Harold wants to determine the best way to improve patient satisfaction at his clinic.

Kumar wants to test the viability of OTC antihistamines to treat low blood pressure from excess vasodilation.

Maria wants to determine whether there are any genetic effects of long-term metformin use.

Which of the above projects require IRB approval before inception? Does **your** proposed project? Many – but not all –projects involving living subjects or their Personal Health Information (PHI) will require IRB review, if not IRB approval. Some that do may surprise you. It is not possible to get retroactive IRB approval for a project, because ethical performance of human subjects research has *already* occurred. Conducting human subjects research without IRB approval can lead to invalidation of the data, institutional penalties, or even lawsuits. In most instances, the Common Rule (45 CFR 46) lays the federal ground work, but determining the IRB requirements for your particular proposed project is critical. Experiments involving a test article and one or more human subjects (or their PHI) must meet Food and Drug Administration (FDA) requirements for submission. To learn more, read on.

Determining your Project's Status:

Use this Important link to access the UCR Office of Research Integrity (ORI) forms website: http://research.ucr.edu/about/forms/research-integrity-forms.aspx. Final determination regarding the review status of any study is determined by the UCR (or partner institution) IRB.

Harold is performing a study at the clinic where he is undertaking his residency. He is asking patients and their families to fill in a Likert scale questionnaire about their satisfaction with the operations of and staff in the clinic. No personally identifiable information is obtained as part of this questionnaire, and Harold plans to share the information at a clinic staff meeting. The sole purpose of the questionnaire is to determine what can be done in the clinic to improve patient satisfaction. ***At this stage****, Harold's work probably falls under QA/QI and does* not *require IRB approval.*

QA/QI: Quality Assurance/Quality Improvement. An activity conducted to assess, analyze, critique, and improve current processes in an institutional setting, involving data-guided, systematic activities designed to bring about prompt improvements (e.g., a survey that is intended only to improve patient experience at the *local* clinic).

Kumar has a proposal in which he intends to compare the effectiveness of OTC antihistamines with alpha receptor antagonists for treatment of chronic orthostatic hypotension. His research will involve a control group (low blood pressure with no medication), an alpha receptor antagonist group, and the antihistamine group. Individuals will be randomized into one of the three groups. Kumar intends to publish his findings in journals and present them at a national conference. Kumar's project meets both the Office of Human Research Protocols (OHRP) definition of research and the FDA/UC IRB definitions of Human Subjects Research, and will require a full IRB review and approval.

Research: Per the OHRP, r*esearch* is any systematic investigation designed to develop or contribute to generalizable knowledge (e.g., if you plan to publish or present your results, suggest they are adopted by other locations, or provide them to government officials for use in policy decisions). FDA regulations apply for certain types of experiments.

Maria has proposed a project examining the potential genetic effects of long-term metformin use. She will be gathering information, including human tissue samples, from several previously-funded NIDDK investigations. She has requested no PHI or identifying information of any sort be appended to either the data or the samples, only an unaffiliated alphanumeric code. Maria will not be approaching any patients, living or deceased, to gather information. Her proposal uses previously collected *human tissue, from living hosts, and may require full IRB approval or, after Office of Research Integrity review of her submitted Determination of Activity Form, may be determined to be Exempt Human Subjects Research.*

Human Subjects Research: Per the FDA, these are clinical investigations involving human subjects and must submit an IRB application. For the UCR IRB, research involving human subjects is *any* research involving living individuals or their PHI, intervention (including manipulation of a person or a person's environment), interaction (e.g., surveys, interviews, tests, or observations, etc.), and/or obtaining identifiable private information *about* living individuals.

First Steps:

If you have any question at all about where your own project falls, the first step would be to go to the ORI website (http://research.ucr.edu/ORI.aspx) and fill out and submit a Determination of Activity Form (http://research.ucr.edu/webdocs/RI/Forms/IRB/Determination_of_Activity_Form_Final.docx). The act of filling out the form may clarify where your research falls; if not, submit the form and ORI will review and let you know the next necessary steps.

If your research includes interaction with anything related to a living individual (or their PHI) *and* is a systematic investigation designed for generalizable knowledge (e.g., publication, presentation, expansion to an institution other than the research location, approaches to lawmakers), then it **is Human Subjects Research** and requires an application form to be submitted to ORI (form available at: http://research.ucr.edu/about/forms/research-integrity-forms.aspx). Because federal regulations and forms change on a regular basis, it is best to always go to the website for the most current IRB application form.

For additional information regarding what ORI confirms is in place before an application is sent to the IRB for review, see the criteria provided to the IRB members when they are considering review (http://research.ucr.edu/webdocs/RI/Forms/IRB/IRB_Reviewer_Placemat_UCR_IRB.pptx).

The main website for UCR SOM IRB is: http://research.ucr.edu/ori/committees/irb-clin.aspx

Test Your knowledge:

1. Juana has been working with her LACE preceptor and finished a QI project examining clinic flow and patient experience. They noted some interesting findings and are now interested in publishing those results. How do they proceed?

2. Ella finished a QI project with her LACE preceptor and has become more interested in patient experience. She would like to randomly assign future patients to either a telemedicine visit or usual care. How should she proceed?

3. Raja is interested in Urology and met a community physician (Urologist) at RCH. She would like to do a chart review in that physician's office on the relationship between nocturia, BPH, and PSA. What should she do?

4. Keith is working with a volunteer clinical faculty on an elective rotation. The faculty member is researching the appearance of scars 6 months post-op. Keith wishes to look at this same group of patients 12 months post-op. What should he do?