Physicians can receive CME credit for these, and everyone receives GCP Education credit towards the GCP Education requirements.

The Mediasite presentations give you the actual video of the person giving the lecture along with the slides presented in the same sequence and timing as the original lectures. If you click on the slide portion of the Mediasite presentation, the slide will open in a new window and you can print out selected slides if you find them helpful for future reference.

After viewing the 2015 RCR Lectures you choose, answer the CME/GCP questions on the answer sheet. When you finish, scan the answer sheet and email to irb@ochsner.org. The answer sheets for the 2015 RCR lectures must be sent within 3 years of the lecture to obtain CME credit for physicians; GCP credit may be obtained as long as the lectures remain on Mediasite. To receive credit, you must answer at least 75% of the questions correctly. You cannot receive credit from these Mediasite presentations if you already received it from the live presentations.

<table>
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<tr>
<th>2015 Responsible Conduct in Research Lecture Series (held in Monroe Hall on 2nd Tuesdays of the month)</th>
<th>Maximum credit 8.0 hours (1.0 hour per lecture; 8 lectures)</th>
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<tbody>
<tr>
<td><strong>Accreditation</strong></td>
<td>The Ochsner Clinic Foundation is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.</td>
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<tr>
<td>To view the lectures, click <a href="#">here</a>.</td>
<td>and locate the 2015 RCR lectures under the IRB tab</td>
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<td>See CME questions below</td>
<td></td>
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</table>
Consent – It's not Just the Form
Stephanie Gaudreau

For credit – Fill out, sign, and scan this one sheet ONLY to the Ochsner IRB Office at irb@ochsner.org
Questions? Call the IRB Office at 504-842-3563 or email them at irb@ochsner.org
Note: even if you are not a physician, and CME does not apply, the CME/IRB offices are using the same documentation and testing methods to track GCP credits for continuing GCP education requirements for those involved in human subject research at Ochsner.

Attestation: I certify that I have spent ____.__ hours* reviewing the video and slides of this educational activity at the Ochsner CGP Mediasite, related materials, and filling out the post-test questionnaire. I hereby claim ____.__ hours of CME/GCP credit [maximum of 1.0 credit hours, limited to time spent in this educational activity. *Note: "Assigning credit for enduring materials: ...Sixty minutes equals one (1) AMA PRA Category 1 Credit. To calculate the Designation Statement’s credit maximum, providers may round to the nearest quarter hour or credit." See link, page 6].

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Signature Date Print Name

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POST-TEST ANSWER SHEET (see below for the questions; only fax this signature page; circle answers, all questions have only one answer)

1. A  B
2. A  B
3. A  B
4. A  B

1. Federal laws require that individuals who are considering participating in a study are given information about the study and time to think about if they want to be in the study. This process is called “informed consent.”
   a. True
   b. False

2. Informed consent is not one of the primary ethical principles governing human subject research
   a. True
   b. False

3. Voluntary consent means participants are able to consent, are not being coerced and understand the risks and benefits involved
   a. True
   b. False

4. Consent does not have to be free from coercion or undue influence
   a. True
   b. False
Statistics in Research
Quingyang Luo

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POST-TEST ANSWER SHEET (see below for the questions; only fax this signature page; circle answers, all questions have only one answer)

1. A   B
2. A   B
3. A   B
4. A   B

1. Categorical variable has two main sub types: ordinal and nominal.
   a. True
   b. False

2. Censored data is the type of data that is only partially known.
   a. True
   b. False

3. Sample size can be only calculated for a specific hypothesis
   a. True
   b. False

4. Regression analysis is a generalization of the bivariate analysis
   a. True
   b. False
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POST-TEST ANSWER SHEET (see below for the questions; only fax this signature page; circle answers, all questions have only one answer)

1. A  B
2. A  B
3. A  B  C  D
4. A  B

1. Custodianship is the caretaking responsibility of banked biospecimens.
   a. True
   b. False

2. Unintended release or disclosure of information can place donors at risk of discrimination.
   a. True
   b. False

3. Risk mitigation steps include the following:
   a. Data encryption
   b. Coding methods
   c. Access control
   d. All of the above

4. Ochsner access to biospecimens and related data is governed by the Institutional Review Board (IRB), Institutional Biosafety Committee (IBC) and the Biobank Steering Committee (BSC)
   a. True
   b. False
This presentation is not available via mediasite. Therefore, credit cannot be given for this lecture.
Community Based Participatory Research
Eboni Price-Haywood

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Questions? Call the IRB Office at 504-842-3563 or email them at irb@ochsner.org
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available on the mediasite.

POST-TEST ANSWER SHEET (see below for the questions; only fax this signature page; circle answers, all questions
have only one answer)

1. A  B
2. A  B
3. A  B
4. A  B

1. Participatory research is an approach that recognizes the value of engaging in the research process those who are
the intended beneficiaries or stakeholders of the research.
   a. True
   b. False

2. Community Based Participatory Research (CBPR) promotes bi-direction and co-learning and capacity building
among all partners.
   a. True
   b. False

5. The value of the participatory approach to research includes:
   a. Shaping the purpose and scope
   b. Enhancing research implementation
   c. Enhancing the interpretation and application of results
   d. All of the above

3. Patient centered outcomes research compares an alternate approach to clinical management.
   a. True
   b. False
2015 Responsible Conduct of Research Lecture #6 – August 11, 2015
Conducting Investigator Initiated Research
Lydia Bazzano

For credit – Fill out, sign, and scan this one sheet ONLY to the Ochsner IRB Office at irb@ochsner.org
Questions? Call the IRB Office at 504-842-3563 or email them at irb@ochsner.org
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POST-TEST ANSWER SHEET (see below for the questions; only fax this signature page; circle answers, all questions have only one answer)

1. A  B
2. A  B
3. A  B
4. A  B

1. Investigator initiated research is any type of research initiated by an investigator rather than a drug or device company, foundation or government agency.
   a. True
   b. False

2. To start a study protocol you should never share your ideas with colleagues.
   a. True
   b. False

3. A study plan or protocol document describes the structure of the research.
   a. True
   b. False

4. A study protocol describes every step of a study including identification of the problem and application of the results.
   a. True
   b. False
Minimizing Threats to Intervention Fidelity
Karen Rice & Shelley Thibeau

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POST-TEST ANSWER SHEET (see below for the questions; only fax this signature page; circle answers, all questions have only one answer)

1. A  B  
2. A  B  
3. A  B  
4. A  B  

1. A hypothesis is supported by scientific evidence from empirical data and well designed studies.
   a. True
   b. False

2. Intervention fidelity is a demonstration that experimental manipulation was conducted as planned.
   a. True
   b. False

3. Poor measurement limits validity of research conclusions.
   a. True
   b. False

4. In planning an intervention one should identify and plan for sources of variation due to confounding and/or contextual factors.
   a. True
   b. False
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POST-TEST ANSWER SHEET (see below for the questions; only fax this signature page; circle answers, all questions have only one answer)

1. A  B  C  D
2. A  B  C   D
3. A  B
4. A   B

1. All studies, including investigator initiated trials, should be submitted in iRES for feasibility review if there is:
   a. Funding
   b. A draft contract that has been provided by the Sponsor
   c. The study requires an informed consent
   d. All of the above

2. Ochsner’s AAHRPP accreditation requires a written agreement with a Sponsor addressing:
   a. Medical care for research related injuries
   b. Data and safety monitoring (if appropriate)
   c. Dissemination of findings (publication)
   d. All of the above

3. The parties involved in a Clinical Trial Agreement (CTA) include Ochsner (the site) and the Sponsor (and/or a CRO, acting on behalf of the Sponsor).
   a. True
   b. False

4. The Clinical Trial Agreement (CTA) must address confidentiality.
   a. True
   b. False