Mission / Purpose

The purpose of the Office for Research Compliance (ORC) is to provide internal oversight on compliance relating to the performance of research and scholarly activities including human and animal research, conflict of interest, export control, responsible conduct of research, and scientific misconduct. ORC emphasis is to ensure the rights and well being of human and animal subjects, ensure regulatory compliance, support our investigators and staff, protect the University and advance science.

Goals

G 1: ORC Purpose and Goal

The purpose of the Office for Research Compliance (ORC) is to provide internal oversight on compliance relating to the performance of human and animal research, conflict of interest, scientific misconduct and export control. ORC emphasis is to ensure the rights and well being of human and animal subjects, ensure regulatory compliance, support our investigators and staff, protect the University and advance science. Enhancement of the programs managed within the ORC is part of the overall University strategic goals related to research and service.

Other Outcomes, with Any Associations and Related Measures, Targets, Findings, and Action Plans

OthOtcm 1: An Effective Human Subjects Research Program

An Effective Human Subjects Research Program will include: Demonstrated expertise in IRB policies and procedures by IRB members and ORC staff; the provision and maintenance of a high quality level of education in the protection of human subjects in research and process that enable faculty, staff and students to conduct research in a timely and efficient manner. The ORC strives to create a culture of respect for, and awareness of, the rights and welfare of human research participants, while advancing knowledge and facilitating the highest quality research.

Connected Document
Office of Research Compliance Assessment Timetable

Relevant Associations:
The ORC strives to create a culture of respect for, and awareness of, the rights and welfare of human research participants, while advancing knowledge and facilitating the highest quality research.

Related Measures

M 1: Assessment of IRB member retreat
Assessment of IRB member retreat
Source of Evidence: Activity volume

Target:
The target is to get > 50% of IRB members to attend the annual member retreat. The retreat is used to provide training on federal regulations, university policy and techniques for review of applications.

Related Action Plans (by Established cycle, then alpha):

IRB Member Retreat and other IRB educational initiatives
Established in Cycle: 2013-2014
The IRB Member retreat is an annual event sponsored by the ORC to provide IRB members with information to further demonstrate ...

For full information, see the Details of Action Plans section of this report.

M 2: IRB member self evaluation
IRB member self evaluation.
Source of Evidence: Evaluations

Target:
Demonstrate expertise in in IRB policies and procedures through IRB member self evaluation.

Related Action Plans (by Established cycle, then alpha):

IRB Member Retreat and other IRB educational initiatives
Established in Cycle: 2013-2014
The IRB Member retreat is an annual event sponsored by the ORC to provide IRB members with information to further demonstrate ...

For full information, see the Details of Action Plans section of this report.

Status of Human Research Protection Program accreditation; Demonstrate expertise of the management of the human research protection program though the full accreditation of the program by a international accrediting body.
Source of Evidence: Evaluations

Target:
Full Accreditation of the University of Alabama’s HRPP.
Related Action Plans (by Established cycle, then alpha):

**IRB Member Retreat and other IRB educational initiatives**
*Established in Cycle: 2013-2014*
The IRB Member retreat is an annual event sponsored by the ORC to provide IRB members with information to further demonstrate ...

For full information, see the Details of Action Plans section of this report.

**M 10: ORC staff feedbacks**

**Source of Evidence:** Evaluations

**Target:**
Evaluate ORC staff knowledge of IRB polices and procedures though regularly scheduled meetings and review of IRB projects.

**M 11: HRPP User Evaluation Survey**

*Source of Evidence:* Evaluations

**Target:**
Utilize the Human Research Protection Program (HRPP) User Evaluation Survey feedback to make process improvements.

**Finding (2013-2014) - Target: Not Reported This Cycle**

This measure is set to occur on an bi-annual basis. The next scheduled review will occur during spring of 2014.

**M 12: Length of Non-Medical IRB Meetings**

*Source of Evidence: Efficiency*

**Target:**
An efficient length to ensure the agenda is effectively covered.

**Finding:**
Length of Non-Medical IRB Meetings. It is expected that the overall length of IRB meetings will decrease (assessed by comparing average meeting times, pre and post intervention with ongoing use of the protocol review form) and by increasing educational offering for IRB members and ORC staff.

**Related Action Plans (by Established cycle, then alpha):**

**IRB Member Retreat and other IRB educational initiatives**
*Established in Cycle: 2013-2014*
The IRB Member retreat is an annual event sponsored by the ORC to provide IRB members with information to further demonstrate ...

**New protocol review form for use during full board meetings.**
*Established in Cycle: 2013-2014*
New protocol review form for use during full board meetings.

For full information, see the Details of Action Plans section of this report.

**M 13: Approval time for new full-board projects**

The measure is utilized to assess approval time for new full board projects. This measure will allow ORC to evaluate if the average time from initial submission to the time of final approval of full board applications will decrease by assessing by comparison a subset of IRB protocols, examining the average review time, pre and post intervention and educational offerings.

**Source of Evidence: Efficiency**

**Target:**
A reasonable number of days until approval.

**Related Action Plans (by Established cycle, then alpha):**

**IRB Member Retreat and other IRB educational initiatives**
*Established in Cycle: 2013-2014*
The IRB Member retreat is an annual event sponsored by the ORC to provide IRB members with information to further demonstrate ...

**New protocol review form for use during full board meetings.**
*Established in Cycle: 2013-2014*
New protocol review form for use during full board meetings.

For full information, see the Details of Action Plans section of this report.

**OthOtcn 2: Utilization of electronic submission for IRB (Human Subjects)**

Utilization of electronic submission vs. non-electronic submission for IRB (Human Subjects) protocols.

**Connected Document**

[Office of Research Compliance Assessment Timetable](#)

**Related Measures**

**M 3: Evaluation of number of electronic submissions vs. non-electronic**

Evaluation of number of electronic submissions vs. non-electronic protocol submissions.

**Source of Evidence:** Evaluations

**Target:**
The target is to have researchers (both faculty and students) submit IRB applications through the electronic system to streamline operations.
M 4: ORC staff feedback
ORC staff feedback
Source of Evidence: Evaluations
Target:
To get monthly feedback from ORC staff on interaction with researchers and overall office operations.

M 10: ORC staff feedbacks
ORC staff feedback
Source of Evidence: Evaluations
Target:
Evaluate ongoing feedback from ORC staff about the electronic system. Feedback to include information provided by researchers (faculty, staff and students).

OthOtcm 3: Utilization of electronic submission for IACUC (Animal Subjects)
Utilization of electronic submission vs. non-electronic submission for IACUC (Animal Subjects) protocols.
Connected Document
Office of Research Compliance Assessment Timetable

OthOtcm 4: Inform investigators of important changes to policies and procedures.
Inform investigators of important changes to policies and procedures.
Connected Document
Office of Research Compliance Assessment Timetable
Related Measures

M 6: Bi-monthly training sessions and measure of number of accurately submitted protocols
Bi-monthly training sessions on protocol submissions evaluations and measure of number of accurately submitted protocols.
Source of Evidence: Administrative measure - other
Target:
Provide information about changes in procedures to investigators in a timely manner. All changes should be communicated to investigators at the time of implementation.

M 7: Website updates via announcement and notes.
Website updates via announcement and notes.
Source of Evidence: Administrative measure - other
Target:
Inform investigators at the time of implementation.

M 8: Report number of protocols submitted
Report number of protocols submitted using correct forms and guidance.
Source of Evidence: Activity volume
Target:
Provide annual report of the number of protocols submitted and approved.

M 9: ORC feedback
ORC feedback from users of the services provided by the office.
Source of Evidence: Evaluations
Target:
Receive feedback from investigators about how changes to policies and procedures impact their understanding of how to submit protocols.

OthOtcm 5: Six Sigma plan for IRB application process
Continuous improvement of Six Sigma plan for IRB application process.
Connected Document
Office of Research Compliance Assessment Timetable
Related Measures

M 10: ORC staff feedbacks
ORC staff feedback
Source of Evidence: Evaluations
Target:
Full implementation of the improvements identified by the Six Sigma Process.

Details of Action Plans for This Cycle (by Established cycle, then alpha)

IRB Member Retreat and other IRB educational initiatives
The IRB Member retreat is an annual event sponsored by the ORC to provide IRB members with information to further demonstrate expertise in IRB policies, procedures and regulations. The goal of this retreat is to foster scientific and social interactions among faculty, staff and community members affiliated with the IRB. The itinerary includes a full agenda of presentations and discussions as well as informational and social events.

Established in Cycle: 2013-2014
Implementation Status: In-Progress
Priority: High
Relationships (Measure | Outcome/Objective):
<table>
<thead>
<tr>
<th>Measure</th>
<th>Outcome/Objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval time for new full-board projects</td>
<td>An Effective Human Subjects Research Program</td>
</tr>
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<td>Assessment of IRB member retreat</td>
<td>An Effective Human Subjects Research Program</td>
</tr>
<tr>
<td>IRB member self evaluation</td>
<td>An Effective Human Subjects Research Program</td>
</tr>
<tr>
<td>Length of Non-Medical IRB Meetings</td>
<td>An Effective Human Subjects Research Program</td>
</tr>
<tr>
<td>Status of Human Research Protection Program</td>
<td>accreditation. An Effective Human Subjects Research Program</td>
</tr>
</tbody>
</table>

**Implementation Description:** Provide continuing education on IRB policies, procedures, guidelines and updates to federal regulations.

**Responsible Person/Group:** ORC Staff and IRB Chairs

**New protocol review form for use during full board meetings.**

New protocol review form for use during full board meetings.

**Established in Cycle:** 2013-2014

**Implementation Status:** In-Progress

**Priority:** High

**Relationships (Measure | Outcome/Objective):**

<table>
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<th>Measure</th>
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**Responsible Person/Group:** ORC staff
Mission / Purpose

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Other Outcomes, with Any Associations and Related Measures, Targets, Findings, and Action Plans

OthOtcm 1: Demonstrate expertise in in IRB policies and procedures

Demonstrate expertise in IRB policies and procedures by IRB members and ORC staff.

Related Measures

M 1: IRB member retreat and assessment after the retreat

IRB member retreat and assessment after the retreat

Source of Evidence: Activity volume

Target: 
The target is to get 90% of IRB members to attend the annual member retreat. The retreat is used to provide training on federal regulations, university policy and techniques for review of applications.

Finding (2012-2013) - Target: Met

During the annual IRB review there were 94% of the membership in attendance. Feedback provided from the membership was positive and provided the needed overview of the federal regulations and the importance of accreditation of the Human Research Protection Program.

M 2: IRB member self evaluation

IRB member self evaluation.

Source of Evidence: Evaluations

Target: 
Demonstrate expertise in in IRB policies and procedures through IRB member self evaluation.

Finding (2012-2013) - Target: Met

Every IRB member completed a self evaluation during the month of April or May. The information provided is used to set the agenda of the upcoming IRB member retreat and IRB education presentation that are provided during at least 50% of the meeting during the year.

M 5: Maintain accredited Human Research Protection Program

Demonstrate expertise of the management of the human research protection program through the accreditation of the program by a international accrediting body.

Source of Evidence: Evaluations

Target: 
Full Accreditation of the University of Alabama's HRPP.

Finding (2012-2013) - Target: Met

The University of Alabama has maintained accreditation of its Human Research Protection Program (HRPP) for the last three years. As stated by AAHRPP, UA follows rigorous standards for ethics, quality, and protections for human research and has earned a place among the world's most respected, trustworthy research organizations.

M 10: ORC staff feedbacks

ORC staff feedback

Source of Evidence: Evaluations

Target: 
Evaluate ORC staff knowledge of IRB policies and procedures through regularly scheduled meetings and review of IRB projects.

Finding (2012-2013) - Target: Met
ORC staff demonstrate mastery of the IRB policies, procedures and regulations based on knowledge shared during regularly scheduled meeting and evaluation of the work summaries provided each month.

**M 11: HRPP User Evaluation Survey**

Human Research Protection Program user survey of Institutional Review Board Program.

Source of Evidence: Evaluations

**Target:**
Utilize the Human Research Protection Program (HRPP) User Evaluation Survey feedback to make process improvements.

**Finding (2012-2013) - Target: Not Reported This Cycle**
The HRPP User Evaluation is being revised to collect more specific information that will be better used for improvements to the program.

**OthOtcm 2: Utilization of electronic submission for IRB (Human Subjects)**
Utilization of electronic submission vs. non-electronic submission for IRB (Human Subjects) protocols.

**Connected Document**
Office of Research Compliance Assessment Timetable

**Related Measures**

**M 3: Evaluation of number of electronic submissions vs. non-electronic**

Evaluation of number of electronic submissions vs. non-electronic protocol submissions.

Source of Evidence: Evaluations

**Target:**
The target is to have researchers (both faculty and students) submit IRB applications through the electronic system to streamline operations.

**Finding (2012-2013) - Target: Partially Met**
There has been an increase in the number of submissions in the electronic system.

**M 4: ORC staff feedback**

ORC staff feedback

Source of Evidence: Evaluations

**Target:**
To get monthly feedback from ORC staff on interaction with researchers and overall office operations.

**Finding (2012-2013) - Target: Met**
Monthly feedback from ORC staff has initiated the purchase and implementation of an updated release of the electronic submission software and exploration of workflow solutions.

**M 10: ORC staff feedbacks**

ORC staff feedback

Source of Evidence: Evaluations

**Target:**
Evaluate ongoing feedback from ORC staff about the electronic system. Feedback to include information provided by researchers (faculty, staff and students).

**Finding (2012-2013) - Target: Met**
Monthly feedback from ORC staff has initiated the purchase and implementation of an updated release of the electronic submission software and exploration of workflow solutions.

**OthOtcm 3: Utilization of electronic submission for IACUC (Animal Subjects)**
Utilization of electronic submission vs. non-electronic submission for IACUC (Animal Subjects) protocols.

**Connected Document**
Office of Research Compliance Assessment Timetable

**Related Measures**

**M 6: Bi-monthly training sessions and measure of number of accurately submitted protocols**

Bi-monthly training sessions on protocol submissions evaluations and measure of number of accurately submitted protocols.

Source of Evidence: Administrative measure - other

**Target:**
Provide information about changes in procedures to investigators in a timely manner. All changes should be communicated to investigators at the time of implementation.

**Finding (2012-2013) - Target: Met**
Any procedural changes have been communicated to investigators via email and website posting at the time of implementation.

**M 7: Website updates via announcement and notes.**

Website updates via announcement and notes.

Source of Evidence: Administrative measure - other

**Target:**
Inform investigators at the time of implementation.

**Finding (2012-2013) - Target: Met**
Investigators have been informed about changes to policies and procedures via email and web notes.

**M 8: Report number of protocols submitted**
Report number of protocols submitted using correct forms and guidance.

Source of Evidence: Activity volume

**Target:**
Provide annual report of the number of protocols submitted and approved.

**Finding (2012-2013) - Target: Met**
Annual report is provided at the end of each calendar year.

**M 9: ORC feedback**
ORC feedback from users of the services provided by the office.

Source of Evidence: Evaluations

**Target:**
Receive feedback from investigators about how changes to policies and procedures impact their understanding of how to submit protocols.

**Finding (2012-2013) - Target: Partially Met**
Feedback has been limited and ORC is looking for more effective ways to communicate with investigators.

**OthOtcn 5: Six Sigma plan for IRB application process**
Continuous improvement of Six Sigma plan for IRB application process.

**Connected Document**
Office of Research Compliance Assessment Timetable

**Related Measures**

**M 10: ORC staff feedbacks**
ORC staff feedback

Source of Evidence: Evaluations

**Target:**
Full implementation of the improvements identified by the Six Sigma Process.

**Finding (2012-2013) - Target: Met**
The implementation of the Six Sigma plan caused a 50% reduction in review and approval time for expedited projects. Allowing for the start of research sooner and could assist with increased research funding or a decrease in the amount of time to graduate.
University of Alabama

Detailed Assessment Report
2011-2012 Research Compliance
As of: 7/18/2014 11:05 AM CENTRAL

Mission / Purpose

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Other Outcomes, with Any Associations and Related Measures, Targets, Findings, and Action Plans

OthOtcm 1: Demonstrate expertise in IRB policies and procedures
Demonstrate expertise in IRB policies and procedures by IRB members and ORC staff.

Connected Document
Office of Research Compliance Assessment Timetable

Related Measures

M 1: IRB member retreat and assessment after the retreat
IRB member retreat and assessment after the retreat
Source of Evidence: Activity volume

M 2: IRB member self evaluation
IRB member self evaluation
Source of Evidence: Evaluations

OthOtcm 2: Utilization of full electronic submission for IRB (Human Subjects)
Utilization of full electronic submission for IRB (Human Subjects)

Connected Document
Office of Research Compliance Assessment Timetable

Related Measures

M 3: Evaluation of number of electronic submissions vs. electronic
Evaluation of number of electronic submissions vs. electronic
Source of Evidence: Evaluations

M 4: ORC staff feedback
ORC staff feedback
Source of Evidence: Evaluations

OthOtcm 3: Utilization of full electronic submission for IACUC (Animal Subjects)
Utilization of full electronic submission for IACUC (Animal Subjects)

Connected Document
Office of Research Compliance Assessment Timetable

Related Measures

M 5: Evaluation of number of electronic submission vs. electronic
Evaluation of number of electronic submission vs. electronic
Source of Evidence: Evaluations

OthOtcm 4: Inform investigators of important changes to policies and procedures.
Inform investigators of important changes to policies and procedures.

Connected Document
Office of Research Compliance Assessment Timetable

Related Measures

M 6: Bi-monthly training sessions and measure of number of accurately submitted protocols
Bi-monthly training sessions on protocol submissions evaluations and measure of number of accurately submitted protocols.
Source of Evidence: Administrative measure - other

M 7: Website updates via announcement and notes.
Website updates via announcement and notes.
Source of Evidence: Administrative measure - other

M 8: Report number of protocols submitted
Report number of protocols submitted using correct forms and guidance.
Source of Evidence: Activity volume

OthOtcm 5: Implementation Six Sigma plan to improve IRB application process
<table>
<thead>
<tr>
<th>Related Measures</th>
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<tbody>
<tr>
<td><strong>M 9: ORC feedback</strong></td>
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<tr>
<td>ORC feedback</td>
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<tr>
<td>Source of Evidence: Evaluations</td>
</tr>
<tr>
<td><strong>M 10: ORC staff feedbacks</strong></td>
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<tr>
<td>ORC staff feedback</td>
</tr>
<tr>
<td>Source of Evidence: Evaluations</td>
</tr>
</tbody>
</table>
Administrative Office
2011-12 Assessment Plan

Division Name: Office for Research
Administrative Office Name: Office for Research Compliance

I. Department Mission Statement:

The Office for Research Compliance (ORC) is to provide internal oversight on compliance relating to the performance of research including human and animal research, conflict of interest, export control, responsible conduct of research, and scientific misconduct. ORC emphasis is to ensure the rights and well being of human and animal subjects, ensure regulatory compliance, support our investigators and staff, protect the University and advance science.

II. Expected Outcomes

Outcome 1. Demonstrate expertise in IRB policies and procedures by IRB members and ORC staff.

| Measure 1.1 IRB member retreat and assessment after the retreat |
| Measure 1.2 IRB member self evaluation |
| Measure 1.3 (Optional) |

How would you categorize Outcome 1?  
☐ Administrative Support/Operational Effectiveness outcome  
☐ Educational Support outcome  
☐ Research outcome  
☐ Community Service outcome

This outcome best relates to which UA Strategic Plan Goal and Objective?  
Strategic Plan Goal # 1  Objective # 6

Outcome 2. Utilization of full electronic submission for IRB (Human Subjects)

| Measure 2.1 Evaluation of number of electronic submissions vs. electronic |
| Measure 2.2 ORC staff feedback |
| Measure 2.3 (Optional) |

How would you categorize Outcome 2?  
☐ Administrative Support/Operational Effectiveness outcome  
☐ Educational Support outcome  
☐ Research outcome  
☐ Community Service outcome

This outcome best relates to which UA Strategic Plan Goal and Objective?  
Strategic Plan Goal # 1  Objective # 8
**Outcome 3. Utilization of full electronic submission for IACUC (Animal Subjects)**

Measure 3.1 Evaluation of number of electronic submission vs. electronic

Measure 3.2

Measure 3.3 (Optional)

How would you categorize Outcome 3?  
[ ] Administrative Support/Operational Effectiveness outcome  
[ ] Educational Support outcome  
[ ] Research outcome  
[ ] Community Service outcome

This outcome best relates to which UA Strategic Plan Goal and Objective?  
Strategic Plan Goal # 1  Objective # 8

**Outcome 4. Inform investigators of important changes to policies and procedures.**

Measure 4.1 Bi-monthly training sessions on protocol submissions evaluations and measure of number of accurately submitted protocols.

Measure 4.2 Website updates via announcement and notes.

Measure 4.3 (Optional) Report number of protocols submitted using correct forms and guidance.

How would you categorize Outcome 4?  
[ ] Administrative Support/Operational Effectiveness outcome  
[ ] Educational Support outcome  
[ ] Research outcome  
[ ] Community Service outcome

This outcome best relates to which UA Strategic Plan Goal and Objective?  
Strategic Plan Goal # 1  Objective # 3

**Outcome 5. Implementation Six Sigma plan to improve IRB application process**

Measure 5.1 ORC feedback

Measure 5.2 ORC staff feedback

Measure 5.3 (Optional)

How would you categorize Outcome 5?  
[ ] Administrative Support/Operational Effectiveness outcome
This outcome best relates to which UA Strategic Plan Goal and Objective?

Strategic Plan Goal # 1  Objective # 6

Outcome 6. (Optional)

Measure 6.1
Measure 6.2
Measure 6.3 (Optional)

How would you categorize Outcome 6?

Administrative Support/Operational Effectiveness outcome
Educational Support outcome
Research outcome
Community Service outcome

This outcome best relates to which UA Strategic Plan Goal and Objective?

Strategic Plan Goal # 6  Objective #

III. Timetable: What Assessment Measures will be Administered When for Each Expected Outcome

<table>
<thead>
<tr>
<th>Outcome #1</th>
<th>Outcome #2</th>
<th>Outcome #3</th>
<th>Outcome #4</th>
<th>Outcome #5</th>
<th>Outcome #6</th>
</tr>
</thead>
<tbody>
<tr>
<td>September</td>
<td>Training</td>
<td>ORC feedback</td>
<td>ORC feedback</td>
<td>Training/announcements/notes</td>
<td>Training on use of Six Sigma Plan</td>
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<tr>
<td></td>
<td>session &amp; eval</td>
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<td>October</td>
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<td>ORC Feedback</td>
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<td>Training/announcements/notes</td>
<td>Pilot use of Six Sigma Plan</td>
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<td>January</td>
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<td>Month</td>
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<tr>
<td>February</td>
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<td>June</td>
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**Optional Additional Narrative** (Use this space to provide any additional detail concerning the 2011-12 Administrative Office Assessment Plan)