

**CSULB**

# **Ethical & Compliance Regulations in Biomedical Research and Drug Development**

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<http://web.csulb.edu/divisions/aa/research/compliance/conduct/>

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# Topics – Ethical & Compliance Regulations (ECR)

- **What** covered under -ECR?
- **Why** - Important?
- **How** - Implemented?
- **Format** – Workshop/ **discussion/video clips**
- **Welcome** - Questions & Inputs
- **References/websites** – Provided

# ECR - What & How ?

## RCR - Responsible Conduct of Research

- Human subjects - IRB
- Live animals - IACUC
- Human embryonic stem cells - SCRO
- Recombinant DNAs – IBC
- Radioactive materials/equipments - RSC
- Intellectual Property- Patents, Licensing
- Imports & Exports vs. Spy
- Financial conflict of interest- FCOI
- Controlled substance - OSHA

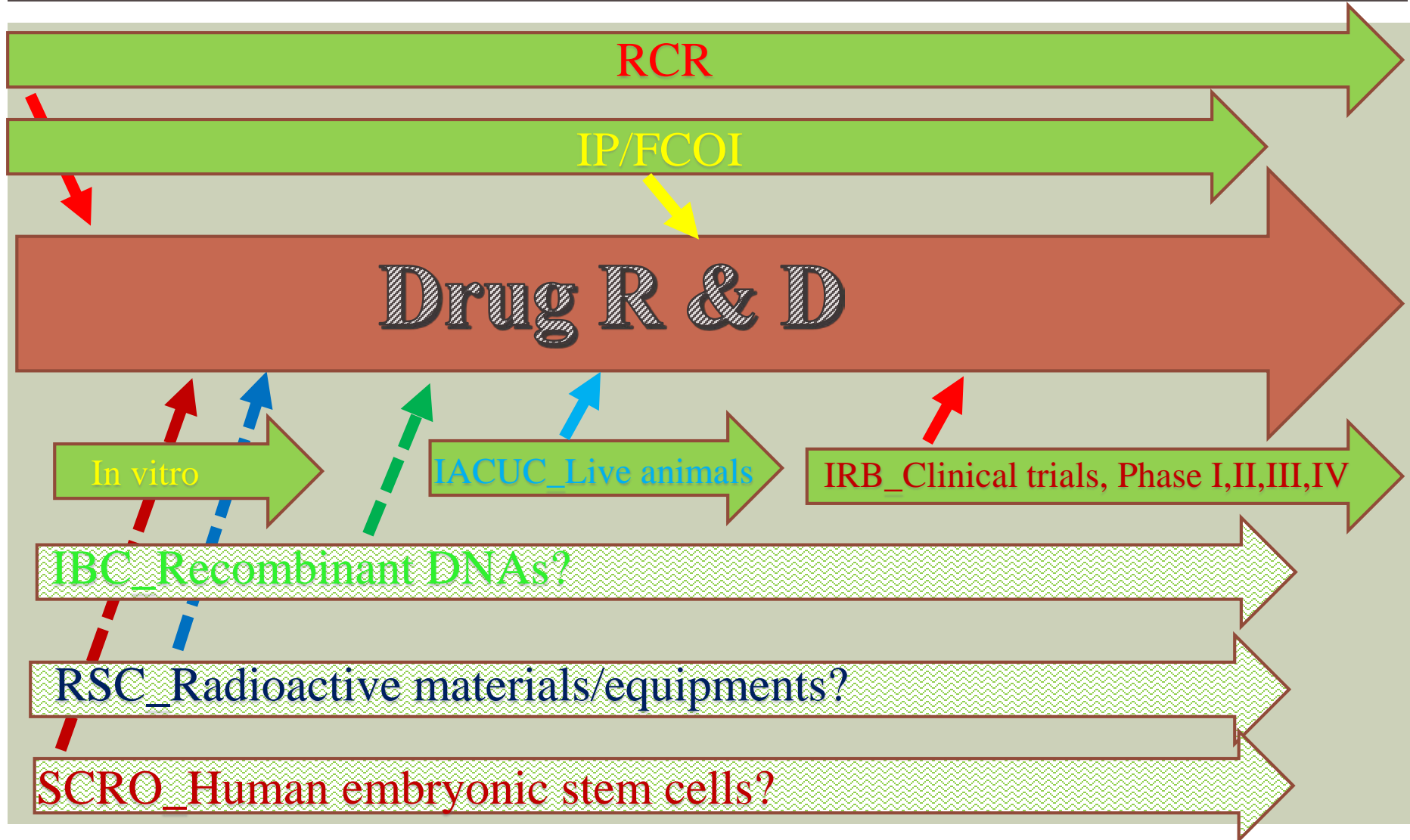
# RESPONSIBLE CONDUCT OF RESEARCH

The National Science Foundation (NSF), the National Institutes of Health (NIH), and the United States Department of Agriculture (USDA) have requirements for training in the **Responsible Conduct of Research (RCR)**.

**Objective - Enhance academic *integrity* by *training* in the accepted professional standards and norms in the conduct of research:**

- **Increase proficiency of ethical dimensions of research/scholarship;**
- **Develop and refine the skills needed to question, analyze, and resolve ethical dilemmas;**
- **Learn relevant legal, institutional and professional standards;**
- **Know where to access various institutional, national and *Internet resources* that address ethical and responsible research practices; and,**
- **Facilitate discourse with peers about ethical dimensions of research within their discipline.**

# ECR governs Drug R & D Flowchart




# China Food and Drug Administration

**CFDA**

China Food and Drug Administration

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## What's New

- [CFDA Minister Bi Jingquan meets German Ambassador to China](#) (2017-02-24)
- [China issues five-year plan on food and drug safety](#) (2017-02-22)
- [CFDA issues Amendment to the Provisions for In-vitro Diagnostic Reagent Registration](#) (2017-



## ABOUT CFDA



- ▶ [Main Responsibilities](#)
- ▶ [Internal Structure](#)

## REGULATORY GUIDE



- ▶ [Drugs](#)
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## LAWS & REGULATIONS



- ▶ [Drug Administration Law of the People's Republic of China](#)
- ▶ [Regulations for Implementation of](#)

# Case-1

## Santa Cruz Biotechnology Agrees to \$3.5M Fine, License Revocation

Friday, May 20, 2016

*Agreement represents an unprecedented settlement under the Animal Welfare Act*

Washington, DC—The **Animal Welfare Institute (AWI)** lauds the U.S. Department of Agriculture (USDA) for reaching a **settlement agreement** in its multiple cases against **Santa Cruz Biotechnology, Inc. (SCBT)**—one of the world's largest research antibody suppliers—resulting in the cancellation of the facility's research registration, revocation of its dealer license and payment of a historic \$3.5 million civil penalty.

“On this 50<sup>th</sup> anniversary of the Animal Welfare Act, the USDA has at long last secured a penalty that is commensurate with the allegations,” said Cathy Liss, president of AWI. Since 2012, AWI has brought public scrutiny to the allegations against SCBT and called for the USDA to take action. “It should serve as a loud and clear message to all research facilities, animal dealers, exhibitors and airlines regulated under this law. Previously, the highest penalties paid to the USDA were less than \$300,000, demonstrating the monumental nature of this settlement.”

The settlement requires SCBT to pay the fine and cancel its research registration by May 31, 2016. The facility's dealer license will also be revoked by December 31, 2016. Although the December deadline allows the company to continue selling antibodies through the remainder of the year, it can only sell such products derived from live animals on or before August 21, 2015. After that, the company is permanently banned in the U.S. from selling antibodies derived from species covered under the Animal Welfare Act. Additionally, the USDA's hearing against SCBT—which had been postponed to August 2016 from April 2016—has been cancelled.



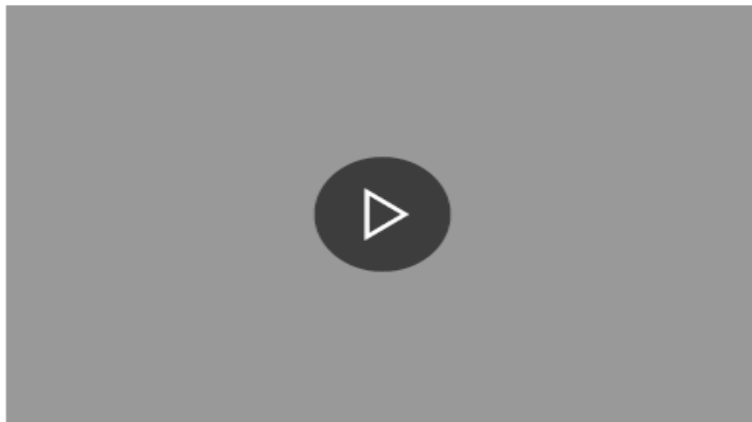


# Case-2

## UCLA, Professor Charged In Lab Fire That Killed 23-Year-Old Assistant

December 27, 2011 11:30 PM

Filed Under: [Lab Death](#), [Organic Chemistry Lab](#), [Professor Patrick Harran](#), [Sheharbano "Sheri" Sangji](#), [Student Died](#), [UCLA](#), [UCLA Chemistry Laboratory](#)



**LOS ANGELES (CBS)** — Los Angeles County prosecutors have filed criminal charges against the [University](#) of California and a UCLA professor in the death of a 23-year-old assistant who was killed in a lab fire.

A warrant has been issued for the arrest of Professor Patrick Harran, A UCLA lab director and organic chemistry professor. Prosecutors said the 42-year-old could face up to 4 1/2 years in prison if [convicted](#) of three counts of occupational health and safety standards causing death.



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# Case-3

## Animal-Rights Activists Claim Responsibility for Arson of UCLA Professor's Car

MARCH 10, 2009

The FBI is investigating yet another attack on a university researcher involved in animal experimentation.

A car was burned on Saturday outside the home of the researcher, an associate professor of behavioral neuroscience at the University of California at Los Angeles, an FBI spokesman said. No one was physically injured in the attack, the spokesman said.

A group called the Animal Liberation Front posted a message on its Web site from an entity calling itself the Animal Liberation Brigade claiming responsibility for the arson attack. The statement said the professor “addicts monkeys to methamphetamines and other street drugs” and promised future attacks that cause “a lot more damage than to your property” if the experimentation continues.

UCLA said in a statement that the professor had been investigating treatments for various psychiatric disorders, including schizophrenia, as well as drug addiction. Gene D. Block, UCLA’s chancellor, said in the statement that the university remained committed “to

<http://www.chronicle.com/article/Animal-Rights-Activists-Claim/42539>

# Case-4a

## Human–animal hybrid

From Wikipedia, the free encyclopedia

The term **human–animal hybrid** or **animal–human hybrid** refers to an entity that incorporates elements from both humans and non-human animals.<sup>[1][2][3][4][5][6]</sup> For thousands of years, these **hybrids** have been one of the most common themes in **storytelling** about animals throughout the world. The lack of a strong divide between humanity and animal nature in multiple traditional and ancient cultures has provided the underlying historical context for the popularity of tales where humans and animals have mingling relationships, such as in which one turns into the other or in which some mixed being goes through a journey.<sup>[7]</sup> **Interspecies friendships** within the animal kingdom, as well as between humans and their pets, additionally provides an underlying root for the popularity of such beings.<sup>[1]</sup>

In various mythologies throughout history, many particularly famous hybrids have existed, including as a part of Egyptian and Indian spirituality.<sup>[2][7]</sup> According to artist and scholar **Pietro Gaietto**, "representations of human-animal hybrids always have their origins in religion". As well, "successive traditions they may change in meaning but they still remain within spiritual culture" in his view.<sup>[2]</sup> The entities have also been characters in fictional media more recently in history such as in **H.G. Wells**' work *The Island of Doctor Moreau*, adapted into the popular 1932 film *Island of Lost Souls*.<sup>[4]</sup> In legendary terms, the hybrids have played varying roles from that of trickster and/or villain to serving as divine heroes in very different contexts, depending on the given culture.<sup>[7]</sup>

For example, **Pan** is a deity in **Greek mythology** that rules over and symbolizes the untamed wild, being worshiped by hunters, fishermen, and shepherds in particular. The mischievous yet cheerful character has the hindquarters, legs, and horns of a goat while otherwise being essentially human in appearance, with stories of his encounters with different gods, humans, and others being retold for centuries on after the days of early Greece by groups such as the **Delphian Society**.<sup>[8]</sup> Specifically, the human-animal hybrid has appeared in acclaimed works of art by figures such as **Francis Bacon**.<sup>[6]</sup> Additional famous mythological hybrids include the Egyptian **god of death**, named **Anubis**, and the fox-like Japanese beings that are called **Kitsune**.<sup>[7]</sup>

When looked at scientifically, outside of a fictional and/or mythical context, the real-life creation of human-animal hybrids has served as a subject of legal, moral, and technological debate in the context of recent advances in **genetic engineering**.<sup>[3][5][9]</sup> Defined by the magazine *H+* as "genetic alterations that are blendings [sic] of animal and human forms", such hybrids may be referred by other names occasionally such as "para-humans".<sup>[1][2]</sup> They may additionally may be called "humanized animals".<sup>[9]</sup> Technically speaking, they are also related to "cybrids" (**cytoplasmic hybrids**), with "cybrid" cells featuring foreign human **nuclei** inside of them being a topic of interest. Possibly, a real-world human-animal hybrid may be an entity formed from either a **human egg** fertilized by a nonhuman **sperm** or a nonhuman egg fertilized by a human sperm.<sup>[3]</sup> While at first being a concept in the likes of legends and **thought experiments**, the first stable human-animal **chimeras** (not hybrids but related) to actually exist were first created by **Shanghai Second Medical University** scientists in 2003, the result of having fused human cells with rabbit eggs.<sup>[5]</sup> As well, a U.S. patent has notably been granted for a mouse chimera with a human **immune system**.<sup>[9]</sup>

In terms of **scientific ethics**, restrictions on the creation of human–animal hybrids have proved a controversial matter in multiple countries. While the state of **Arizona** banned the practice altogether in 2010, a proposal on the subject that sparked some interest in the **United States Senate** from 2011 to 2012 ended up going nowhere. Although the two concepts are not strictly related, discussions of experimentation into blended human and animal creatures has paralleled the discussions around **embryonic stem-cell research** (the '**stem cell controversy**').<sup>[3]</sup> The creation of **genetically modified organisms** for a multitude of purposes has taken place in the modern world for decades, examples being specifically designed foodstuffs made to have features such as higher crop yields through better disease resistance.<sup>[10]</sup>

Despite the legal and moral controversy over the possible real-life making of such beings,<sup>[3][5][9]</sup> then President **George W. Bush** even speaking on the subject in his 2006 **State of the Union**,<sup>[11]</sup> the concept of humanoid creatures with hybrid characteristics from animals, played in a dramatic and **sensationalized** fashion, has continued to be a popular element of fictional media in the digital age. Examples include *Soi-ice*, a 2009 **movie** about experimental genetic research.<sup>[3]</sup> and *The Evil Within*, a **survival horror** video game released in 2014 in



In this 19th-century piece by **Edward Burne-Jones**,<sup>[6]</sup> the human woman **Psyche** receives affection from the hybrid deity **Pan**.

# Case-4b

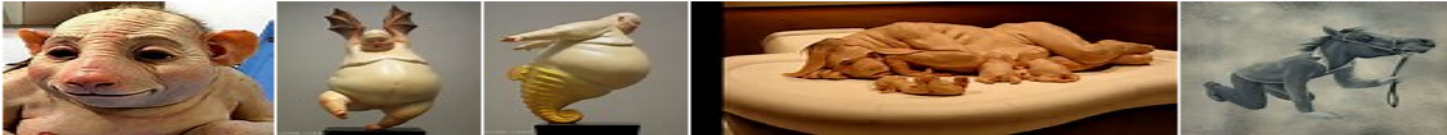
US scientists create 'human-animal hybrids' by growing ...

[www.independent.co.uk](http://www.independent.co.uk) > News > Science

US scientists are growing human organs inside farm animals like sheep and pigs, in research that could one day save the lives of people in need of organ donations.

Images of animal human hybrids

[bing.com/images](http://bing.com/images)



See more images of animal human hybrids

Horrifying Human Animal DNA Experiments Shows ...

[www.inquisitr.com/1343284/horrifying-human-animal-dna-experiments...](http://www.inquisitr.com/1343284/horrifying-human-animal-dna-experiments...)

Horrifying Human Animal DNA Experiments Shows ... Horrifying Human Animal DNA Experiments Shows Transhumanism ... there is a lot of news on the human-animal hybrids ...

[VIDEO] Best Kept Secret!!! Human Animal Hybrids Exist Today ...



[www.youtube.com/watch?v=zfA9I-G-JwM](http://www.youtube.com/watch?v=zfA9I-G-JwM)

BY + WAKE UP + 3M VIEWS

Oct 24, 2014 - Human Animal Hybrids Exist! Animal human #hybrids, secret lab experiments, future technology, ancient ...

Videos of animal human hybrids

[bing.com/videos](http://bing.com/videos)



Human Dog Hybrid DNA

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Human Hybrids Are Real!

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# Case-5

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## SPECIALS



### Woo Suk Hwang

The South Korean stem-cell researcher Woo Suk Hwang has been at the centre of one of the largest investigations of scientific fraud in living memory.

In January 2006, Hwang's home research institution, Seoul National University, delivered a damning report about Hwang's work on cloned human embryos, concluding it was all based on fraudulent data. The revelation has destroyed the best evidence so far that stem cells can be extracted from a clone matched to a specific patient. With Hwang discredited, both the field of therapeutic cloning and the public's trust in science have suffered a serious setback.

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<http://http://www.nature.com/news/specials/hwang/index.html>

# Case-6

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## Researchers question design of fatal French clinical trial

UK's Royal Statistical Society among those demanding more information after the release of trial's protocol.

**Ewen Callaway & Declan Butler**

22 January 2016 | Updated: 23 January 2016 | Corrected: 25 January 2016

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### False memories



**How Facebook, fake news and friends are warping your memory**

Research on collective recall takes on new importance in a post-fact world.

<https://http://www.nature.com/news/researchers-question-design-of-fatal-french-clinical-trial-1.19221>



# References/websites

- **HHS** - <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>
- **PRIM&R** - <http://www.primr.org>
- **NIH-OLAW** - <https://grants.nih.gov/grants/olaw/olaw.htm>
- **USDA-APHIS** - <https://www.aphis.usda.gov/aphis/home>
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