

THE IRBuzz

A monthly educational newsletter of updates, training & education, and outreach for the KPSC-HI Institutional Review Board (IRB) and research community.

What's Buzzing?

Spotlight: Dr. Stacey Honda and Kathy Higuchi, CHRC

Advancing Ethical Research with Trust: KP Hawaii's Role in Strengthening the HRPP

In the evolving world of clinical research, ethical oversight is not just a regulatory obligation — it's a relationship built on **trust, integrity, and respect**. That's why we honor the powerful contributions of **Dr. Stacey Honda** and **Kathy Higuchi, CHRC** from

Kaiser Permanente Hawaii, whose leadership within the Human Research Protection Program (HRPP) reflects not only professional excellence, but the deeper spiritual values that guide their work.

Grounded in the Hawaiian principles of **aloha**, **pono** (righteousness), and **kuleana** (responsibility), Dr. Honda and Ms. Higuchi approach research oversight as more than a process — it's a practice of care. Their efforts protect participants, support investigators, and uphold the ethical foundations of science. But perhaps even more importantly, their work honors **mana**, the life force, dignity, and spiritual power that resides in every person and every act of service.

In Hawaii, to offer **mahalo** is not just to say "thank you," but to recognize the **mana in others**, to return honor with honor, spirit with spirit. The work of Dr. Honda and Ms. Higuchi embodies this sacred moral reciprocity: they ensure that our research practices not only meet the highest standards of compliance, but also reflect **compassion, trust, humility, and cultural respect**. To our fellow physicians and researchers, their leadership reminds us that ethical research is not just about protocols — it's about people. And when we protect participants, we protect the mana of our communities and the purpose behind our work.

Mahalo nui loa to Dr. Honda and Kathy Higuchi for their unwavering dedication and for holding this kuleana with such integrity and heart!



Updates



On September 5, 2025, the National Institutes of Health (NIH) [announced](#) that it is now accepting Certificate of Confidentiality (CoC) requests for non-NIH funded research. However, with the current lapse in government funding, NIH staff [may not be available](#) to provide normal oversight and administrative support services.

Call for Action: If you are unsure whether your research needs a CoC, contact Sarah Luery at Sarah.X.Luery@kp.org. NIH-funded researchers can also direct questions to grantspolicy@od.nih.gov.

Knowledge Transmission

Researcher Resources

SOP-012 Booster: Initial Review of Proposed Research

Your research journey starts here! Before any big ideas take flight at KPSC-HI, [SOP-012](#) makes sure your proposal is ready for takeoff. What's SOP-012 all about? It covers the initial review process for new research proposals—ensuring everything is clear, feasible, and aligned with KP standards before heading to the IRB.

The Main Steps:

- Proposal completeness check – Is everything filled out and in order?
- Scientific merit review – Does your research make sense and add value?
- Feasibility assessment – Can KPSC-HI realistically support your study?
- Regulatory alignment – Getting things in shape for IRB review.



Why it matters: This early review helps spot any issues before they slow you down. It's about setting your research up for success—from day one.

Ready for Action Step: A well-prepared submission moves faster. So, dot your i's, cross your t's, call Isabel Marcela Sanchez at Isabel.M.Sanchez@kp.org for help, and let SOP-012 put your best proposal forward!

History, Culture & Education Buzz

Reflections Booster: What Happened to Ellen Roche?

In 2001, Ellen Roche, a 24-year-old healthy volunteer and lab technician at Johns Hopkins, died after participating in a research study designed to better understand the mechanisms behind asthma. As part of the study, she inhaled **hexamethonium**, a drug that had once been used to treat high blood pressure but was no longer in active clinical use and had limited safety data in inhaled form. Shortly after receiving the drug, Ellen developed lung damage and multi-organ failure. Despite intensive medical care, she passed away a few weeks later.

A Call to Thoughtful Action

Ellen Roche's story reminds us that even in well-intentioned research, the unknowns can have serious consequences. Her case underscores the importance of:



- Thorough protocol review, especially when using older drugs or novel delivery methods.
- Transparent consent language that reflects both what we know and what we don't.
- Supportive research oversight, where teams feel encouraged to pause, ask questions, and explore uncertainties.
- Ongoing reflection, not only on what went wrong, but on how systems can be strengthened.

Ellen volunteered to help advance science. We honor her by continuing to build a research culture rooted in care, humility, and learning.

Participant Experience & Community Pulse

What Participants Want Before Joining a Study

Recent focus groups and data gathered from participant calls to the IRB revealed what participants care about most when deciding whether to join a study:

- ✓ **Clear, Simple Information.** Participants want a straightforward explanation of the study's purpose, time commitment, procedures, and who's conducting it—without jargon.
- ✓ **Trust and Transparency.** They expect honest communication about any risks and their right to withdraw at any time. Trust in the research team and institution is essential
- ✓ **Purpose and Impact.** Many are motivated by contributing to something meaningful—especially when the study has personal or community relevance.
- ✓ **Fairness, Flexibility, and Access.** Participants value reasonable compensation, flexible scheduling, and accessible options like paper surveys when computers aren't available, or survey platforms that work.
- ✓ **Return of Study Results.** Participants want to know how their involvement made a difference. They appreciate receiving a summary of the study results—even if it's brief. "I'd like to know what came out of the research even if there are no incidental findings, it is always interesting to know what researchers find out."



These insights remind us that the participant experience begins well before consent. Building trust, offering clear communication, and showing appreciation are key to ethical, participant-centered research.

Buzz Trivia and Input

Last month, we asked: In the Belmont Report, which principle emphasizes treating individuals as autonomous agents and protecting those with diminished autonomy?

You Answered: Respect for Persons. **That is correct!** Researchers can optimize the [Respect for Persons](#) principle of the Belmont Report by providing clear information about their study (including risks, benefits and alternatives to participation) in the consent form, confirming participant comprehension as part of the consent process, and emphasizing that research is voluntary and that participants will not lose health services if they decide not to participate.

This month, we want to know: The Nuremberg Code, established after World War II, primarily addresses which aspect of human research?

Test your knowledge and give feedback: <https://forms.office.com/r/PuQ1FuMLeC>

