Ken Easterday helps approve, support clinical studies

Mixing Ethics, Drugs All in a Day’s Work for UCH Pharmacist

By Todd Neff

One minute, you might find UCH pharmacist Ken Easterday at his Anschutz Inpatient Pavilion desk, mulling the ethics of a proposed clinical investigation. Does it show respect for the people participating? Have they been properly informed of the risks and possible benefits? Does the research protocol ensure their well-being?

The next, Easterday might be around the corner, mixing stable isotopes for a diabetes study whose ethics he once similarly pondered.

Easterday’s is a world of forests and trees, of philosophical consideration and fine-toothed action. Twenty percent of his day goes to his work as co-chair of the Colorado Multiple Institutional Review Board (COMIRB), a group dedicated to ensuring the safety of medical studies involving human subjects. He spends the balance of his time with the UCH Department of Pharmacy’s Inpatient Investigational Drug Service, where he ensures some of the very studies he played a role in assessing get the proper supply of pharmaceuticals.

Both are quiet, supporting roles. To those who work with him, though, Easterday is a star.

“We could not do our jobs without him,” said University of Colorado School of Medicine endocrinologist Bryan Bergman, PhD, who, together with wife and collaborator Leigh Perreault, MD, has worked with Easterday for 13 years.

“Literally,” he adds, “human research would not be advancing as quickly without Ken. He’s that vital.”

The ethicist. Easterday has been on COMIRB boards for more than 20 years. The nine-member panels consider anywhere from a half dozen to 15 proposed investigations at each biweekly meeting, and take part in annual (and occasionally, semi-annual) follow-ups, as well as countless informal discussions with investigators preparing studies.

COMIRB considers studies proposed to take place at UCH, Denver Health, the VA Medical Center, Children’s Hospital Colorado and other CU health sciences schools. About 3,800 studies are under active oversight at a given time, Easterday says.

COMIRB seats five boards covering adult; pediatric; oncology and high-risk; social and behavioral; and expedited (minimal risk) research. Easterday chairs one of two adult COMIRB boards. In that role, he’s not so much a pharmacist as an ethicist whose goal is to keep patients safe.

Easterday has a long list of questions he asks himself – and investigators – about each study that crosses his desk. Among them: Why are you doing this study? What’s the hypothesis? What are you trying to accomplish? What are you doing to achieve the objectives? Who can be in it? Who’s excluded? What medications are involved? What previous studies have been done with those medications? How are you monitoring for safety?

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He urges investigators to get in touch with him and COMIRB colleagues early in the process, which can save headaches later. “We’re doing everything we can to minimize risks,” Easterday said.

**Risk aversion.** That’s hard to do. If a therapy was well-understood, it wouldn’t be investigational. Early-phase trials of new drugs are more about figuring out what doses are safe than healing participants. That can make for some profound ethical quandaries.

One study, Easterday recalled, was of a temporary blood replacement intended for those who might otherwise bleed to death. But testing it meant giving it to seriously injured or unconscious patients who were in no position to thoughtfully consider their participation. The board sent the team back several times to make study revisions before ultimately approving it, Easterday said.

“It was fascinating, but I don’t know if I’d want to do that one again, to be honest,” he said.

Guiding Easterday though this and all other research proposals is the U.S. Department of Health & Human Services’ (HHS) *Belmont Report*, published in 1979. Formally titled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research,” the document outlines three core ethical principles (respect for persons, beneficence and justice) to guide human medical research.

It also established three broad ways to address them: informed consent of patients, the investigators’ assessment of the study’s risk versus possible benefits, and the fair and unbiased selection of subjects.

“I think the most significant role we have is trying to have a consent process where someone who’s volunteering to be in a study truly can understand the study’s purpose, its risk, its benefits, and what they’re getting into,” Easterday said.

That said, most potential study participants have no idea COMIRB, UCH’s Human Research Review Committee, HHS’s Office of Human Research Protections and others are looking out for them, he acknowledged.

“The ultimate customer – our human subjects – I don’t think [they] know this is being done on their behalf,” he said.

Sometimes, looking out for patients means taking investigators to task. Easterday has a knack for doing it without ruffling feathers, said Warren Capell, MD, an endocrinologist who co-chaired a board with Easterday and now is COMIRB’s director.

Capell said he considers Easterday a mentor. “He just knows the job so well. He’s an incredibly patient person and incredibly diplomatic.”

Perreault, the endocrinologist, added that Easterday has helped her and Bergman navigate the “enormously complicated process” of designing safe human studies and getting them approved, which can mean walking a fine line between the desire to push the boundaries of scientific discovery and the need to protect patients.

“I can’t think of anybody better able to walk that fine line than Ken,” she said.

“**A wonderful thing.**” All that’s just for his COMIRB side job. Easterday’s main focus is managing UCH’s Investigational Drug Service. In his office, opposite the dozens of binders of studies, are three towering cabinets full of medicine and other items fillable by research participation only.

Around the corner, one finds refrigerators with glass doors not unlike those in the frozen foods section of a supermarket. No Ben & Jerry’s here: rather, medicines are chilled and waiting for one of the perhaps 100 clinical investigations Easterday and colleague Julie
McLaughlin, PharmD, pharmaceutically manage (the Cancer Center has its own investigational pharmacy team).

The role differs from that of a typical inpatient pharmacist, who often acts as a consultant to physicians, suggesting and adjusting therapies according to a given patient’s status. Here, he says, “it’s protocol-driven,” meaning patient X gets therapy Y at dose Z, as prescribed by the study.

There are plenty of wrinkles, though. Easterday manages relationships with the pharmaceutical companies that deliver drugs and placebos, and sometimes mixes placebos himself, depending on the study.

For Perreault and Bergman’s studies on the nature of diabetes, he prepares stable isotopes to help the investigators see, ”If you eat pizza…where the cheese or the crust is going without having to biopsy,” as Perreault put it.

More than once, Perreault and Bergman have needed something very quickly. Despite his crowded work schedule, Easterday delivers, Bergman says.

“He has the most amazing attitude you’ve ever seen in the workplace,” Bergman said. “It’s a wonderful thing to behold.”