Office of Research Integrity
Who Are We?

Presented by: Carolyn Strong, MRA, CRA, CIM
Objectives

- History
- Who are we?
- Programs under ORI’s Umbrella
- Services
- Milestones
- Programs’ Statistics
- Trends
- Outreach
- Vision
History

- Administration of human and animal research reported to Director of the Office of Sponsored Programs
- Biosafety was managed by the Institutional Biosafety Committee Chair
- Relied on Office of International Programs for Export Control regulations regarding research
- Director of Compliance managed Financial Conflicts of Interest, Responsible Conduct of Research, and served as an independent voice to all areas of compliance
Announcement Made

- May 9, 2013 – Office of Research Integrity now exists
Who are we?
Who are we?

• Centralized office under the Office of Research and Scholarship

• Responsible for
  ◦ monitoring regulatory changes
  ◦ recommending institutional responses to ensure compliance, and
  ◦ overseeing the development and implementation of policies, procedures, programs and educational activities which satisfy federal, state and institutional regulations governing the research ethics and the responsible conduct of research
Mission Statement

The Office of Research Integrity (ORI) promotes a culture of compliance, research integrity, and high quality research within the University community.
What are our core values?

Core Values

- Integrity
- Collaboration
- Service
- Accountability
- Responsiveness
- Commitment
Programs

- Institutional Review Board (IRB)
- Institutional Animal Care and Use Committee (IACUC)
- Institutional Biosafety Committee (IBC)
- Research Ethics and Financial Conflict of Interest
- Export Controls (as related to research)
Services

- Monitors federal and state compliance regulations
- Presents to faculty/students to assist with the IRB process
- Conducts preliminary reviews of all human subject protocols prior to forwarding them to the IRB for review, checking for completion
- Assist in providing for the humane care and use of all animals in research and instruction
- Oversees research protection as it relates to human subject research, recombinant DNA research, and bio-hazardous materials research
- Collaborates with offices on campus to maintain research compliance
Services (cont’d.)

- Receives, reviews, and monitors financial conflict of interest disclosure forms
- Coordinates with compliance committees by providing administrative support, recordkeeping, and reporting
- Ensures all certifications and assurances are completed, approved, and filed as required by the federal government
- Ensures research related policies are updated and monitored outside of the JMU Policy Committee
Office Milestones

• Grown from an office of (1) to an office of (6)
  ◦ (1) full-time Assistant Director
  ◦ (1) full-time Administrative Assistant
  ◦ (1) full-time Vivarium Facility Manager (VFM)
  ◦ (1) part-time Attending Veterinarian (AV)
  ◦ (2) wage students assistants

• Now providing outreach for animal research
  ◦ Training Researchers, Students working in labs, and the IACUC

• Worked with Deans of each college to form a Conflict of Interest (COI) Committee

• Collaboration formed with Environmental Health and Safety
  ◦ Assistance with IACUC and IBC lab inspections

• Collaborations with the following to identify an electronic research database management system:
  ◦ Office of Sponsored Programs, IT-Information Systems, Corporate & Foundation Relations, Academic Resources and Grant Accounting, and Procurement

• Collaboration formed with Instructional Technologies and Library Services
  ◦ Data management security
2016-2017 IACUC Statistics

- Animal Research (IACUC) = 67
  - New Protocols = 12
  - Annual/Final Progress Report & Continuation = 12
  - Amendment Form – Research = 21
  - Amendment Form – Personnel = 22
  - Adverse Event = 0
  - TOTAL: 67
- Animal Research Online Training = 228
- IACUC Convened Meetings = 11
- Semi-Annual Inspections = 3
**IACUC 5 Year Trend**

<table>
<thead>
<tr>
<th>Type</th>
<th>FY 17</th>
<th>FY 16</th>
<th>FY 15</th>
<th>FY 14</th>
<th>FY 13</th>
<th>Trend</th>
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<tbody>
<tr>
<td>New Protocols</td>
<td>12</td>
<td>18</td>
<td>17</td>
<td>8</td>
<td>11</td>
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<tr>
<td>Progress Reports</td>
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<td>13</td>
<td>6</td>
<td>3</td>
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<td>Research Amendments</td>
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<td>12</td>
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<td>Personnel Amendments</td>
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<td>20</td>
<td>21</td>
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<td>Adverse Events</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Continuation: No Change</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Continuation: Minor Changes</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td></td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>67</strong></td>
<td><strong>60</strong></td>
<td><strong>56</strong></td>
<td><strong>20</strong></td>
<td><strong>26</strong></td>
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</table>

*Note: Prior to FY 14, amendments were not tracked. The breakdown was: new protocols, continuation with no changes, continuation with minor changes, and adverse events.*
2016-2017 IACUC Outreach

- Attending Veterinarian conducted (1) training session for the IACUC
- ORI conducted (1) training session for new IACUC members
- ORI hosted (3) IACUC training sessions (offered by Public Responsibility in Medicine & Research (PRIM&R))
- ORI hosted (3) IACUC training sessions (offered by Office of Laboratory and Animal Welfare (OLAW))
### 2016-2017 IRB Statistics

- **Human Subject Research (IRB) = 873**

<table>
<thead>
<tr>
<th>Category</th>
<th>Faculty/Staff</th>
<th>Grad Students</th>
<th>Undergrad Students</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>Full Board -New</td>
<td>51</td>
<td>56</td>
<td>14</td>
<td>121</td>
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<tr>
<td>Expedited</td>
<td>172</td>
<td>80</td>
<td>104</td>
<td>356</td>
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<tr>
<td>Exempt</td>
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<td>7</td>
<td>110</td>
<td>132</td>
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<td>Extension Request - ORI</td>
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<td>7</td>
<td>1</td>
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<td>Addendum Request - EXP</td>
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<td>13</td>
<td>117</td>
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<td>Addendum Request - ORI</td>
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<td>4</td>
<td>11</td>
<td>77</td>
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<tr>
<td>Addendum Request - FB</td>
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<td>0</td>
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<tr>
<td>Adverse Event- EXP</td>
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<td>2</td>
<td>1</td>
<td>3</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>430</strong></td>
<td><strong>189</strong></td>
<td><strong>254</strong></td>
<td><strong>873</strong></td>
</tr>
</tbody>
</table>

- **Human Research Online Training = 1924**
- **IRB Convened Meetings = 21**
# IRB 5 Year Trend

![Bar chart showing IRB trend from FY13 to FY17](chart.png)

<table>
<thead>
<tr>
<th>Type</th>
<th>FY17</th>
<th>FY16</th>
<th>FY15</th>
<th>FY14</th>
<th>FY13</th>
<th>Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Board- New</td>
<td>121</td>
<td>96</td>
<td>154</td>
<td>94</td>
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<tr>
<td>Expedited</td>
<td>356</td>
<td>404</td>
<td>393</td>
<td>372</td>
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<tr>
<td>Exempt</td>
<td>132</td>
<td>122</td>
<td>74</td>
<td>48</td>
<td>75</td>
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</tr>
<tr>
<td>Extension Request- ORI</td>
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<td>68</td>
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<tr>
<td>Addendum Request ( Expedited)</td>
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<tr>
<td>Addendum Request ( ORI)</td>
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<td>119</td>
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<tr>
<td>Addendum Request ( Full Board)</td>
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<td>4</td>
<td>4</td>
<td>1</td>
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<tr>
<td>Adverse Event ( Expedited)</td>
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<td>1</td>
<td>9</td>
<td>1</td>
<td>0</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>873</strong></td>
<td><strong>908</strong></td>
<td><strong>876</strong></td>
<td><strong>682</strong></td>
<td><strong>580</strong></td>
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</table>

**Note:** Prior to FY 14, Addenda Requests not approved internally or by the Full Board were only tracked as Expedited.
2016-2017 IRB Outreach

- Held Drop-In hours to assist researchers with their human subject protocol
- Conducted (9) classroom presentations regarding the IRB Process
- Conducted 3 “Take Ten” sessions - started at IRB convened meetings allowing researchers/representatives from departments to come speak with the IRB regarding questions regarding proposed research, attempts to educate IRB members on certain types of research department members conduct, frustrations within departments, etc.
- Hosted (2) IRB Training Sessions (webinars offered through the Public Responsibility in Medicine & Research (PRIM&R))
- Conducted (1) IRB New Member training session
- Co-presented (2) Data Security Workshops with the Center for Instructional Technology
2016-2017 Additional Areas of Statistics & Outreach

- **Biosafety**
  - Attending Veterinarian conducted (1) training session for IBC members (AV has background in microbiology)
  - Meetings = 3
  - Protocols Reviewed = 24

- **Financial Conflict of Research**
  - Online Training = 51
  - Meetings = 0 (called as necessary)
2016-2017 Additional Areas of Statistics & Outreach

- **Responsible Conduct of Research**
  - Online Training = 339
  - Meetings = 0  (called as necessary)

- **Export Controls (as related to research)**
  - Participated in (1) webinar entitled “Export Sanctions Compliance: Breathing Life Into Your Policies” (offered by Society of Research Administrators International)
  - Hosted (1) workshop entitled “EAR/ITAR Compliance Workshop: Understanding and Managing Export Control in University Research and Technology Transfer” (offered by Tech Transfer Central)
  - Hosted an export controls presentation on campus entitled “Exports in Academia”. Presentation presented by Special Agents from Homeland Security
  - Hosted (1) workshop entitled “EAR/ITAR Compliance Workshop: Understanding and Managing Export Control in University Research and Technology Transfer”
  - Presented “The Basics of Export Controls” to the Compliance Committee at the request of the Vice Provost of Research and Scholarship
ORI’s Vision

• To maintain the highest standard of application towards regulatory initiatives.
  ◦ Our office strives to be the best in developing and executing faculty/researcher/staff training, educational and technological tools, as well as exceptional service.
  ◦ We promise to continue to exercise honesty, integrity, competency, due diligence, and conservative use of resources.
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ORI Website

- **Web link:** [http://www.jmu.edu/researchintegrity/index.shtml](http://www.jmu.edu/researchintegrity/index.shtml)
Questions