STAR Logistics

- STAR Certificate consists of 11 courses. To obtain a certificate, you must complete all 11 courses within two (2) years.
- For any STAR Program questions: contact Betsy Lazarine and/or Clarissa Cabrera at training@research.ucsb.edu
- Reminder to complete the STAR Evaluation. Emailed to registered participants via e-mail used in UCLC.

Research Compliance

Human Subjects, Animal Subjects, Stem Cell Research, and Responsible Conduct of Research

We will respond to any questions at the end of each segment.

- Melodie Blakemore, Associate Director
  Research Integrity

UC SANTA BARBARA
Office of Research

The Human Subjects Committee (HSC)

What

- HSC = UCSB's Institutional Review Board (IRB)
- Ethics review to protect people in research, at UCSB primarily social-behavioral research

Who

- Minimum 5 members
- Diverse: scientists, non-scientist, community members, variety of backgrounds, cultures

How

- Title 45 CFR 46 - Code of Federal Regulations
- The Belmont Report 3 Ethical Principles: respect for persons, beneficence & justice

Human Subjects
45 CFR 46 "The Common Rule"

Federal policy for the protection of human participants in research.

- Applicable to all federally funded research activities

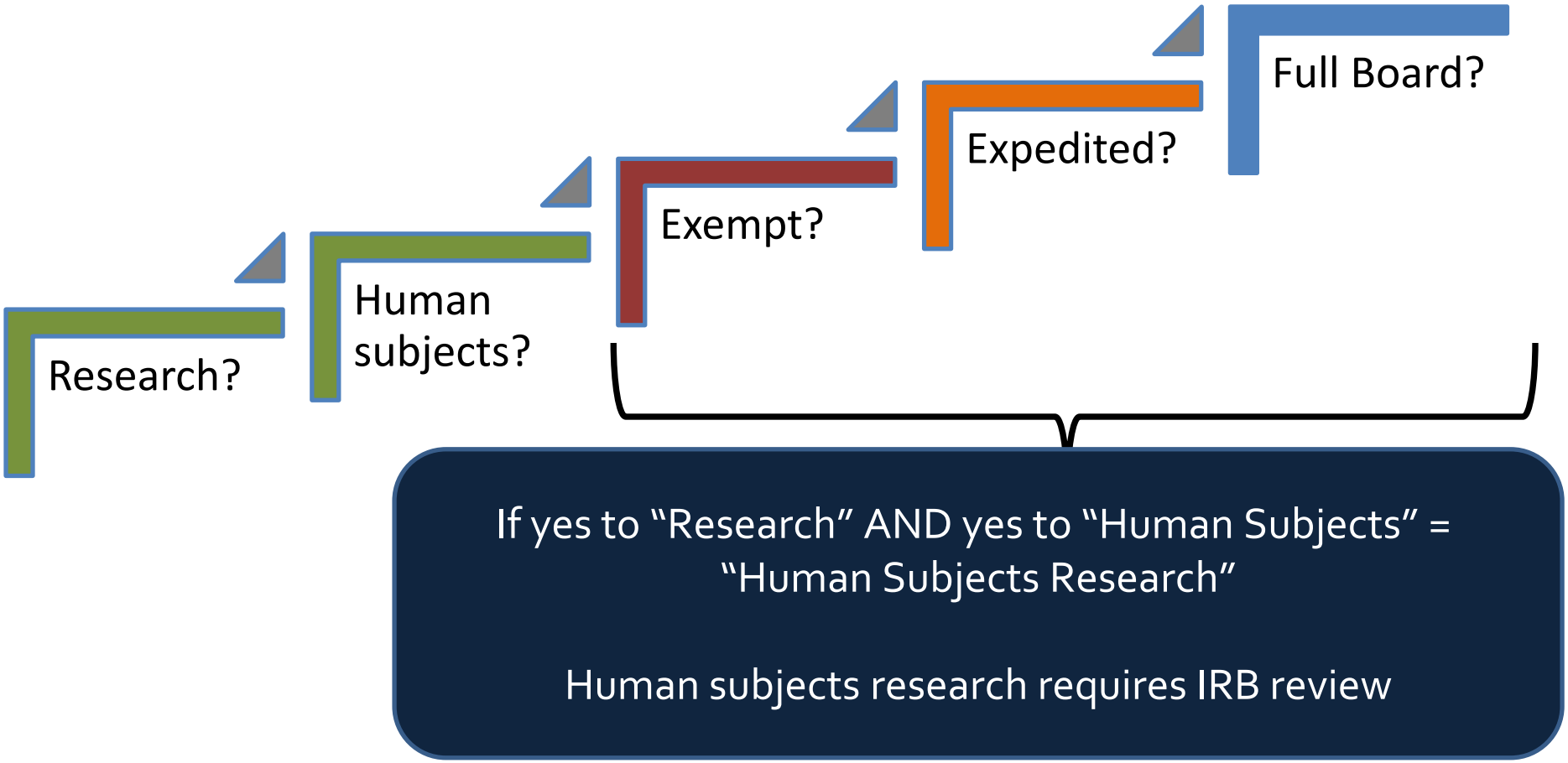
Requirements include:

- Research institutions assure compliance
- Identification of research activities based on the level of risk
- Researchers obtain and document informed consent, unless a waiver is requested/granted
- IRB membership, function, operations, review and criteria for approval of research activities, and record keeping
- Protections of vulnerable research subjects (subparts)

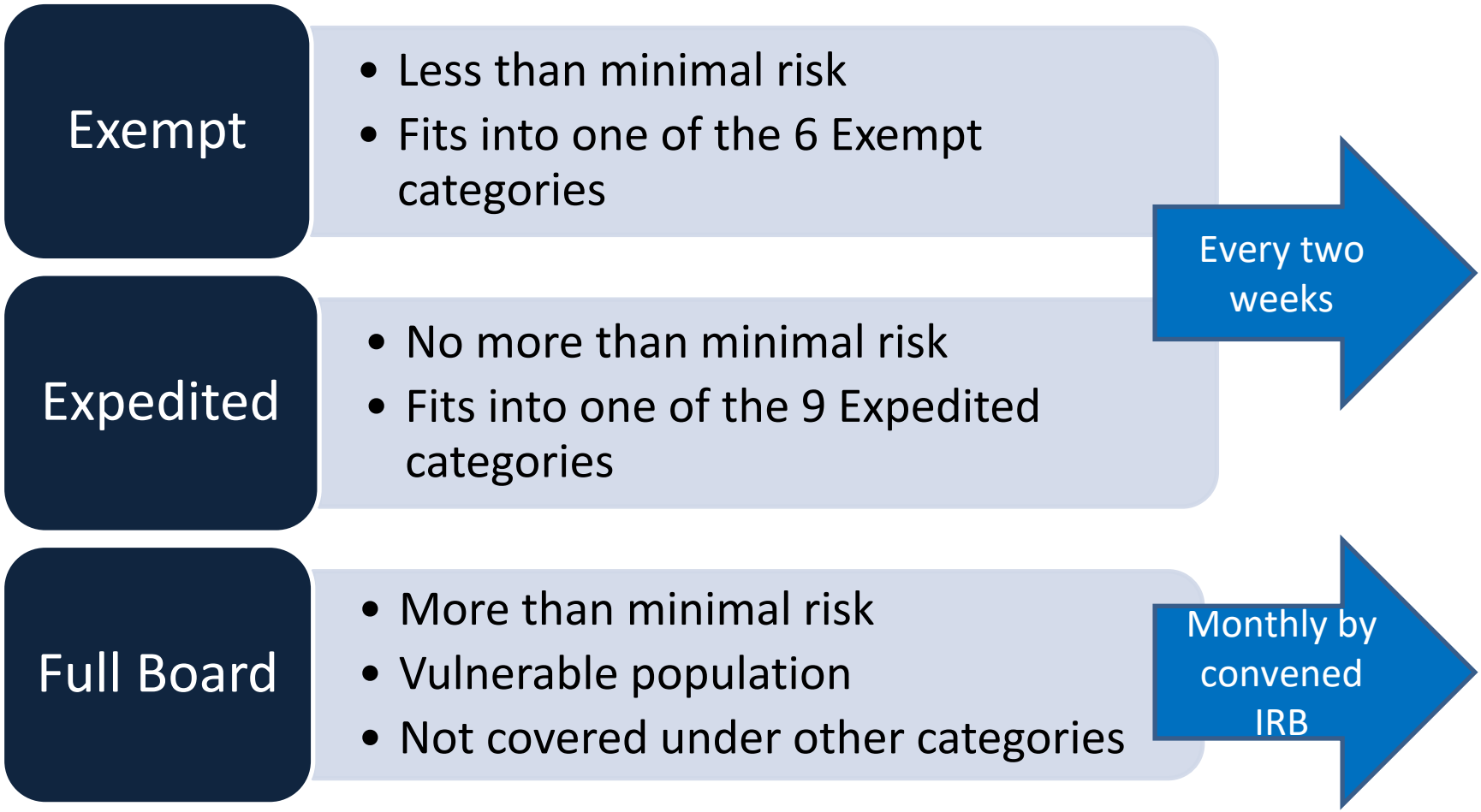
Human Subjects Research

Which One is a Human Subject?

IRB Approach



Levels of IRB review



Exempt Research

<u>Is</u> human subjects research and requires IRB review

Includes surveys, interviews, educational tests, benign behavioral interventions

- Surveys on peoples' attitudes about the influence of Facebook use
- Interviews with instructors on how they develop inclusive course materials
- Focus groups with college students about their STEM experiences.
- Randomly assign subjects to take a test under various noise conditions

Exempt limited review – studies involving ***identifiable private*** information with adequate provisions for protecting privacy and maintaining confidentiality

- Surveys on peoples' attitudes in the workplace

❖ *Exemptions may include incomplete disclosure or deception, provided subjects are made aware of, and agree to, the manipulation, before participation*

UCSB OR Exempt Guide

Expedited and Full Board Research

Expedited – studies that are no more than minimal risk

- MRI or EEG procedures; studying the effects of creativity while completing tasks in a fMRI
- Collection of biological specimens through non invasive means; collection of blood by finger prick, collection of spit to measure cortisol levels while completing math problems under time constraints
- Measuring heart rate variability in determining mindfulness based meditation
- Requesting and analyzing data sets that are considered sensitive

Full Board – studies involving more than minimal risk

- Active deception involving a confederate posing as a research subject
- Treatment interventions with minors diagnosed with Autism Spectrum Disorder
- Research involving illegal activities, research involving undocumented immigrants
- Longer/more frequent MRI studies

ORahs

Office of Research Application for the Use of Human Subjects

- Web-based protocol application
- New researchers (i.e., PIs) must contact the HSC to gain access to ORahs
- Exemption Decision Tree
- ORahs Tutorials (how to add a grant, associate investigator, print approval letter, etc.)
- FAQs posted on website

Datasheets and Orbit Reminders

Datasheet Assurances

- **Question 2 Use of Single IRB** – relates to **federally funded multisite studies** in which one or more domestic institutions are conducting human subjects research
- **Question 3 Clinical Trials** – relates to **federally funded studies** that are considered a clinical trial by definition. This does include social-behavioral research
- **Questions 4 & 5** – If a PI checks yes to use of HIPAA or PII data, then this should trigger an automatic email to the HSC. Datasheet Q1 should be marked as a "yes" if a PI is proposing to use HIPAA and/or PII data in their research
- **Question 6 Human Genomic Data** – for NIH if a PI is using or generating large scale human genomic data, then an Institutional Certification will be required to be submitted at JIT stage. Allow for ample time for the IC to be reviewed and processed.

Human Subjects Research Reminders

.118 Determinations to Release Funding

- Preliminary IRB approval is being requested, however the project lacks immediate plans for involvement of human subjects
- Requires a "blanket in concept only" submission via Orahs to release ORBiT funding

Single IRB Requirements

- Non-exempt multi-site research conducting the **same protocol** across sites
- NIH sIRB requirements already in effect (**January 25, 2018**)
- All Common Rule agencies (e.g., NSF, DOD) sIRB took effect **January 21, 2020**

NIH Data Sharing Expectations

- In effect, **January 25, 2023** – Researchers should have a robust consent process that includes future sharing and use of scientific data, including limitations on future use, and general aspects regarding how data will be managed
- Researchers can visit our website for more guidance: https://www.research.ucsb.edu/human-subjects/NIH-Data-Sharing

Human Subjects Research Reminders

DOD HRPPO Review

- Researchers may not start their human subjects research until they have received the "green light" from DOD

Clinical Trial Registration and Reporting

- Basic experimental studies involving humans (BESH) are studies that meet both the federal definition of basic research and the NIH definition of a clinical trial
- These studies are subject to all NIH clinical trials policies

Clinical Trial Consent Form Posting

- Revised Common Rule requires one consent form to be posted on publicly available **Federal** website.
  - ClinicalTrials. gov
  - Regulations. gov (Docket ID: HHS-OPHS-2018-0021)

  New OHRP guidance on posting informed consent document to Regulations.gov

  Consent forms must be posted after recruitment has closed, and no later than **60 days** after the last study visit by any subject

Animal Subjects

The IACUC (Institutional Animal Care and Use Committee)

What

- IACUC = UCSB's animal care and use committee
- Federally mandated committee reviews use of vertebrate animals in research, teaching and/or testing

Who

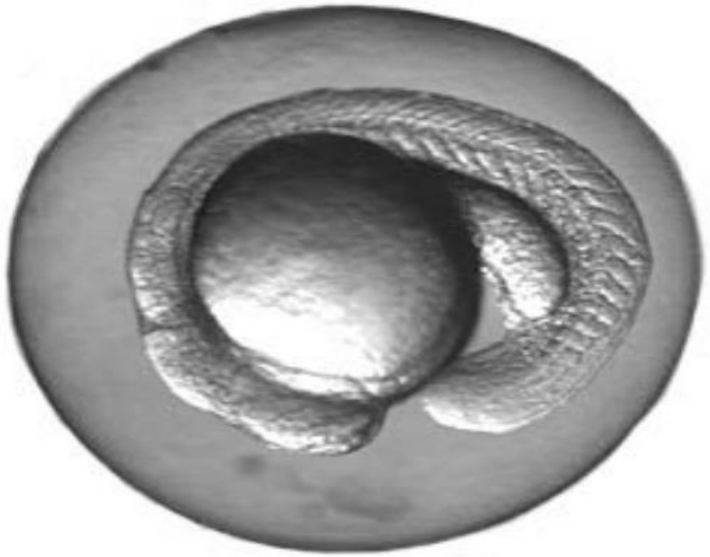
- Minimum 5 members
- Diverse: chair, scientist, non-scientist, community member, veterinarian

How

- PHS Policy – The Guide
- Animal Welfare Act & Animal Welfare Regs.
- AAALAC – voluntary accreditation

Vertebrate Animals

Invertebrate Animals



Why Regulate Animal Use?

- Research or teaching that utilizes animals is a privilege, not a right, and the IACUC is responsible for ensuring animals are used according to the highest standards
- For the kinds of research being done by UCSB PIs, vertebrate animals are being used to either:
  - Further understanding of human biology/behavior
  - Further understanding animal biology/behavior, particular to a group or species
- The IACUC protects the investigator and institution, while also ensuring the use of animals in research or teaching in an ethical manner

Why Regulate Animal Use? (cont.)

- PHS (i.e., NIH, NSF) recognizes that animal research is generally a moral imperative before subjecting humans to new procedures or drugs
- Animal use must be performed in accordance with all federal & state regulations, local laws, and institutional policies and procedures

Examples of governing regulations we are subject to:

- Nuremberg Code
- Guide for the Care and Use of Laboratory Animals
- PHS Policy on Humane Care and Use of Laboratory Animals
- CA Department of Fish and Wildlife Regulations
- American Veterinary Medical Association Guidelines on Euthanasia
- USDA Animal Care Policies

How Does a Researcher Apply for Animal Use?

- Contact the IACUC Coordinator (iacuc@lifesci.ucsb.edu)
- Consult with the Attending Veterinarian
- Plan accordingly – submission to review and approval typically takes 2 months or more
  - No summer meetings during July – August
  - Meeting dates and timelines are posted online
- Protocols may be approved for a maximum of 3 years
- PIs are also responsible for obtaining Biological Use Authorizations, Radiation Use Authorizations, DEA licenses, and applicable wildlife research permits from agencies (state, federal, NPS, etc.)

What About Risks to Researchers?

- All animal users must enroll in the Occupational Health and Safety Program (OHSP)
- OHSP consists of a medical health history form, animal use information, and a risk assessment
- EH&S should be providing support to PIs to mitigate any identified hazards
  - Biological, chemical, laboratory, or field

Where Does UCSB Animal Research Take Place?

Campus Operated Facilities

- Central Vivaria
- Approved satellite facilities
- Natural reserves

Field Sites

- Many field locations, given the nature of the research

Subawardee Institutions

What Triggers an IACUC Request?

- A request to use vertebrate animals must be reviewed and approved by the IACUC prior to initiation of any studies.
- Review is required regardless of animal use site, funding source, species, or animal numbers.
  - Includes use of animals in teaching and field studies
  - "Do I Need a Protocol" form if unsure whether project involves vertebrates
- Datasheets marked as "yes" to Animal Subjects Use.
  - Includes sub awards involving vertebrate animal research

Animal Subjects Research Reminders

Change to USDA-APHIS IACUC review requirements

- Effective **December 27, 2021**, the USDA implemented an amendment to the Animal Welfare Act regulations to reduce duplicative requirements and administrative burden for research facilities by removing the requirement for IACUCs to conduct Annual Reviews of protocols involving covered species.

- In ORBiT, this means that the AS Expiration Date will now almost always be the same as the AS Protocol End Date. For awards where only a subawardee is working with animals, it may still be different.

Change to USDA-APHIS vertebrate animal regulations

- Effective **August 21, 2023** regulations established for the humane treatment, care, handling, and transportation of captive birds that are not bred for research.

Animal Subjects Research Reminders

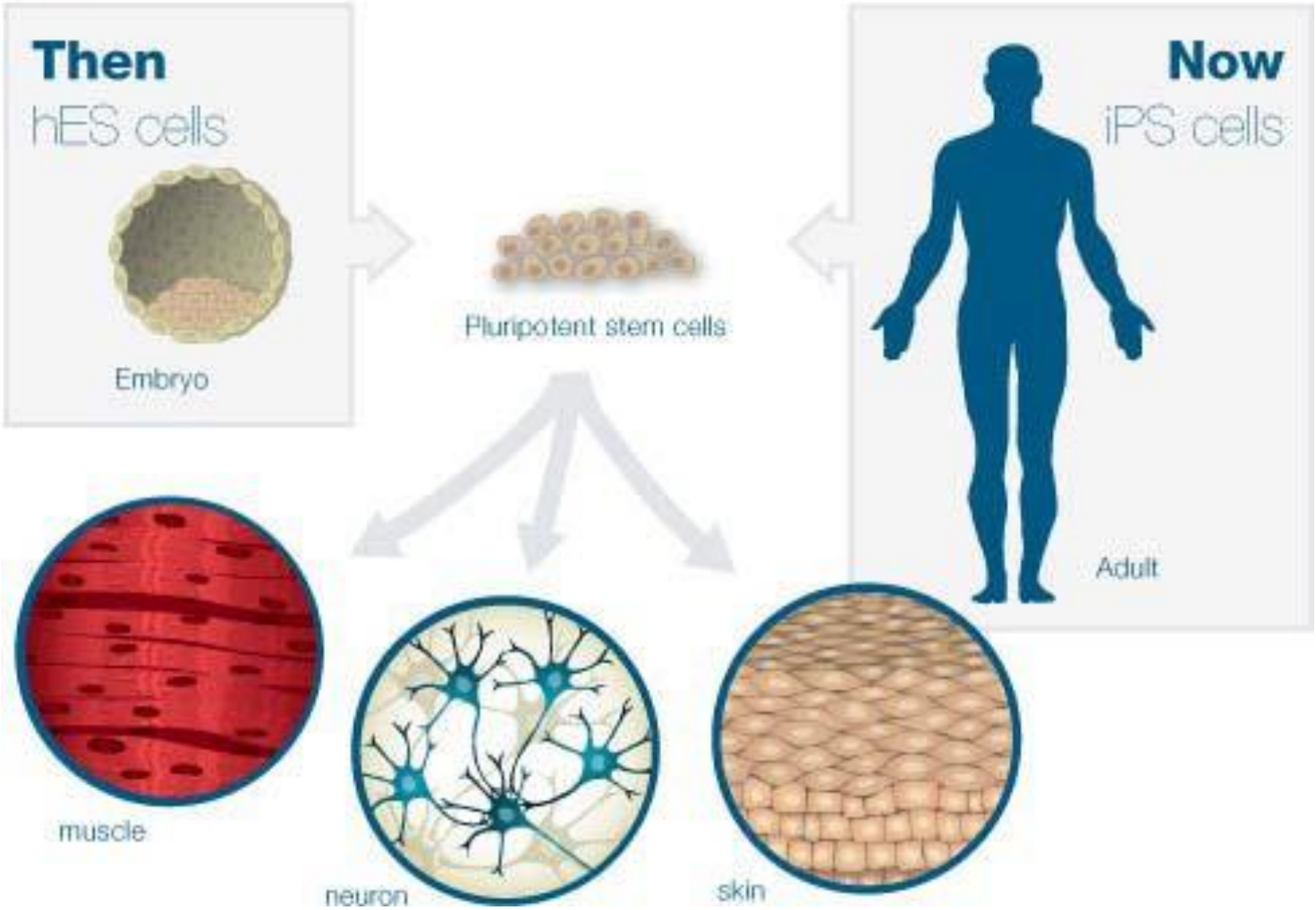
Office of Research Animal Management System (ORAMS)

- System is in implementation phase
- Protocol submission and review process, researcher training, animal number tracking
- Automated email reminders
- All researchers working with animals are **required to use ORAMS**

Subawards

- Subawards involving animal subjects may require a Memorandum of Understanding (MOU) between institutions to delineate animal care and use responsibilities
- Foreign subawards may take time to negotiate terms and obtain approvals. Translated copies of protocols and approvals are required
- Researchers should plan accordingly as obtaining documentation for subawards may (and usually do) take additional processing time

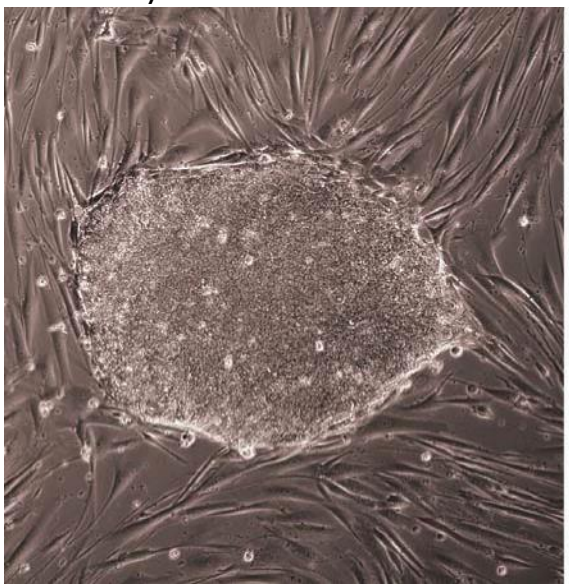
Stem Cell Research



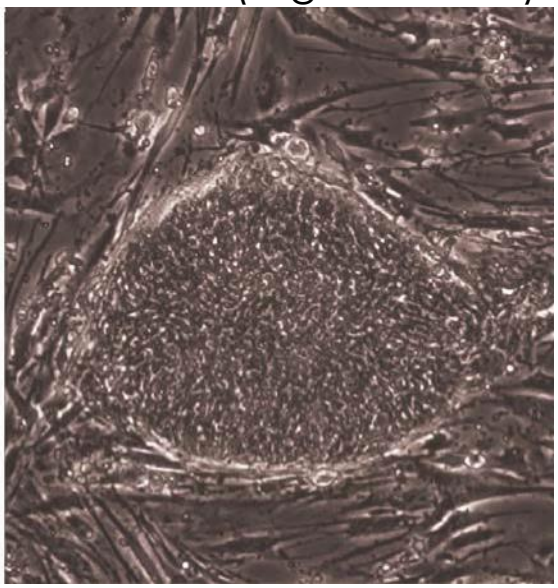
What are Stem Cells?

- All stem cells – regardless of their source – have three general properties:
  - (1) They are capable of dividing and renewing themselves for long periods;
  - (2) They are unspecialized
  - (3) They can give rise to specialized cell types

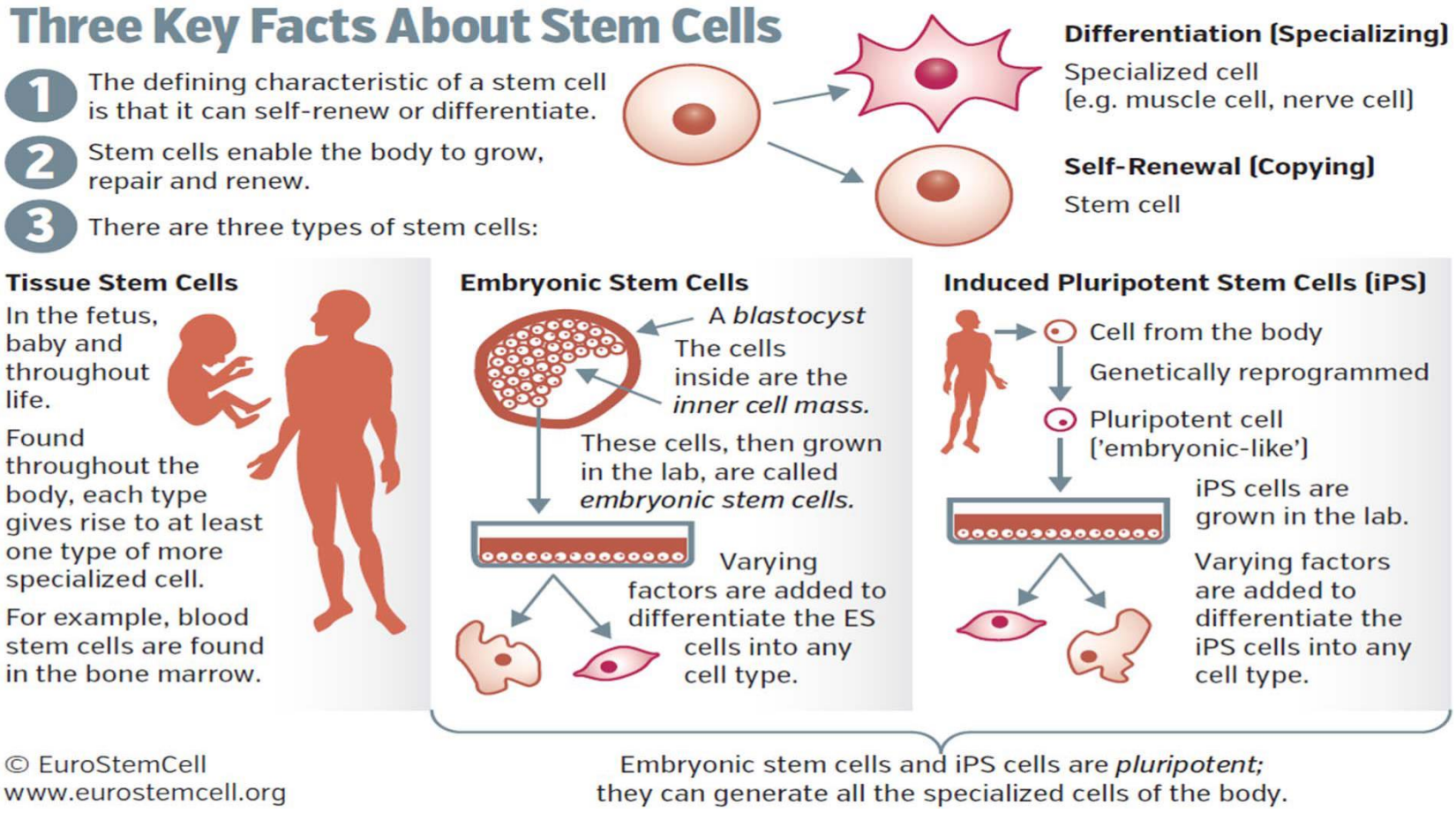
embryonic stem cells



adult cells (e.g., skin cells)



What are Stem Cells? (cont.)



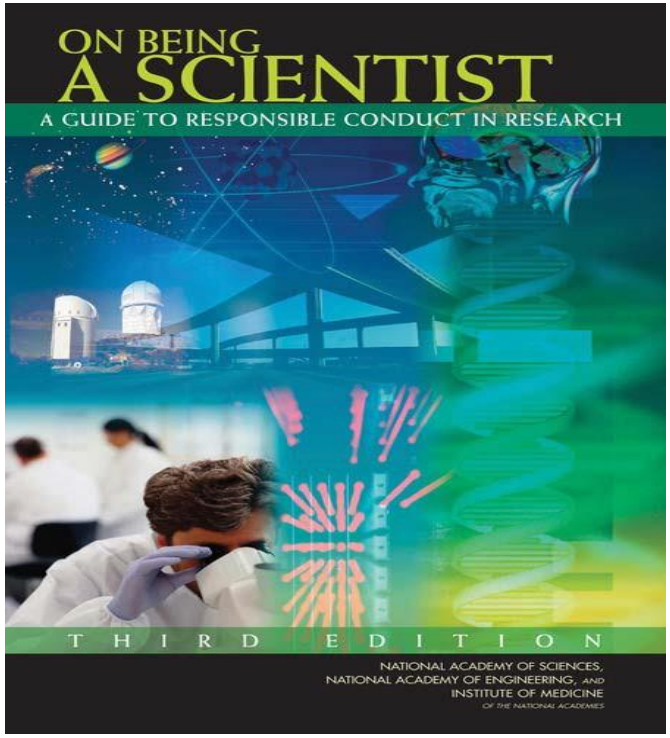
What is Available to our Researchers?

- "Approved" cell lines – according to rules of derivation
- Newly established stem cell lines (e.g., NIH repository)
- iPS stem cell lines (e.g., Coriell Institute, collaborators, generated by UCSB)
- Depending on the source of the cell lines (i.e., how the cells were obtained) will dictate what types of compliance approvals may be needed

Stem Cell Research Reminders

- UCI is the reviewing Stem Cell Research Oversight (SCRO) committee for UCSB. UCSB relies on UCI's review of our stem cell research activities
- hSCRO users must create an account with UCI to submit and access their protocols.
  - SCRO applications should include BUA approval
  - Depending on source, IRB approval may be required
  - In rare cases, IACUC approval may be required
- No changes for UCSB in terms of how proposals and awards are processed
- Datasheet assurances
  - Question 8 for human stem cells – for NIH proposals, if a PI plans to use human fetal tissue derived from an elective abortion, then the PI will be required to submit additional documentation to NIH

Responsible Conduct of Research



Responsible Conduct of Research

- Responsible conduct of research (RCR) is defined as, "the practice of scientific investigation with integrity."

- It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

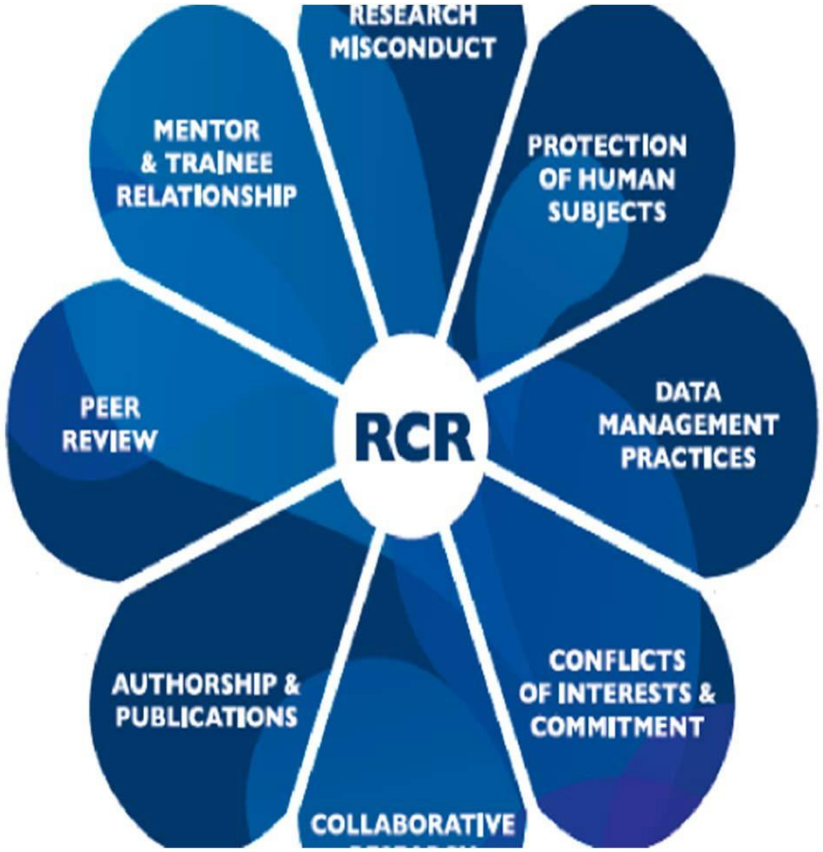
Responsible Conduct of Research

- Mandated RCR training to prepare students as the future generation of scientists and engineers
  - NSF awards
  - USDA-NIFA awards
  - Certain NIH awards (training grants, fellowship awards, career development awards, research education grants, dissertation research grants, etc.)
    - Funding Opportunity Announcement (FOA) may specify instruction in responsible conduct of research
- All undergraduates, graduates, and post-doc researchers should complete the RCR training
  - Ethics seminars
  - Online training
  - Mentorship from researcher's faculty advisor

Responsible Conduct of Research

Training Includes:

- Data acquisition, management, sharing, ownership
- Peer review
- Collaborative research
- Conflicts of interest
- Policies regarding human, animal & stem cell use, and safe lab practices
- Research misconduct
- Responsible authorship and publication
- Other contemporary issues



RCR Reminders

- An NIH training grant has facilitated the creation of an in-person RCR course for graduate students
- Citiprogram is available to all researchers at no cost for the online training component
- New NSF requirements:
  - Expand the training audience to include faculty and other senior personnel.
  - Add the following topics
    - Mentor training and mentorship
    - Research security threats
    - Export control, disclosure, and reporting requirements

Questions?

For Stem Cells, RCR, contact:

- Melodie Blakemore, Blakemore@research.ucsb.edu
- 805-893-4286

For Human Subjects, contact:

- Monica Solorzano, Robert Crouch hsc@research.ucsb.edu
- 805-893-3807, X4286

For Animal Subjects, contact:

- Melissa Wroten, iacuc@lifesci.ucsb.edu
- 805-893-5855