Levels of Review of Research and Quality Improvement

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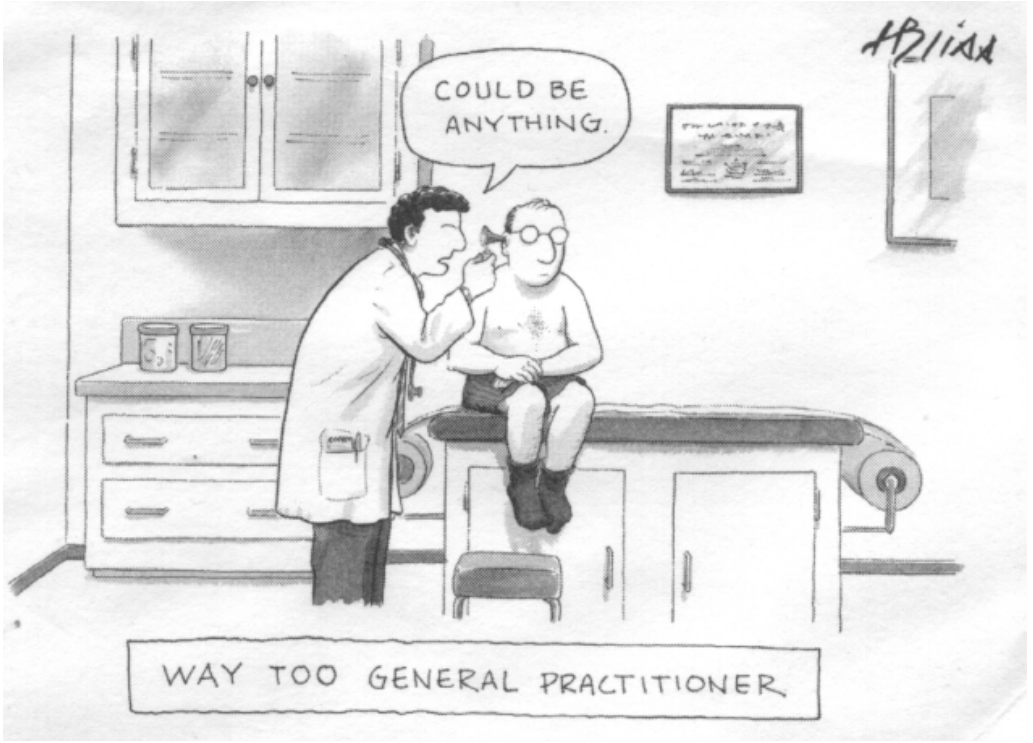
The most common legal definition of standard of care

How a respectable minority of similarly qualified practitioners would have managed the patient's care under the same or similar circumstances.

Standard of Care

- What is standard of care?
  - local custom
  - consensus statements/expert opinion
  - economic factors
    - Insurance payer restriction
    - Health care in the developing world



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TITLE 45
PUBLIC WELFARE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 46
PROTECTION OF HUMAN SUBJECTS

[PDF 215 KB]

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Subpart A-- **Basic HHS Policy for Protection of Human Research Subjects**

Sec.

Treatment vs. research

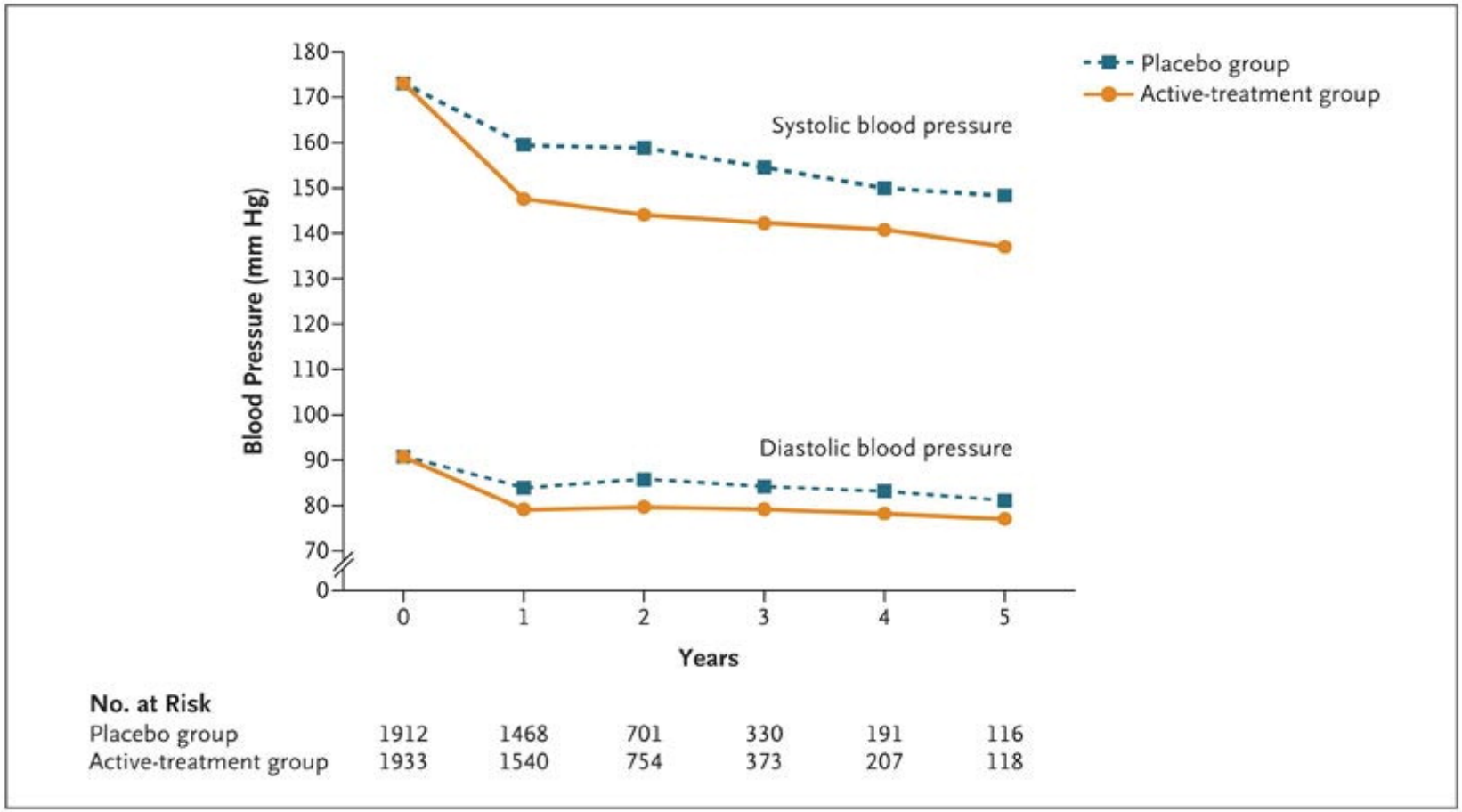
Research—a *systematic* investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable* knowledge in human subjects *CFR 46.102*

Treatment—an intervention designed solely to enhance the well-being of an *individual patient* and that has reasonable expectation of benefit for the patient

Treatment vs. research

- A true dichotomy?
  - Many research protocols do benefit participants
  - “N=1” approach to patient care
- Research must be presented as such
- Non-standard treatment is allowable, but under the auspices of treatment
  - Off label use of medications
  - Novel surgical procedures

Mean Blood Pressure, Measured while Patients Were Seated, in the Intention-to-Treat Population, According to Study Group.



Beckett NS et al. N Engl J Med 2008;358:1887-1898.

Exemptions from Research

- Established educational settings, involving normal educational practices
- Observation of public behavior, survey, or educational test so long as person not identified
- Publically available, de-identified data

Quality Improvement

- Systematic collection of data, with goal of implementing a practice to improve the quality of patient care
- But not generalizable outside walls of institution

Case: Pharmacy Error Rates

A group of affiliated hospitals implements a procedure known to reduce pharmacy prescription error rates, and collects prescription information from medical charts to assess adherence to the procedure and determine whether medication error rates have decreased as expected.

Case: Pharmacy Error Rates

- *Does the project need IRB approval?*
- *Does this change if staff have plans on publishing?*
- *There are interesting findings the staff wants to publish after the study? What needs to be done?*

Expedited Review Criteria

- Activity is minimal risk
- Collection of blood
- Collection of samples or data non-invasively
- Existing clinical data
- Research on individual or group characteristics or behavior
- Voice, video, digital, or image recordings made for research purposes

Full IRB Review

- Everything else
- Reviewed by a duly constituted board with appropriate expertise

What needs to be done?

A radiology clinic uses a database to help monitor and forecast radiation dosimetry. This practice has been demonstrated to reduce over-exposure incidents in patients having multiple procedures. Patient data are collected from medical records and entered into the database. The database is later analyzed to determine if over-exposures have decreased as expected

Overview for new submissions

EXEMPT	EXPEDITED		FULL
"Minimal to no risk" – Administratively reviewed. Does not require Board review.	*"Minimal risk"* – Reviewed by subcommittee.		*"Greater than minimal risk"* – Reviewed by the full Board.
OHR-18 OHR-5 or OHR-3 *Submit 1 copy of OHR forms, protocol or grant, and relevant supplementary materials (surveys, recruitment scripts, brochures, etc.)* Examples: • Survey of staff on medical practices • Retrospective review of de-identified data • Retrospective collection of de-identified tissue • Assessment of student attitudes/skills/ knowledge • Patient surveys where survey subject matter is not of a sensitive nature	Chart/Database Review or Tissue Collection OHR-4 or OHR-15 OHR-3 or OHR-5 *Submit 1 copy of relevant OHR forms and 1 copy of protocol or grant* Examples: • Retrospective chart/database reviews with identifiers • Prospective chart/database reviews • Retrospective tissue collection with identifiers • Prospective tissue collection from tissue banks	Other studies OHR-1 OHR-2/2B OHR-15, OHR16 OHR-3 or OHR-5 or OHR-8/8A/8B, etc. *Submit 1 copy of relevant OHR forms, 1 copy of protocol/ grant and supplementary materials* Examples: • Blood draws • Non-invasive procedures (ECG, MRI, sensory testing, ultrasound, mild physical exercise, etc.) • Surveys involving sensitive protected health information • Observational studies • Some phase IV	OHR-1 OHR-2/2B OHR-8/8A/8B, etc. OHR-16 (if study involves genetic research) *Submit 6 collated sets of OHR forms and supplementary materials, 2 copies of protocol or grant and 2 copies of device or drug brochure or package insert* Examples: • Phase I, II, III & some IV clinical trials involving investigational drugs or devices • Clinical trials involving investigational procedures posing greater than minimal risk • Pilot studies involving investigational drugs, devices or greater than minimal risk procedures • Studies involving vulnerable populations (children, cognitively impaired, elderly, fetuses, etc.) • Studies involving greater than minimal levels of non-physical risks (psychological, social, economic, legal)