# UCI University of California, Irvine FAST FACTS

Human Research Protections Office of Research

### The Institutional Review Board (IRB)

Research involving human subjects must undergo prospective Review by the IRB. The IRB is charged with protecting the safety and welfare of human research subjects and ensuring compliance with federal agencies, state laws and UC/ UCI policies. UCI holds an active Federalwide Assurance of Compliance with the Department of Health and Human Services. The UCI FWA is 00004071. The IRB is also registered as required by the Food and Drug Administration (FDA). The UCI IORG is 0000236.

## The UCI IRB is accredited through the Consortium for Applied Research Ethics Quality (Care-Q), a

collaboration between all UC campuses and Stanford. UCI was the first site to be a fully accredited (and reaccredited) via the Care-Q process.

There are four IRBs at UCI that handle all types of research; biomedical, social-behavioral and educational, and non-compliance. UCI allows for the use of commercial IRBs, and may rely on other, non-UCI IRBs. To ensure basic institutional issues are addressed all human subject research must submit through the UCI IRB first, regardless of the requested IRB of record.

UCI also allows for IRB efficiencies such as a self-determination process of exemption and non-human subject research.

IRB Members are appointed by the Vice Chancellor for Research who is the UCI Official responsible for the human research protections program. Some HRP Staff are also IRB members. The IRB Member Rosters and the most commonly requested information by study sponsors are all available on the HRP web page.

#### WHAT IS RESEARCH?

RESEARCH IS DEFINED AS A SYSTEMATIC INVESTIGATION, INCLUDING RESEARCH DEVELOPMENT, TESTING AND EVALUATION, DESIGNED TO CONTRIBUTE TO GENERALIZABLE KNOWLEGDE.

### WHAT IS A HUMAN SUBJECT?

UVING INDIVIDUAL ABOUT WHOM AN INVESTIGATOR CONDUCTING RESEARCH:

- 1) OBTAINS INFORMATION OR BIOSPECIMENS THROUGH INTERVENTION OR INTERACTION WITH THE INDIVIDUAL, AND USES, STUDIES, OR ANALYZES THE INFORMATION OR BIOSPECIMENS OR
- 2) OBTAINS, USES, STUDIES, ANALYZES OR GENERATES INDIVIDUAL PRIVATE INFORMATION OR IDENTIFIABLE BIOSPECIMENS



THE HRP TEAM

Human Research Protections (HRP) work directly with Researchers and the IRB to help facilitate research. This includes the coordination of the single IRB review process and our education and quality improvement program (EQUIP). Our senior HRP leadership and many of our HRP team are Certified IRB Professionals (CIP).

All are here to help!