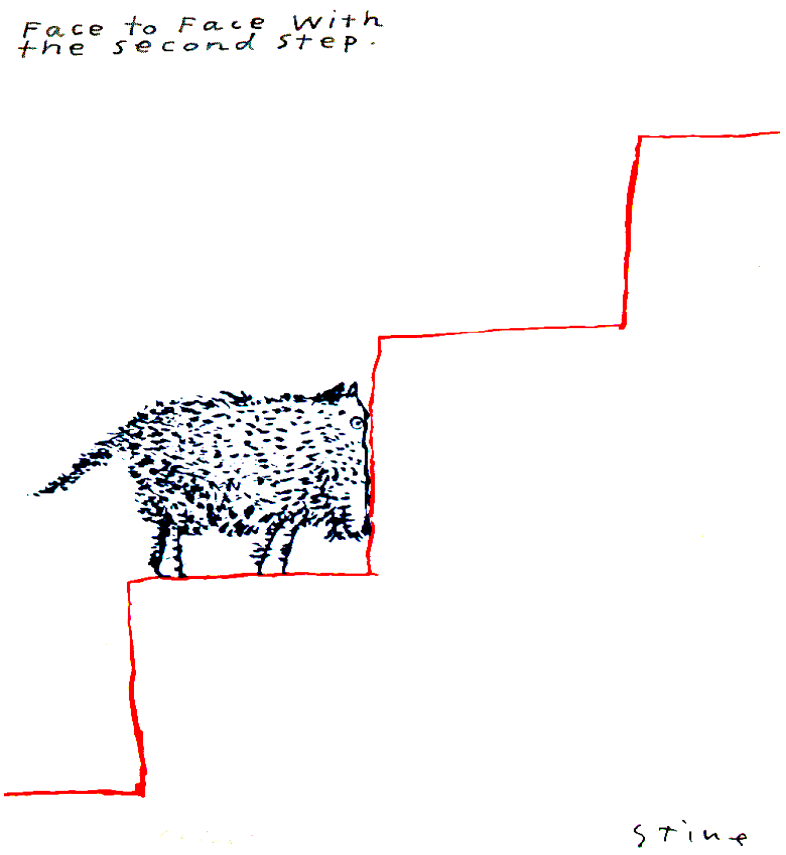
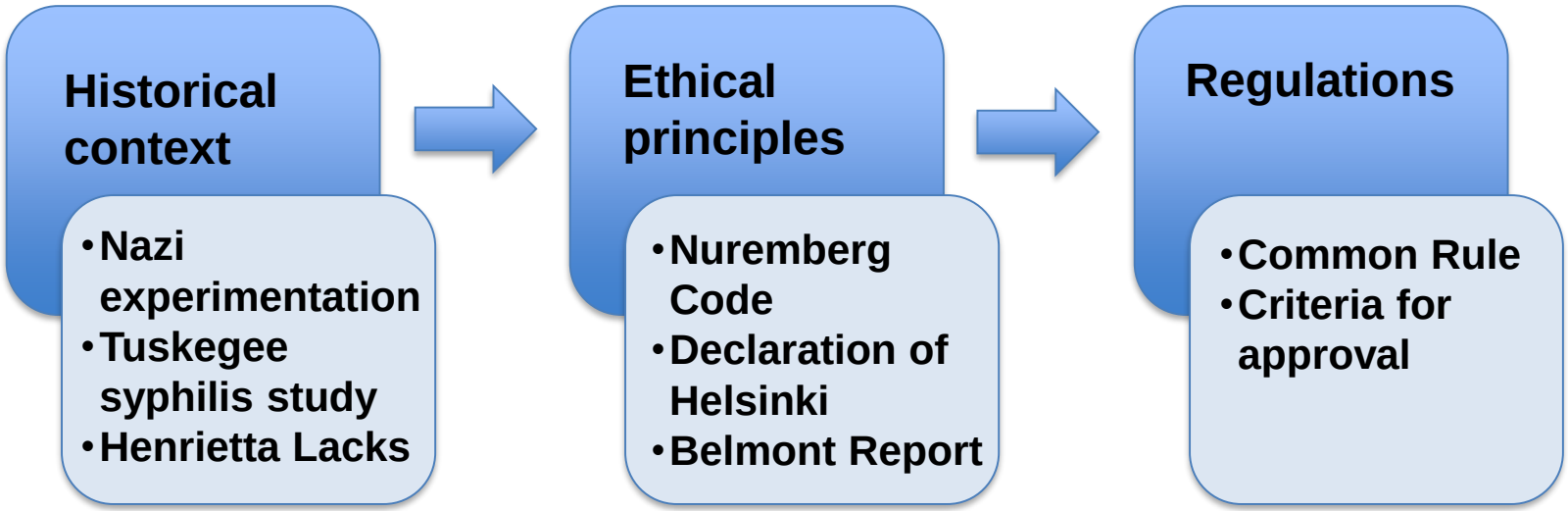
Lawrence Berkeley National Laboratory Revised Common Rule

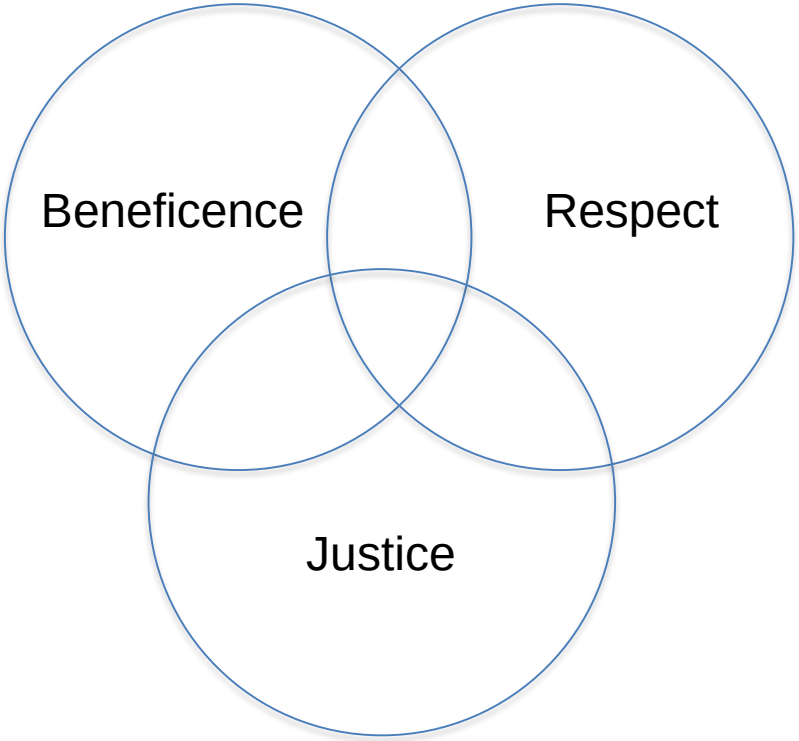


Why IRB review?



Common Rule Principles 1979

Risk/Benefit analysis
PI qualifications
Experimental design



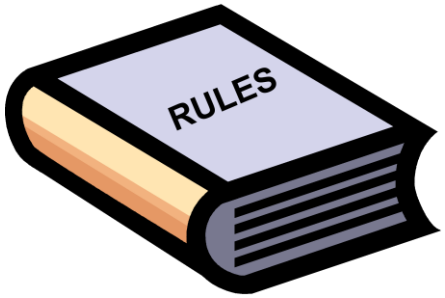
Consent
Inclusion/exclusion
Recruitment

Subject selection
Privacy
Protection of subjects (especially vulnerable populations)

Revised Common Rule

- The Common Rule, which went into effect in 1981, governs the use of humans used as research subjects in the United States.
- The Common Rule is the baseline standard of ethics by which any government-funded research in the US is held; nearly all U.S. academic institutions hold their researchers to these requirements regardless of funding.

Revised Common Rule



- The Common Rule was revised with opportunities for public comment, from 2015-2016. It will go into effect on 20 January 2019.
- LBNL will be following the provisions of the new rule and will update the HARP system, which handles protocols detailing the use of human subjects in research.

When do the regulations apply?

To determine if your project is non-exempt human subjects research…..

The IRB asks these questions in this order:

1. Does the activity involve **research**?
2. Does the research involved **human subjects**?
3. Is the research with human subjects **exempt**?

Question 1: Does the Activity Involve Research?

- …a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**
- **Revised Common Rule**
  - Citation moved from §46.102(d) to §_.102(l) in the revised rule
  - Four types of activities are specifically deemed not to be research

Activities Deemed Not to be Research in the Revised Common Rule

1) Scholarly and journalistic activities

2) Public health surveillance activities

3) Information collection for criminal justice purposes

4) Operational activities for national security purposes

Question 2: Does the Research Involve Human Subjects?

Human subject: a living 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 identifiable private information or identifiable biospecimens

§_.102(e)(1)

Revised Common Rule: no substantive changes in interpretation, only clarifying

Human Subjects Protocol Review

- Non-human subjects research
- Human subjects research of minimal risk deemed **exempt** from further review
- Human subjects research of minimal risk suitable for **expedited** review
- Human subjects research needing **full** convened committee review

All categories of review have been expanded.

Question 3: Is the Research with Human Subjects Exempt?

Pre-2018 Rule

6 exemptions, §46.101(b)(1)-(6)

Revised Common Rule

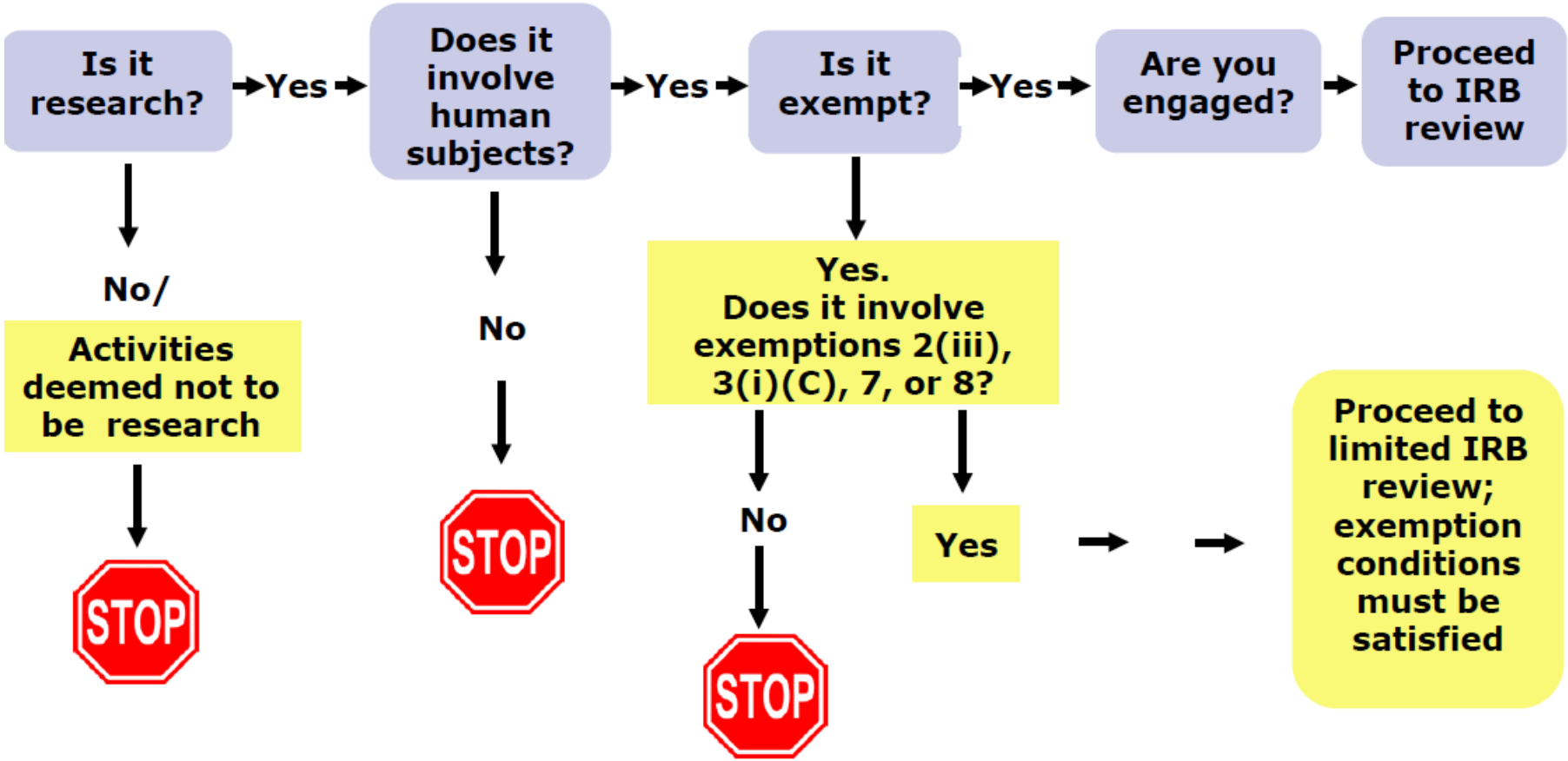
8 exemptions, §_.104(d)(1)-(8)

Exemptions 3, 7, and 8 – new

Exemption 1, 2, 4, and 5 – modified

Exemption 6 – no change

When do the regulations apply?



Summary of Changes in Exemptions in **Revised Common Rule**

Pre-2018 Rule (Current)		**Revised Common Rule**
Ex 1: Educational Practices	→	Restrictions added
Ex 2: Ed test, survey, interview, observation of public behavior	→	Expanded
Ex 3: Research on public officials	→	Replaced by new ex 3
Ex 4: Research on existing data	→	Expanded old and added new
Ex 5: Public benefit programs	→	Expanded with changes
Ex 6: Taste and food evaluation	→	No change + New exemption 7 + New exemption 8 + New: limited IRB review

Exempt Category Reviews

- Most common use of these categories at LBNL are categories using **surveys and questionnaires in research** (exemption 2), and those using **pre-existing, unidentified data and samples** (exemption 4).
- HARP users will find detailed descriptions and a few new questions to be answered for these categories.

Exemption 2: *Expanded*

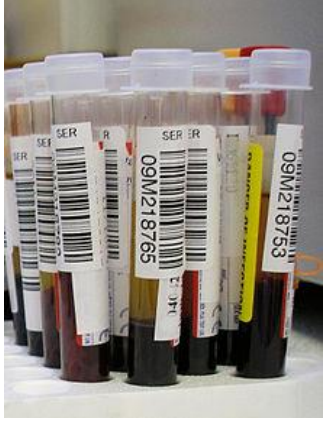
- Research that ***only includes*** interactions involving educational tests, surveys, interviews, and observations of public behavior, exempt when:

  i. Information recorded cannot be readily linked back to subjects, **or**

  ii. Any information disclosure would not place subjects at risk of harm, **or**

  iii. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under §__.111(a)(7)

Exemption 4: Secondary Research Use of Identifiable Private Information or Identifiable Biospecimens



Materials no longer need to be "existing"

Exempt if:

i. Identifiable materials are publicly available, **OR**

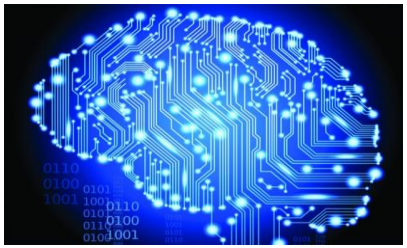
ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, **the investigator does not contact the subjects or re-identify subjects**

Research with Coded Biospecimens or Coded Private Information

If research involves ***only*** coded biospecimens or coded private information ***and*** meets both of the following:

1)is not collected specifically for the research in question, **AND**

2)investigator(s) cannot readily ascertain identity of the individual(s) to whom data/specimens pertain,



- then it is ***not*** **human subjects research.**
- **(Not changed under the revised Common Rule!)**

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Expedited Category Reviews

- Expedited category reviews will no longer require annual review according to the Revised Common Rule.

- However, due to LBNL's contract with DOE, and the annual collection of data on human subject use this requires, LBNL will still be requiring annual review of these protocols. ⌛

Full Review Protocols

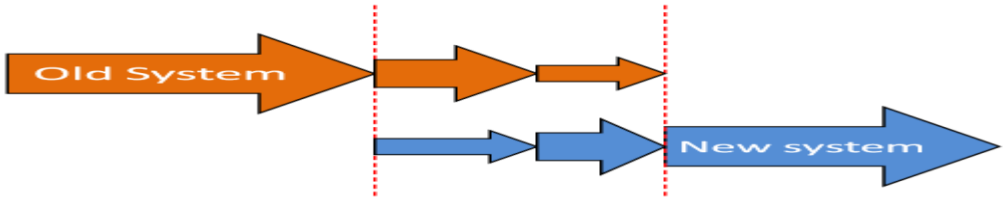
- Longer informed consent forms will now have to begin with a set of key facts about the study.

- Consent forms of four pages or less will not need these.

Full review: Key facts

Title	The effect of a sunny day and beautiful view on blood pressure and blood composition
Researchers	Susan Smiles, MD and Larry Laughs, PhD of LBNL
Participants	Healthy men and women between the ages of 22 and 65
What you will be asked to do	Look out of a window at a panoramic view of the San Francisco Bay for half an hour. A small amount of blood will be drawn and your blood pressure will be taken both before gazing out the window and afterwards.
Length of project	The project will continue for three years. Participant's role will be limited to two participations in the above, separated by nine months.
Potential risks and benefits	There is a small risk of bruising from the blood draw or the blood pressure cuff. Benefits of knowledge gained from this study will be to humanity as a whole.
Participants' options	Participating in this study is voluntary. You will have all your questions answered before you sign this consent form. You may withdraw from the study at any time.

Revised Common Rule and HARP



- Modifying the Human and Animal Research Protocol database (HARP) is currently underway and is projected to be up and running by 1 February 2019.
- HARP will be closed to new submissions of human subjects protocols from January 18 – February 1, 2019, for implementation and testing.
- The requirement for single IRB review in multi-institutional studies goes into effect **January 20, 2020**