



**REGENT
UNIVERSITY**

Regent Institutional Review Board (IRB)

Faculty Training

August 26, 2024

Regent University IRB Faculty Training

August 26, 2024 3:05 – 4:30pm

Robertson Hall 105

Schedule:

3:05 – 3:15 – Welcome and context for the Regent IRB

Dr. Victor Counted
and Provost Dr. Bill Hathaway

3:15 – 3:45 – Orientation to the Regent IRB website (www.regent.edu/irb)

Dr. Danny Hitchcock, Chair IRB

3:45 – 4:15 – Cayuse Video for New User (www.regent.edu/irb under *Resources* drop-down)

Also, see PDF hand out <https://www.regent.edu/wp-content/uploads/2024/08/regent-university-cayuse-user-guide.pdf>

4:15 – 4:30 – Questions/Discussion

Christian Leadership & Research Ethics

William L. Hathaway, Ph.D.



Nuremburg "Doctor" Trials (1947-1947)



Tuskegee Syphilis Studies (1932-1972)

What an IRB will do for Regent

Protects human subjects

Promotes the Mission: God honoring research is ethical research

Gives us access to additional revenue streams

Enhancing our academic culture

Thomas Percival (1740-1804)



- Physician, philosopher, abolitionist from Manchester, England
- Raised as an “orthodox Anglican”, later became a dissenter (likely a Universalist), and a student at the renown “Warrington Academy”
- Studied medicine at University of Edinburgh and received degree from University Leyden.
- Returned to Manchester to practice medicine and assume prominent role in local literary/philosophical society.

MEDICAL ETHICS;

OR, A CODE OF

Institutes and Precepts,

ADAPTED TO THE

PROFESSIONAL CONDUCT

OF

PHYSICIANS AND SURGEONS;

- I. In Hospital Practice.
- II. In private, or general Practice.
- III. In relation to Apothecaries.
- IV. In Cases which may require a knowledge of Law.

To which is added

An Appendix;

containing

A DISCOURSE ON HOSPITAL DUTIES;

ALSO

NOTES AND ILLUSTRATIONS.

BY

THOMAS PERCIVAL, M. D.

F. R. S. AND A. S. LOND. F. R. S. AND R. M. S. EDINB. &c. &c.

Manchester :

PRINTED BY S. RUSSELL,

FOR J. JOHNSON, ST. PAUL'S CHURCH YARD, AND
R. BICKERSTAFF, STRAND, LONDON.

1803.

The First Text on Medical Ethics

- 1794: *A Code of Conduct for Physicians and Surgeons.*
- 1803: Expanded version: *Medical ethics: A Code of institutes and precepts adapted to the professional conduct of physicians and surgeons*
 - - invents key phrases:
 - “professional ethics”
 - “medical ethics”

Historical Legacy of Percival's Code

- 1808: Boston Medical Society formulates ethics code, modeled after Percival's code
- 1847: AMA formed & adopted a Percivalian "Code of Ethics" (1st code of ethics adopted ever by a professional society)
- 20th Century: Codes of Conduct were promulgated for many professions. Having such a code becomes the hallmark characteristic of formal professions in Western societies.

Examples of Percival's religious concern

- Medical students at the 'new universities' of his time often lived alone and found themselves committed to study on the weekends.
- The skeptical bent of their discipline also predisposed them towards 'infidelity'
- He argued these twin factors resulted in non-attendance at 'public worship'
- This was a moral problem for the physician personally but also for the context of care because:
"...non-attendance of public worship will lead to coldness of heart and moral insensibility" (Gregory, 2001, p. 40).

Percival- On the Importance of Public Worship Attendance

Percival's First Chapter: *Of Professional Conduct, Relative to Hospitals, or Other Medical Charities*

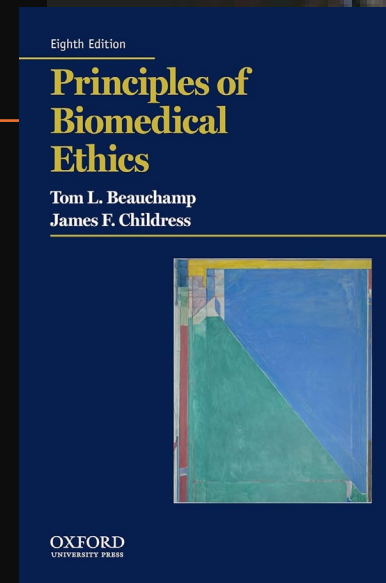
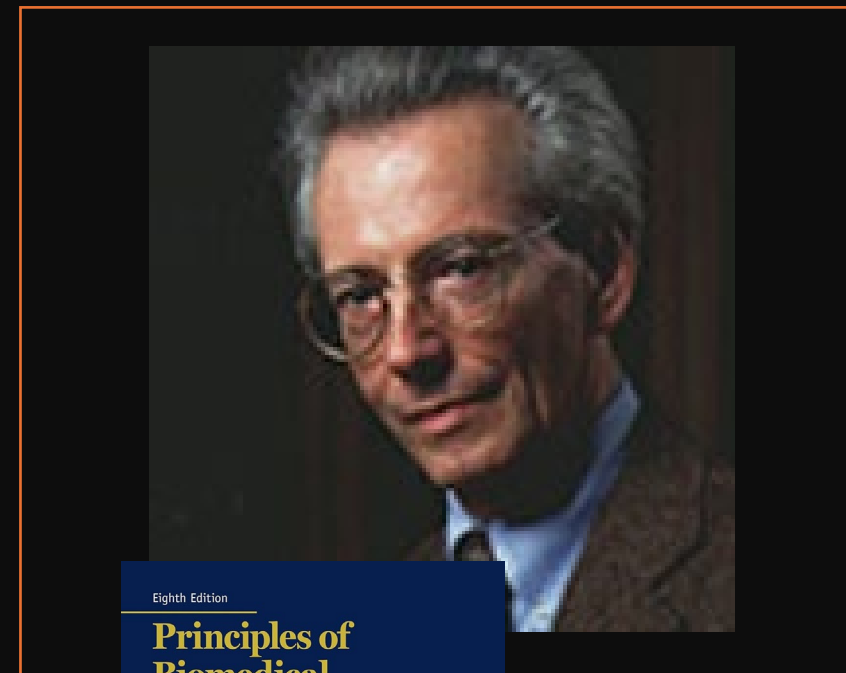
XXIV. Hospital consultations ought not to be held on Sundays, except in cases of urgent necessity; and on such occasions an hour should be appointed, which does not interfere with attendance of public worship. (p. 22)

Percival's Second Chapter: *Of Professional Conduct in Private or General Practice*

- XXX. The observance of the Sabbath is a duty to which medical men are bound, so far as is compatible with the urgency of the cases under their charge. Visits may often be made with sufficient convenience and benefit, either before the hours of going to church, or during the intervals of public worship. An in many chronic ailments, the sick, together with their attendants, are qualified to participate in the social offices of religion; and should not be induced to forego this important privilege, by the expectation of a call from their physician or surgeon.

The Georgetown Mantra

- Seminal text by Tom L. Beauchamp & James F. Childress (1979), *Principles of Biomedical Ethics*, written while they were both at Georgetown University's Kennedy Institute of Ethics (Now in 8th Edition)
- Four Key Principles for Bioethics:
 - **Respect for Autonomy**
 - **Nonmaleficence**
 - **Beneficence**
 - **Justice**
- Since the 5th Edition (2001), they now assert directly that they derive from a **common morality** construed as “ . . . the set of norms that all morally serious persons share” (p. 3)



Influential Statements on Research Ethics

Nuremberg Code (1947)

Declaration of Helsinki (2000)- World Medical Association

[Belmont Report \(1979\)](#)

Council for International Organizations of Medical Sciences (CIOMS 2002)

U.S. Common Rule (1991)

[Revised Common Rule \(2018\)](#)

NIH's 7 Principles of Ethical Research



Social and clinical value



Scientific validity



Fair subject selection



Favorable risk-benefit ratio



Independent review



Informed consent



Respect for potential and enrolled
subjects

Sam Leinster
(2007)-
Christian
Medical
Fellowship

“We need to conduct our research with integrity, diligence, honesty and humility. In so doing, we will be salt and light to our academic colleagues”.

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Regent University IRB

- Our [Research Handbook](#) for Research and Sponsored Programs highlights our Christian Commitments as we encourage Regent faculty and students to pursue research involving human participants.
- The US Federal Government requires all federally funded research to adhere to best practices for conducting ethical research.
- At Regent University, we apply these principles to all work done with human participants regardless of funding.

Regent University IRB

- A few key principles include: (affirmed Federal by policy)
Genesis 1:27 & 31; Matthew 7:12; Micah 6:8
 - Respect – value the dignity & worth of all people, affirm autonomous decision-making
 - Beneficence – promote good and to do no harm
 - Justice – encourage research that distributes risk and promotes benefits equally to all persons.

Regent University IRB

Research Review Process—3 types of Review

1. **Exempt from Review**— minimal risk low potential for harm/distress, public observations, anonymous data
2. **Expedited** – minimal risk but needs review due to non-anonymous data collection (e.g., surveys, interviews with voice, video, or digital records)
3. **Full Review** – higher than minimal risk, especially studies involving vulnerable populations (e.g., minors, pregnant women, prisoners, cognitively impaired)

Regent University IRB

Submission of Proposals will be via the Cayuse Regent Portal.

Training for faculty and students on how to use the Cayuse system for IRB review will take place each Fall semester.

Also, these materials are posted on the Regent IRB website (www.regent.edu/irb).

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