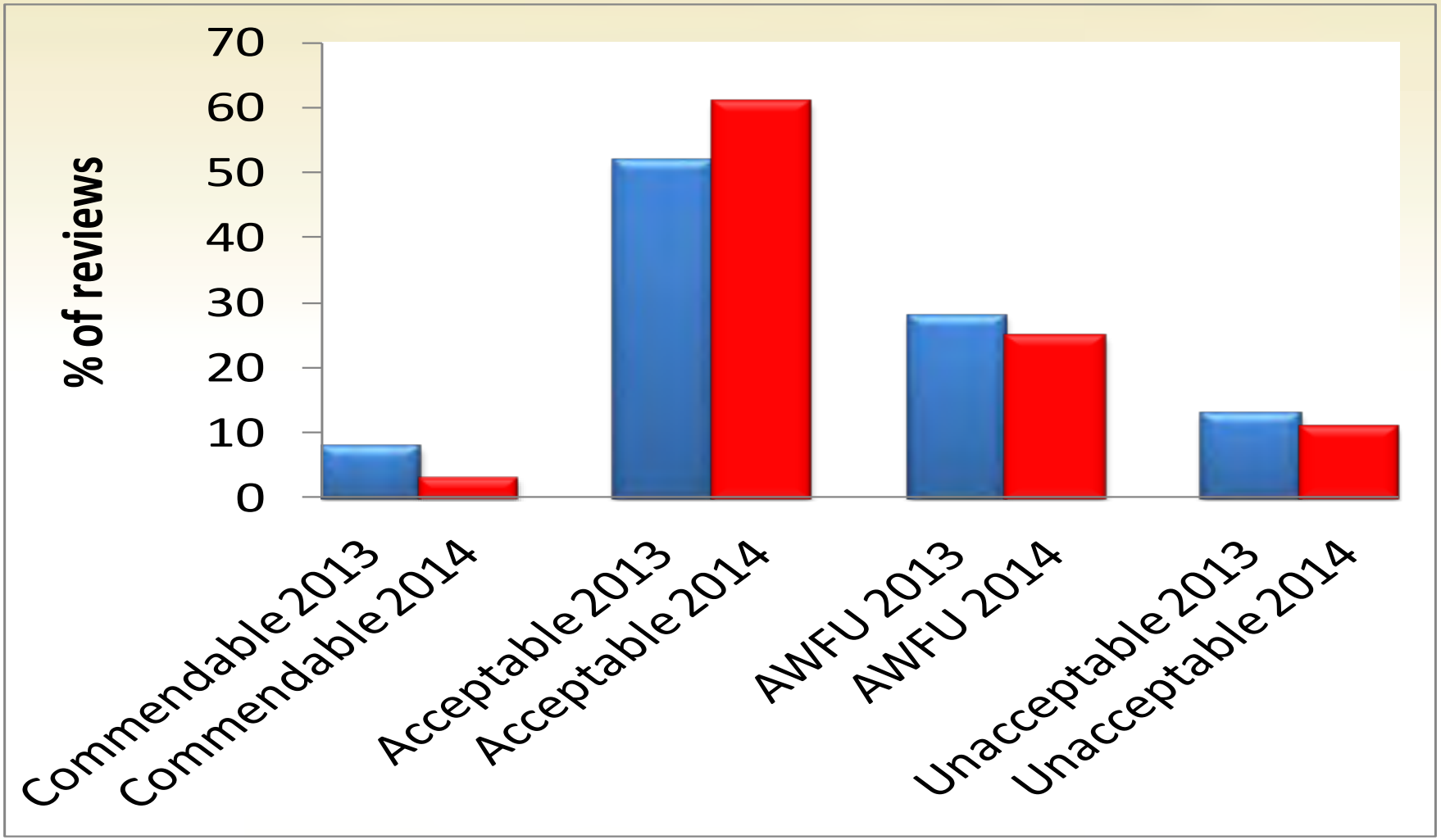
of Reviews


140
120
100
80
60
40
20
0
# of reviews
Overall 2013
Overall 2014
Routine 2013
Routine 2014
For Cause 2013
For Cause 2014
Other 2013
Other 2014

Type of Reviews



Ratings


% of reviews
70
60
50
40
30
20
10
0
Commendable 2013
Commendable 2014
Acceptable 2013
Acceptable 2014
AWFU 2013
AWFU 2014
Unacceptable 2013
Unacceptable 2014

Post-Review Feedback Survey

- 108 surveys completed after routine reviews
- 57% of respondents are study coordinators
- Over 90% agree:
  - ❖ the Reviewer's recommendations were helpful, constructive, relevant, and achievable.
  - ❖ the review process was helpful in identifying and improving study related procedures/processes.
  - ❖ were satisfied with the overall experience

Top 5 Tips to 'Survive' a Review

1. **Be Prepared; double check the study documentation before the reviewer arrives.**
2. **Know your protocol.**
3. **Be a partner in the process, and be a part of the solution.**
4. **If you know of issues, notify the reviewer upon arrival.**
5. **Ask questions.**

Consider….

A Study Start-Up Consultation

What?	An OHSP-QI consultation after obtaining RSRB-approval and before subject enrollment
Who?	Any site can request
When?	Usually within 2 weeks of your request
Why?	To review all study start-up documentation; to work with the Investigator/staff to identify and apply applicable regulations and policies.
Where?	Your location or OHSP office

Resources

- OHSP QI Policy 1001

- The OHSP Quality Improvement Website which includes Self-Audit Tools.

- Corrective and preventative action (CAPA) plan guidance and information: OHSP seminar entitled “CAPA Plans: Solutions, not Blame” dated 2/25/2014, which includes a video recording.

- The Cost of Quality video: http://media.asq.org/109163/web.mp4

Special Thanks to…

Margaret McGrath, RN – Research Nurse, Infectious Disease

Kelley O'Donoghue, MPH, CIP - Director, OHSP

Kelly Unsworth, MS, CCRC, CIP - Director, OHSP Education & Training

Questions