Rule-of-Thumb #1 for an AAHRPP Interview: **Know your resources!**

AAHRPP interviewers will want to see that you are familiar with the information and services available to you, and that you know where to find help if you have questions.

The *IRB Survival Handbook* is a great "catch-all" resource for UK IRB/ORI policies, procedures, forms/applications, and information on special areas of research and/or populations requiring additional protections.


**Sample Question #1: How do you know if your project, survey or academic activity needs IRB review and approval?**

Consider the following scenarios:

- You are a scientist who wants to study pathology specimens labeled with codes but no names
- You are a student completing a class project
- You are a clinician who happens upon an interesting case study that you would like to present at a conference
- You are a teacher trying to compare two methods of teaching to better educate students

Any activity that meets either the Department of Health and Human Services (DHHS) definition of both “research” and “human subjects” requires review and approval by the UK IRB.

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<tr>
<th><strong>Research</strong> - A systematic investigation designed to develop or contribute to generalizable knowledge*.</th>
<th><strong>Human Subjects</strong> - A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.</th>
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<td>DHHS: [45 CFR 46.102(d)]</td>
<td>DHHS: [45 CFR 46.102(f)]</td>
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Also for Food and Drug Administration (FDA) regulated research, any activity that meets the FDA definitions of “human subject” and “clinical investigation” requires IRB review and approval.

These regulatory definitions provide a starting point for making a preliminary decision. For detailed guidance, see the document **“When do activities need Institutional Review Board (IRB) review and approval?”** at www.research.uky.edu/ori/WhatNeedsIRBReview.htm.

While some determinations are clear cut, other situations may be more complicated to apply (i.e. is the investigation “systematic”; what constitutes “generalizable” knowledge, etc.). Anyone unsure if an activity meets the regulatory definitions requiring IRB review should contact the [UK Office of Research Integrity (ORI)](http://www.research.uky.edu/ori) for additional guidance.

Obtaining the determination that the activity does or does need IRB review protects human subjects and ensures your ability to present or publish, particularly if there is any possibility that the activity might become research.