***Protecting Human Subjects in Student Inquiry Projects:   
Addressing the Educational, Ethical, and Legal Obligations of Liberal Arts Institutions***

**Determining whether IRB review is required: Form for Evaluating a Proposed Investigation**

Draft 02-15-12

IRB review is required for any proposed investigation for which the answer is “Yes” to all of the following questions. The accompanying document “Determining Whether IRB Review is Required: Policy for Evaluating a Proposed Investigation” provides definitions of terms and references to federal regulations that must be taken into account in responding to each question.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | **Yes** | **No** |
| **1. *Is the activity “research” as federally-defined?***  [45 CFR 46.102(d)] | 1. Is the project a **systematic investigation**? |  |  |
| 1. Could project results be generalized **beyond the group from which the sample was selected**? [45 CFR 46.102(d)] |  |  |
| 1. Are project design and results intended, or otherwise suitable, for **dissemination to a scholarly or professional audience** beyond the institution? [45 CFR 46.102(d)] |  |  |
| **2. *Does the research activity involve “human subjects” as federally-defined?***  [45 CFR 46.102(f)] | 1. Does the project involve **obtaining information about living individuals** in order to draw conclusions about them? |  |  |
| 1. Does the project obtain that information through:  * **intervention or interaction** with the individuals, OR * procedures that yield **individually-identifiable private information**? |  |  |
| **3. *Is the human subjects research activity subject to the Common Rule?***  [45 CFR 46.101(a)] | 1. Is the project:  * conducted or supported by a **federal agency that has adopted the Common Rule,** OR * **covered by an OHRP-approved Federalwide Assurance** that commits the institution to applying the Common Rule to all non-exempt human subjects research regardless of the source of support? |  |  |
| 1. Is the project **ineligible for exemption** from the provisions of the Common Rule? |  |  |