Human Subjects Research

Human Subjects Research Protection

Ethics and Institutional Review Boards

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Memorial Sloan Kettering Cancer Center

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Disclosures: O'Reilly/Family

Grant/Research Support to MSK

Celgene, Genentech-Roche, AstraZeneca, BMS, Silenseed, BioNTech, Arcus, Elicio, Digestive Care, Revolution Medicine

Lustgarten Foundation, NIH/NCI, NCI-CTEP, Reiss Family Foundation, Endeavor Foundation, Andrea J Will Foundation, Cycle for Survival, Parker Institute, Other Philanthropy

Consulting/DSMB

Uncompensated: Arcus, Amgen, AstraZeneca, Ability Pharma, Alligator BioSciences, Pfizer, Agenus, BioNTech, Ipsen, Ikena, Merck, Moma Therapeutics, Novartis, Astellas, BMS, Revolution Medicines, Regeneron, Tango Therapeutics
Travel: BioNTech, Arcus

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Disclosures: Tuttle

Grant/Research Support to MSK
Elesta

Consulting/DSMB
None

Agenda

What is research?
What is an IRB/PB?
Roles & responsibilities of IRB/PB
Research regulatory oversight
MSK systems, DSMC
Early phase trial designs
Research biopsies
Compensation for research

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What is Research or Not?

1. Retrospective record review to prepare case report?

2. Testing on de-identified specimen?

3. Retrospective record review to determine patterns of drug resistance?

4. Quality of life questionnaire in cancer patients?

5. Post-market survey on safety of contact lenses?

Practice vs Research Definitions

Practice

- The use of accepted (standard) therapy for the benefit of an individual

Research '45 CFR 46'

- An activity to test a hypothesis that will contribute to generalizable knowledge

Characteristics that always require IRB review

- Use of FDA test articles: drugs, devices, biologics
- Randomization

Dept Health Human Services Research Definition

Research

Systematic investigation, including research development testing, and evaluation, designed to develop or contribute to generalizable knowledge *45 CFR 46.102(d)* Common Rule

Definitions

- **Systematic investigation**
  Predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory

- **Design**
  meaning goal, purpose, or intent— develop/ contribute to **generalizable knowledge**
  Draw general conclusions, inform policy, generalize findings beyond single individual or internal program

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Research: Ask These Questions?

1. Does activity involve **Research**?
2. Does research involve **Human Subjects**?
   - Living individual about whom an investigator is conducting research
3. Is the Institution **Engaged**?
   - One whose agent (faculty) recruit and secure consent from subjects, conduct research or receive/share private, identifiable information, identifiable biospecimens
4. Is the human subjects research **Exempt?**
   - Subset of minimal risk involving human subjects does not require approval by IRB

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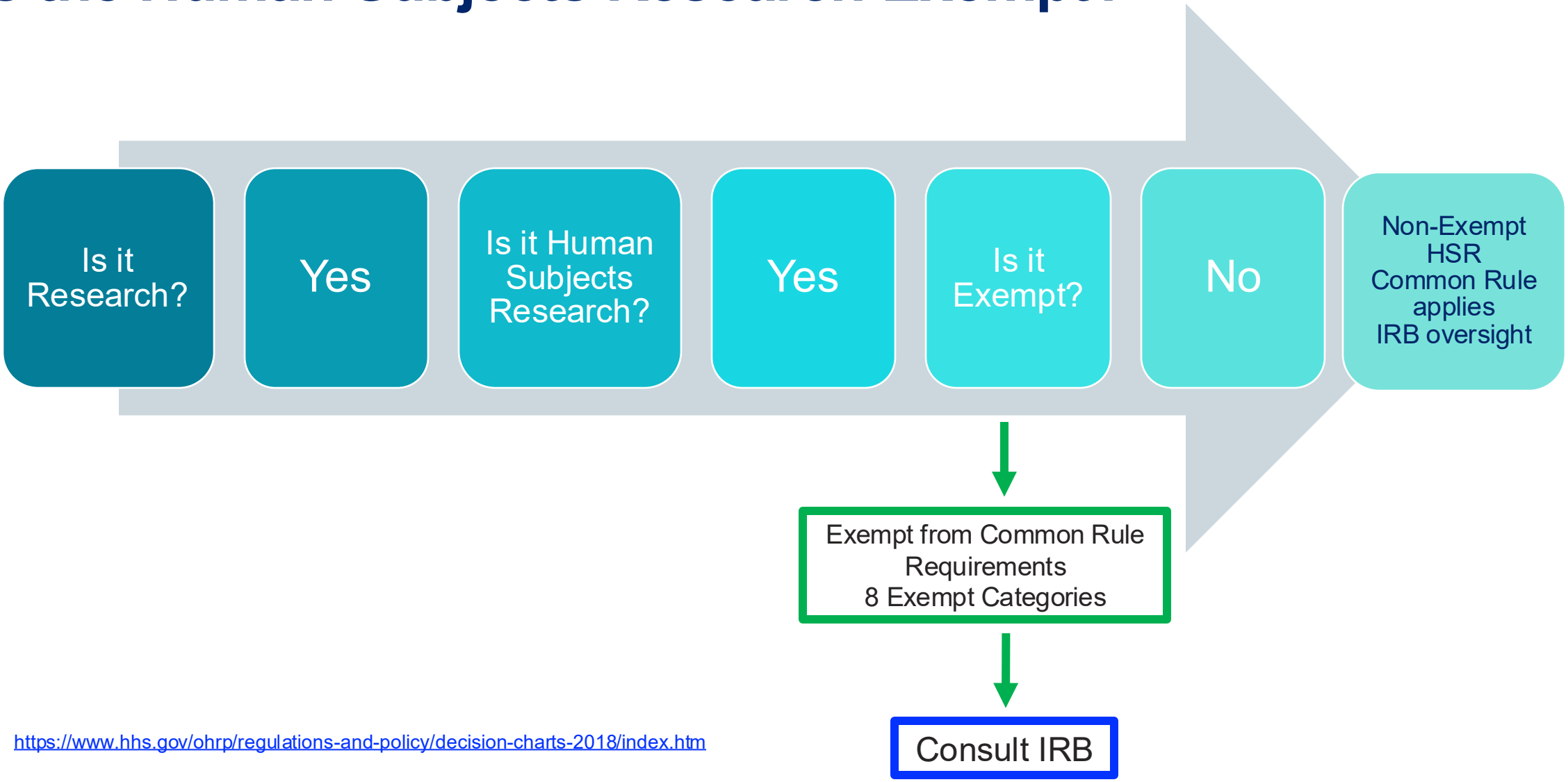
Is the Human Subjects Research Exempt?



https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.htm

What is an IRB?

Differing Perspectives on Safety Requirements

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Institutional Review Board (IRB), Types, Membership

Institutional Review Board: Committee established to review and approve research regarding human subjects

Purpose of IRB: Ensure that human subjects research is conducted in accordance with federal, institutional, ethical and other regulatory guidelines

- Commercial
- Central
- Institutional

<u>IRB composition ≥ 5 members</u>

- At least 1 scientist
- At least 1 non-scientist
- At least 1 lay-member/unaffiliated
- Sufficient qualification: experience, expertise
- Invited member for specific expertise

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IRB/ Independent Ethics Committee Mission

Promote

- Rights and welfare of human subject participants

Facilitate

- Excellence in human subject's research by providing timely and high-quality review

Provide

- Professional guidance, support research community

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IRB, Privacy Board

Privacy Board (PB)

- Governed by privacy regulations (i.e., HIPAA), set forth by Office of Civil Rights

Purpose of PB

- Ensure research meets requirements for proper oversight of participant data

Ethics and Clinical Research: Quote Bioethicist

The ethical issues raised by medical experimentation with human's hinge on one question:

How can the rights of the individual person be reconciled with the demands of the scientific enterprise?

Ezekiel Emanuel, MD, PhD

What Makes Clinical Research Ethical?

Requirement	Justification	Ethical Principle(s)
Social, scientific value	Improves health, well-being, knowledge	Justice
Scientific validity	Use of rigorous science, statistics – reliable, valid data	Respect
Equitable selection	Vulnerable individuals not selected for risky study	Respect Justice
Favorable risk/benefit ratio	Minimization of risks, maximization of benefit	Beneficience Non-malefience
Independent review	Public accountability, conflict, disclosure	Respect
Informed consent	Education about aims, risk, benefit	Autonomy
Respect for person	Permit withdrawal, privacy, confidentiality, update risks, results, maintaining welfare	Autonomy Justice

Emanuel, EJ. JAMA, 2000

Roles & Responsibilities of an IRB

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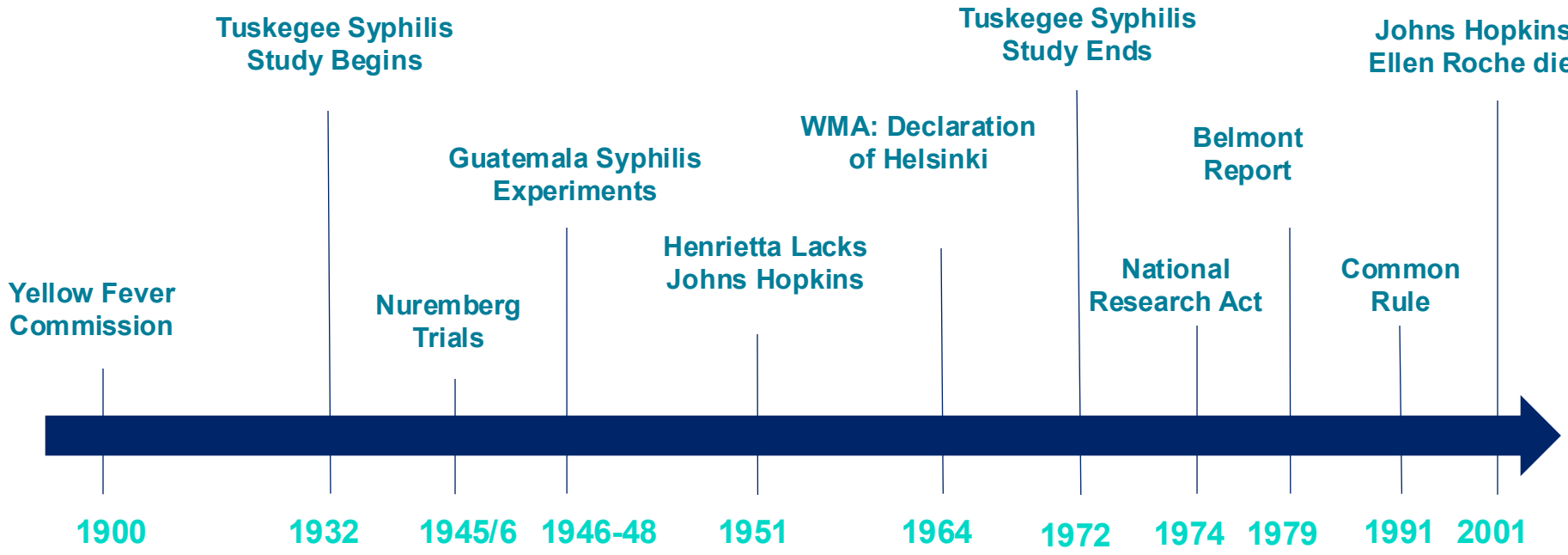
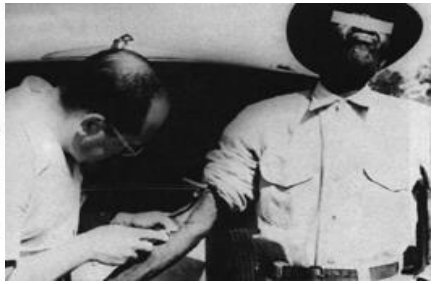
History of Informed Consent





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Historical Events

Nuremberg Trials (Informed Consent)

- Nuremberg Code (1947)

Henry K. Beecher, MD

- Anesthesiology, bioethicist; Ethics of clinical research; NEJM (1966)

Tuskegee Study (IRB's)

- National Research Act (1974)

Contemporary Events

- Geisinger & Roche (1999/2001)

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Nuremberg Code Established 1948

The Code prototype of many later codes intended to ensure that research involving human subjects would be carried out in ethical manner:

- Voluntary consent
- Research necessary
- Reduce risk
- Qualified individuals

Nuremberg Code landmark document; Little response when issued…..

- ‘Researchers working in democratic countries would not do such things….’
- ‘….need to restrain barbarians…’ not applicable to…’rest of us’

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Tuskegee Syphilis Study (1932- 1972)

1932 United States PHS

Macon County, Alabama
Evaluate untreated syphilis in black men

N= 400 infected
N= 200 uninfected controls
Followed x 40 years

Publications 1936 → 1960's

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Tuskegee Experiments Cont.

- Participants were not informed about their disease or participation
- No consent
- Penicillin identified as curative therapy in 1943, widely available 1950's; not utilized
- July 26th,1972, Jean Heller investigative reporter AP: New York Times, Washington Star
- President Clinton – formal apology 1979

Syphilis Victims in U.S. Study Went Untreated for 40 Years

Share full ar

By Jean Heller The Associated Press
July 26, 1972


The New York Times

The New York Times Archives

Tuskegee Syphilis Experiment Exposed by *Washington Star* Newspaper

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Declaration of Helsinki (1949)

1964 World Medical Association

- Recommendations guiding biomedical research in human subjects

Declaration

- Governs international research ethics and sets rules for research combined with clinical care and non-therapeutic research

Declaration of Helsinki

- Basis for Good Clinical Practice (GCP) followed in most clinical trials today
- Expands on voluntariness of Nuremberg Code

National Research Act 1974

National Research Act (Pub. L93-248)

National Commission for Protection of Human Subjects of Biomedical and Behavioral Research

- Identify basic ethical principles that underlie the conduct of biomedical and behavioral research involving human subjects
- Develop guidelines to assure that research conducted according to these principles
  - Informed consent
  - Institutional Review Boards

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Belmont Report Basis of '111 Criteria'

National Commission 1979

Respect for Persons	• Informed Consent • Voluntariness; individual autonomous; if diminished - protection • Confidentiality
Beneficence	• Risk/Benefit Assessment: Minimize harm, maximize benefit (individual, society) • Procedures – least risky
Justice	• Selection of participants without bias • Burden and benefits shared • Who is equal and who is unequal?
(Non-maleficence)	• Added later • Associated with 'primum non nocere'

https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

Varkey, B. Principles of Clinical Ethics and Their Application to Practice. Med Princ Pract. 2021

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Guiding Principles for Ethical Research

1. Social and clinical value

Minimize risk and burden to research participants

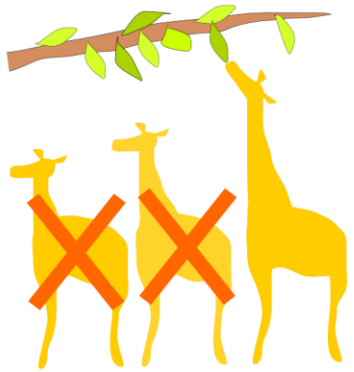
Increase understanding and improvement of health

2. Scientific validity

Is the research designed to answer the question?

Guiding Principles for Ethical Research

3. Fair subject selection



Primary criteria for recruiting participants should be scientific goals of study

- *Inclusive* to all who meet criteria
- *Protects* vulnerable populations or those who may be subject to undue coercion or influence

4. Favorable risk-benefit ratio

- Risks physical, psychological, economic, social
- Obligation to *minimize the risks* and inconvenience to participants and *maximize the potential benefits*

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Guiding Principles for Ethical Research

5. Informed Consent

- Description of study and what to expect
- Voluntary participation
- Identification of risks, benefits, alternatives
- Costs

6. Independent Review

- Manage potential conflicts of interest
- Disclosure

7. Respect

- Respect autonomy, right to make own decision on participating
- Privacy

Research Regulatory Oversight

US Federal Reform

Year	Entity
1966	FDA policy guidelines
1971	NIH policy guidelines
1974	DHEW codified policies
1991	Federal policy ‘Common Rule’
1996	Health Insurance Portability and Accountability Act
2015	Revisions to ‘Common Rule’
2018	Revisions to ‘Common Rule’ implemented

Federal Structure

Department of Health and Human Services (DHSS)

- Office for Human Research Protection (OHRP)
- Food and Drug Administration (FDA)
- Office of Civil Rights (OCR)

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HIPAA: Health Insurance Portability, Accountability Act

Privacy Rule

- Protects rights of individuals to control access and disclosure of their PHI

Security Rule

- Requires organizations to control how PHI remains confidential

18 elements Protected Health Information (PHI)

1. Names
2. Geographical elements
3. Dates related health, identify
4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health insurance beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers
13. Device attributes or serial numbers
14. Digital identifiers, website URL's
15. IP addresses
16. Biometric data – finger, retinal, voiceprints
17. Photographs of face
18. Other identifying numbers, codes

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What is a Research Authorization?

Research Authorization (RA)

- Protocol specific document signed by participant at enrolment on research protocol
- Obtains approval from participant regarding use/disclosure of PHI for research purposes
- Detailed description of how PHI will be shared

Right to Revoke RA

- Participants can decline to sign RA
- Can withdraw from study at any time
- Privacy regulations require written revocation for subsequent use of PHI
- If data used; cannot be retroactively applied

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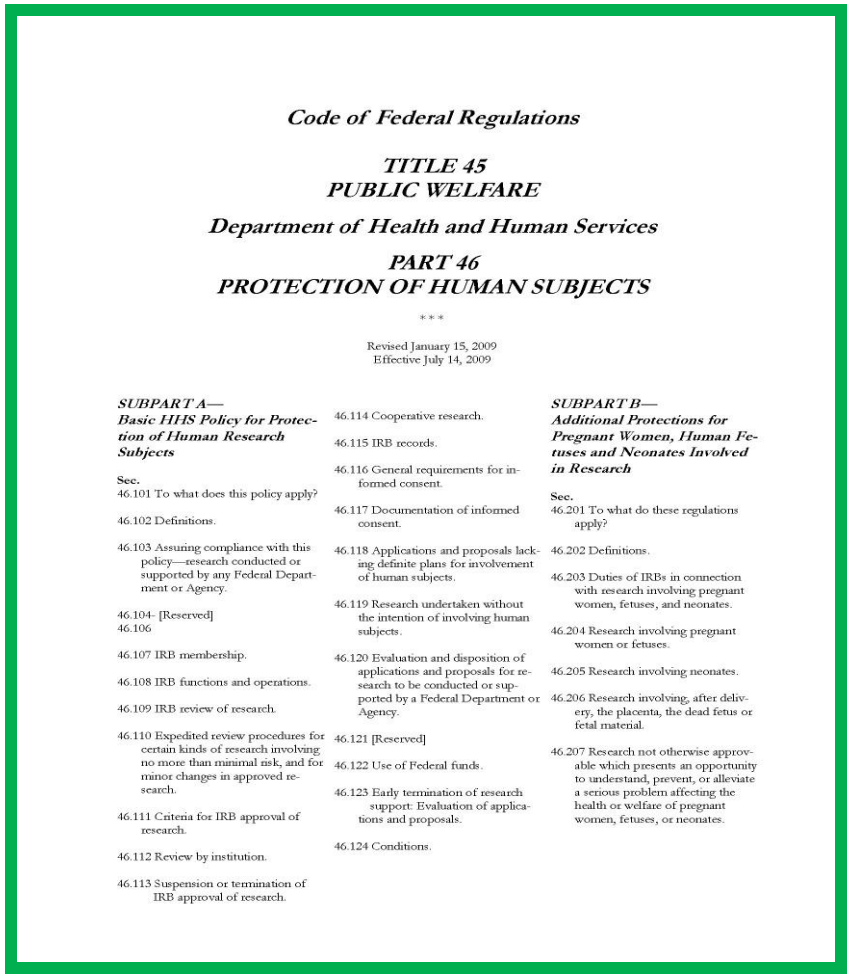
Common Rule Regulations *45 CFR 46*



Code of Federal Regulations

TITLE 45
PUBLIC WELFARE

Department of Health and Human Services

PART 46
PROTECTION OF HUMAN SUBJECTS

* * *

Revised January 15, 2009
Effective July 14, 2009

SUBPART A—
Basic HHS Policy for Protection of Human Research Subjects

Sec.
46.101 To what does this policy apply?

46.102 Definitions.

46.103 Assuring compliance with this policy—research conducted or supported by any Federal Department or Agency.

46.104- [Reserved]
46.106

46.107 IRB membership.

46.108 IRB functions and operations.

46.109 IRB review of research.

46.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

46.111 Criteria for IRB approval of research.

46.112 Review by institution.

46.113 Suspension or termination of IRB approval of research.

46.114 Cooperative research.

46.115 IRB records.

46.116 General requirements for informed consent.

46.117 Documentation of informed consent.

46.118 Applications and proposals lacking definite plans for involvement of human subjects.

46.119 Research undertaken without the intention of involving human subjects.

46.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

46.121 [Reserved]

46.122 Use of Federal funds.

46.123 Early termination of research support: Evaluation of applications and proposals.

46.124 Conditions.

SUBPART B—
Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Sec.
46.201 To what do these regulations apply?

46.202 Definitions.

46.203 Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.

46.204 Research involving pregnant women or fetuses.

46.205 Research involving neonates.

46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

46.207 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Subpart A: Basic HHS Policy for Protection of Human Research Subjects '**Common Rule**'

Subpart B: Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Subpart C: Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Subpart D: Additional Protections for Children Involved as Subjects in Research

Subpart E: Registration of Institutional Review Boards

Subpart D: Research in Children

Definition

- Person who has not attained legal age of consent
- IRB determines 1-4 categories

Assent

- Child's affirmation to participate in research
- MSK Assent age 7- 17 years (or waiver based on age, maturity, cognition, etc.)

Permission

- Agreement of parent(s) or guardian (designated by state/local law)

Level	Description	Consent
Minimal	No greater than minimal risk	1 parent
Standard	**Greater than minimal risk but presenting prospect of direct benefit**	**1 parent**
High	Greater than minimal risk & no prospect of direct benefit; Likely to yield generalizable knowledge	2 parents
Highest	*IRB determines this research does not meet 45 CFR 46.404, 46.405, 46.406, but opportunity to understand, prevent, or alleviate a serious problem affecting welfare of children*	*Not at MSK*

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IRB Review; Reporting to Dept. Health Social Services

IRB Review

1. Exempt research
2. Protocol, consent form, research authorization
3. Continuing review, progress review reports
4. Amendments protocol, consent
5. Serious adverse events, non-compliance, unanticipated problems

IRB Reporting to DHSS

1. Membership changes
2. Serious non-compliance
3. Unanticipated problems, increased risk
4. Suspension or termination by IRB
5. Investigator misadventures

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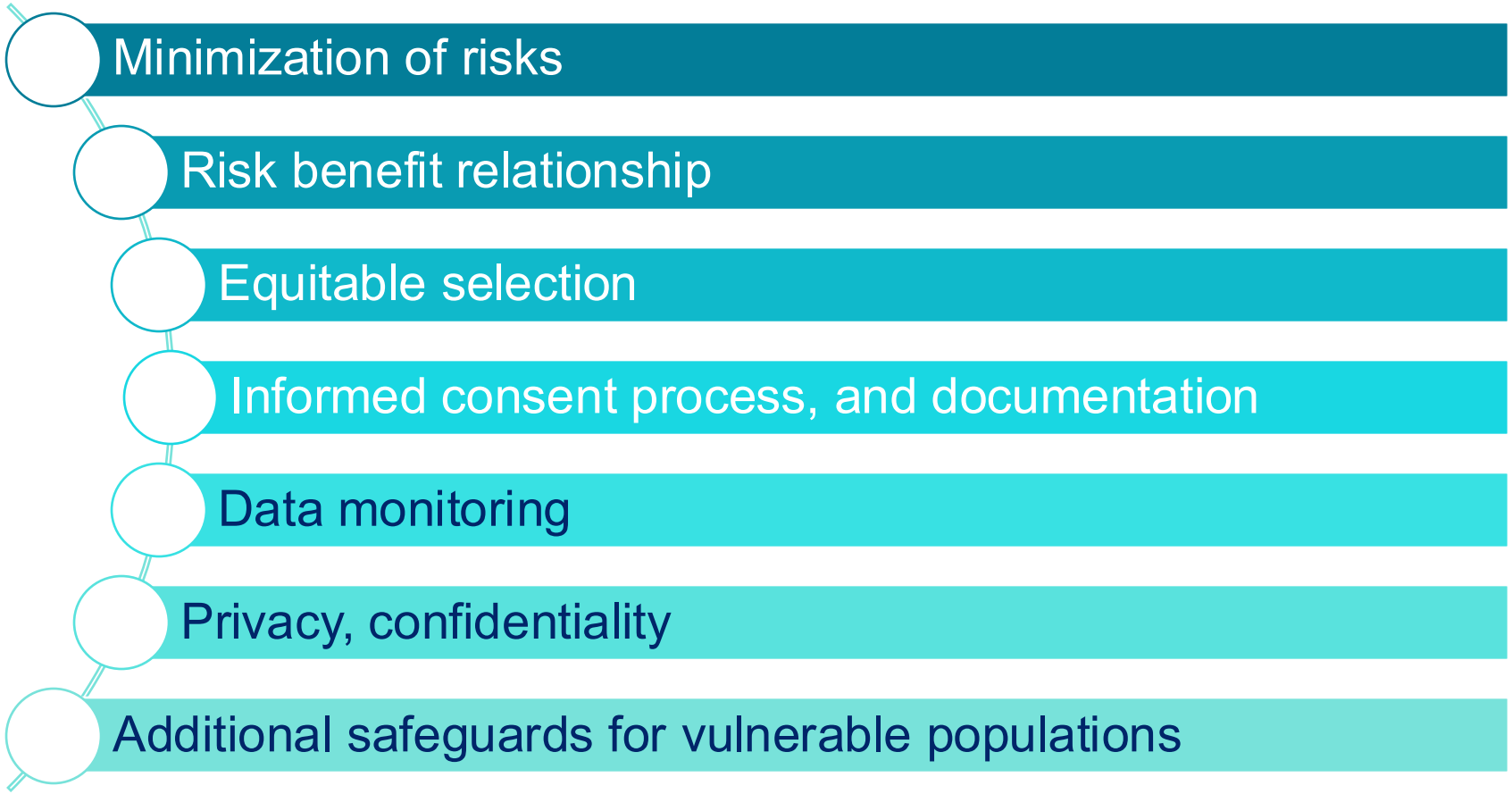
IRB Criteria for Research Approval '111 Criteria'

45 CFR 46.111, 21 CFR 56.111



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Levels of IRB Review

Non-Human Subjects Research (NHSR)	• Determination of NHSR • Does not meet definition of ‘research’ and/or ‘human subjects’
Exempt Research	• Exempt determination • Generally low risk: 8 exemption categories https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/exempt-research-determination/index.html
Expedited Research	• Expedited review • Minimal risk: 9 expedited categories https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html
Full Board Review	• Greater than ‘minimal’ risk • Minimal risk research not eligible for ‘exempt’ or ‘expedited’ review

Risk Categories MSK

Level	Description
Low	Probability of harm/ discomfort not greater than daily life or routine physical/ psychological exam
Moderate	Risks reasonable in relation to anticipated benefits and importance of knowledge gained
High	Greater than minimal risk; may/may not have direct benefit to subject Risks are high in relation to anticipated benefits

MSK Systems, Data & Safety Monitoring

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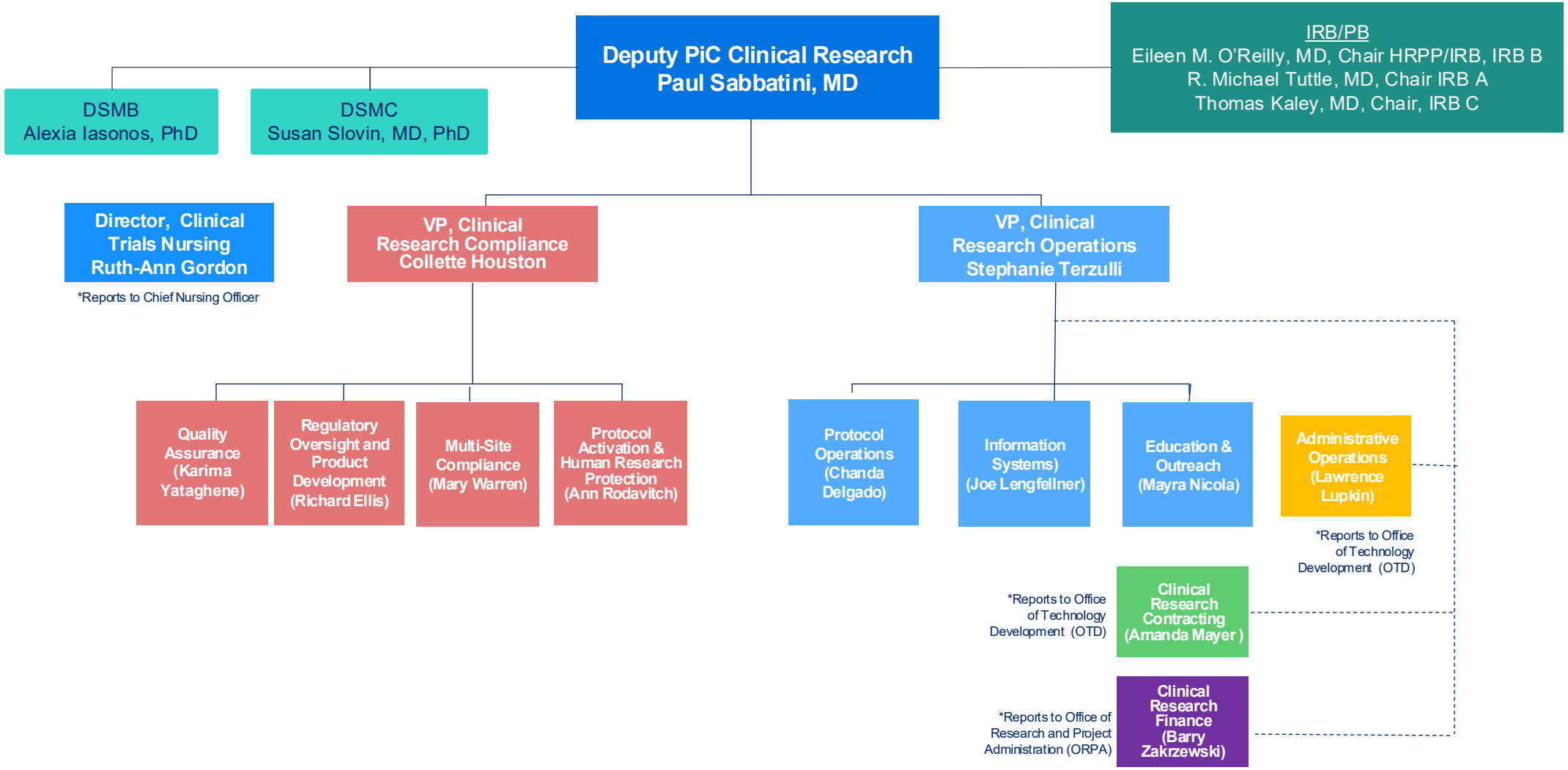
Clinical Research Organization Chart



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MSK IRB Structure

IRB/PB A	• Tues 3- 5 pm • 2nd, 4th each month
IRB/PB B	• Wed 7.30- 9 am • 1st, 3rd each month
IRB/PB C	• Thurs 7.30- 9 am • 2nd, 4th each month

Each board reviews all types of IRB submissions
Visitors welcome

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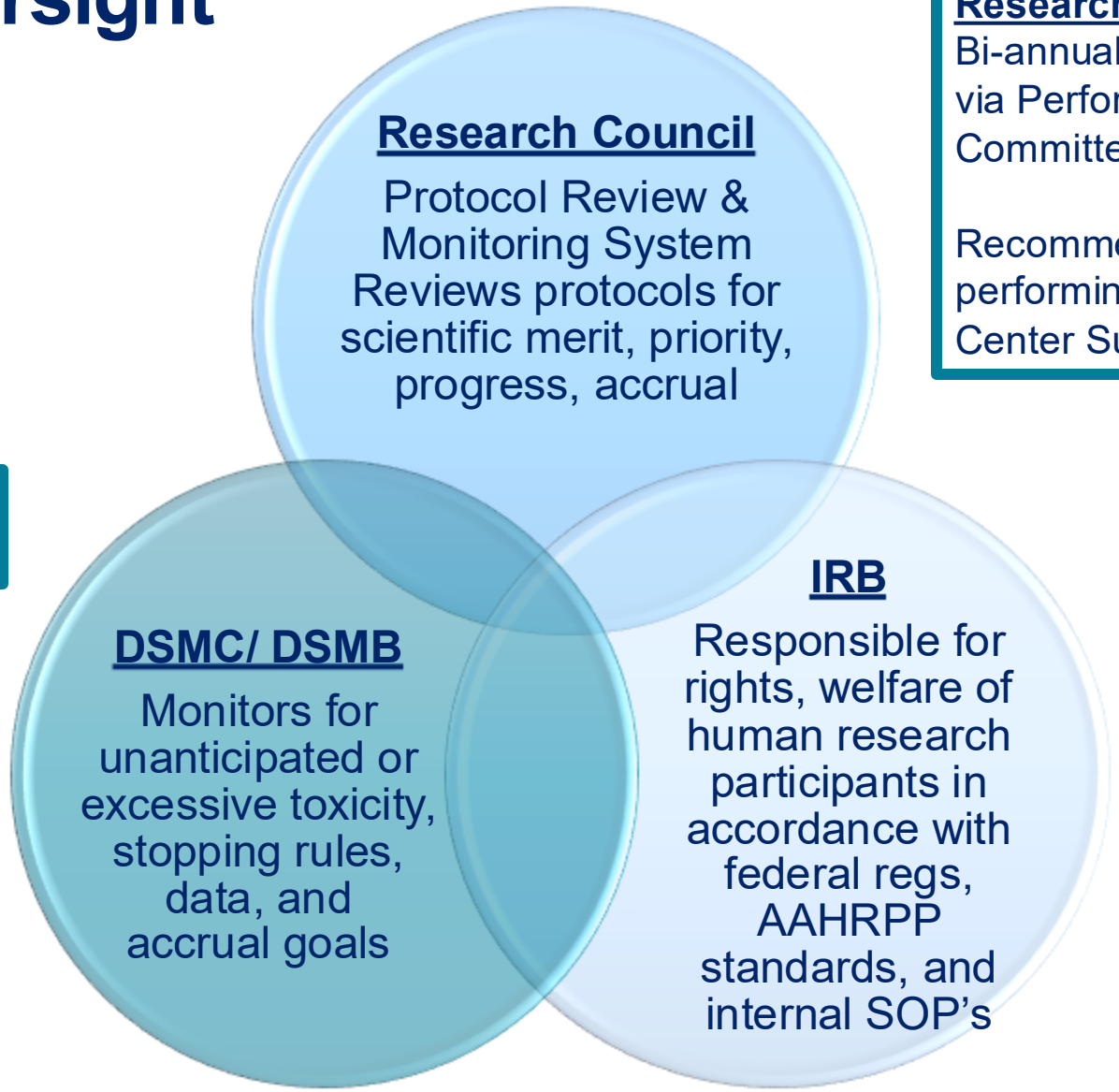
MSK Trial Oversight

DSMC/DSMB/IRB/PMC
Accrual monitoring oversight



Research Council
Bi-annual performance review via Performance Monitoring Committee (PMC)

Recommend closure if not performing according to Cancer Center Support Grant standard

IRB
CRR: progress in enrollment, participant statuses, safety and noncompliance summaries

IRB may request closure for poor accrual, safety and/or non-compliance concerns

Courtesy: Xhenete Lekperic

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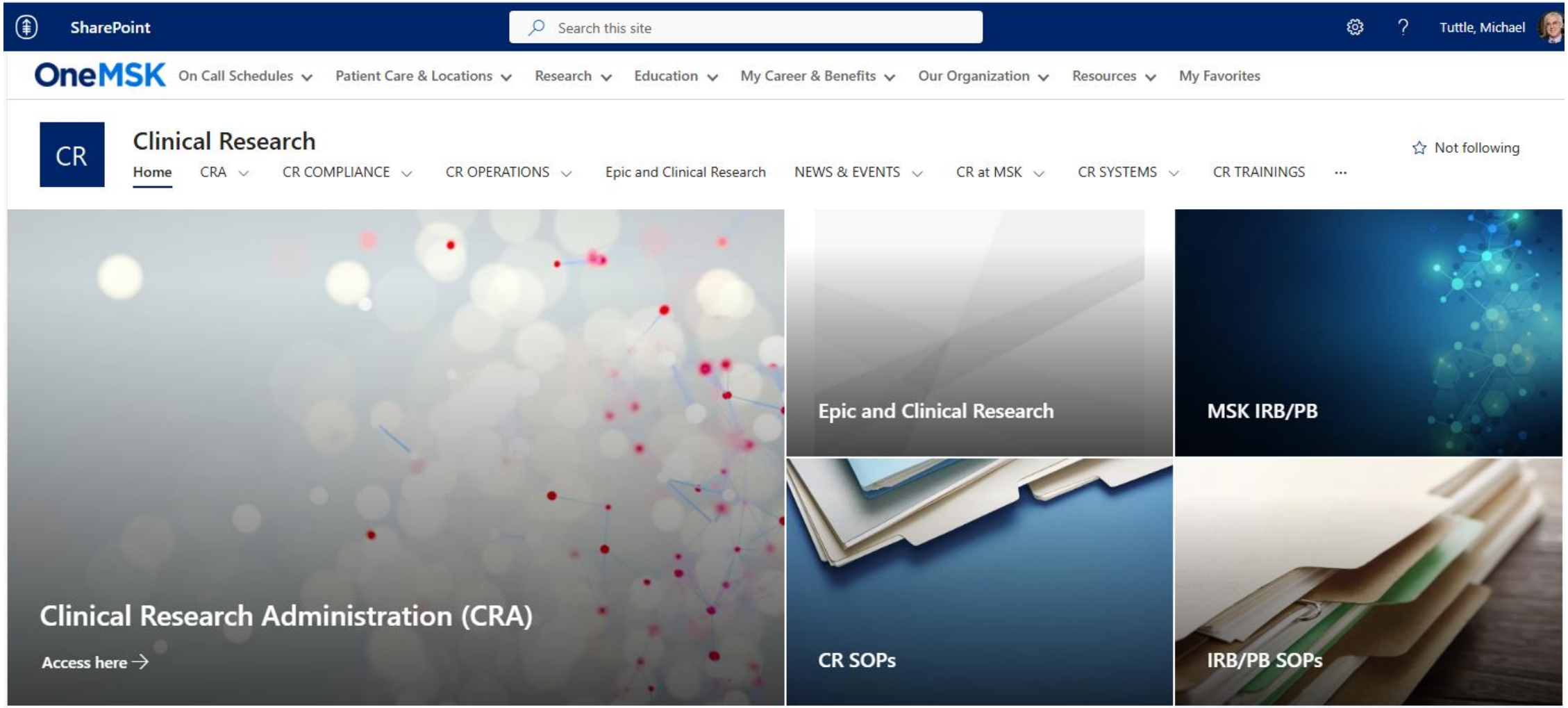
MSK Clinical Research Protocol



https://mskcc.sharepoint.com/sites/pub-ClinResearch/SitePages/Home.aspx

Early Phase Trial Design

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Traditional Clinical Trial Designs Phase I → 4

Phase I trials: Critical role in downstream clinical development; informed by design, implementation, interpretation of clinical trial designs

Ethics Committee

Ethical Issues in Phase I Trials

Why?

Transition point in illness

Exhausted standard therapies

Phase I trials unique importance in drug development

Lots of intersection of ethics and early phase clinical trials

Some examples:

- Patient illness trajectory
- Risk – benefit considerations
- Informed consent
- Research biopsies
- Therapeutic misconception, misestimation
- Clinical trial reporting

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Risks, Benefits to Early Phase Trial Participation

- Most patients enroll in phase I trials with hope of cancer control and improved survival
- Oncologist, professional organizations, advocacy groups encourage trial enrollment

Risks

- Incremental burden participation (travel, time, foregoing end of life care, expense)
- Risks from study medications
- Risks research procedures (biopsies, correlative studies)

Gains

- Enhanced interaction with health care team
- Potential for improved outcome – hard to estimate ~10% (6-14%) – surrogate measures of outcome e.g., response rate (unknown impact on QoL, survival)
- Precision medicine – greater potential for benefit

Meropol, NJ. J Clin Oncol, 2003. American Society of Clinical Oncology. J Clin Oncol, 1997. Bittlinger, M. J Clin Oncol, 2022. Kimmelman, J. J Clin Oncol, 2017

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Informed Consent Form (ICF) – Participant Level

Risk section

- Approximate frequencies of expected side effects
- Theoretical risks if new agent/class
- ICF's do not indicate that a 'toxicity risk target' is goal
- Should this be more clearly stated?
- No standard policy

Acceptability

- Curative intent
- Compelling pre-clinical data, rationale for pathway targeting
- Risks outweight benefits for 'high risk, high toxicity'

Research Biopsies

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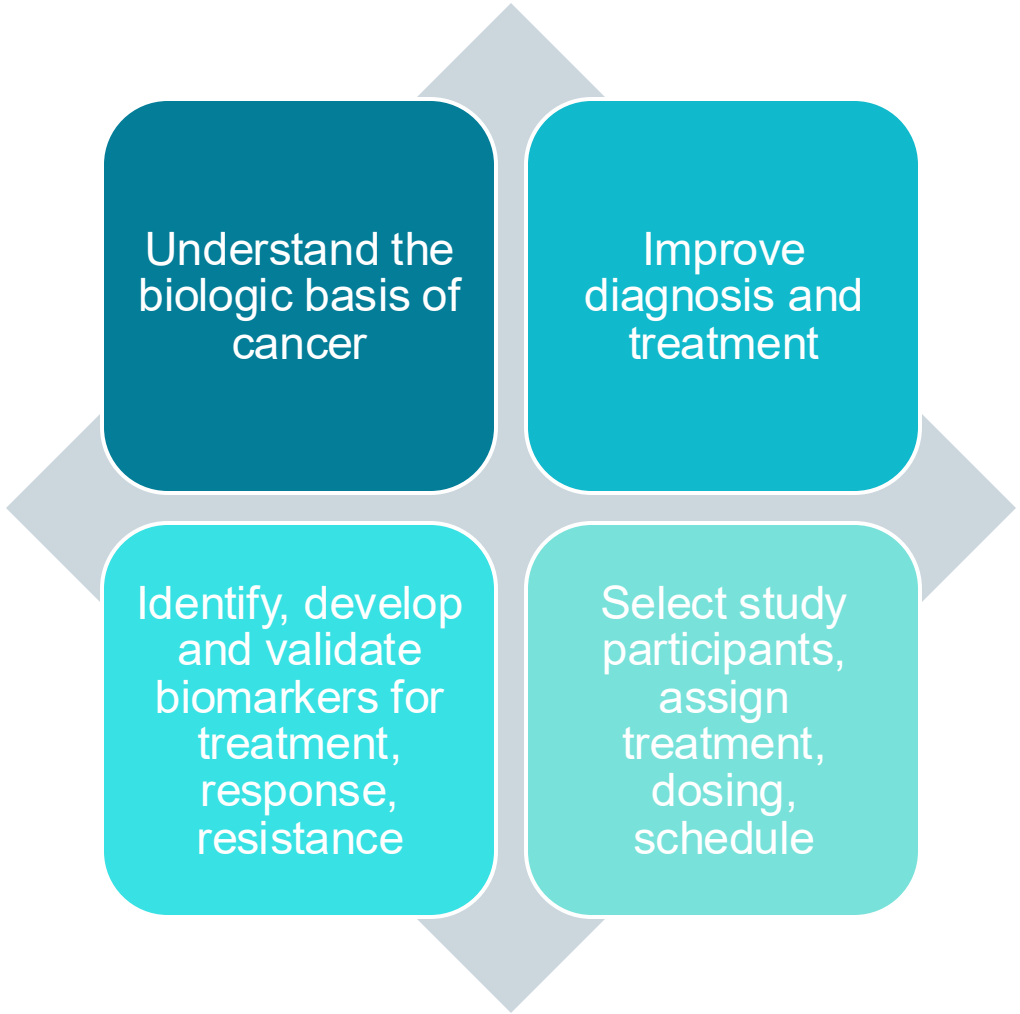
Research Biopsies: Why Are They Performed?



- **Scientific contribution**
  Debated: value derived tissue analyses?
  Unknown vs potential vs expected?
  No direct benefit to participant
- Optional vs mandatory biopsies
  May depend on study phase
- Separate vs add on biopsy
- Research biopsy analyses frequently not reported
- Regulatory, IRB oversight concerns

Levit, J…Ratain, MJ. J Clin Oncol, 2019. Olson, EM…Winer, EP. Nat Rev Clincal Oncol, 2011

Ethical Arguments For and Against Mandatory Research Biopsies in Clinical Trials

Pro Side	Against
• Unethical to avoid biomarker development • Mandatory research biopsy does not limit access to standard therapy	• Mandatory biopsies – form of coercion when paired, or access to investigational agent
• Mandatory biopsies acceptable in context of risk-benefit • Acceptable if correlative assay validated	• Research biopsies should be optional if scientific value of correlative question not well established
• Include ‘opt-out’ section in informed consent	• Optional biopsies – statistically underpowered – can be uninterpretable

Olsen, EM…Winer, EP. Nat Rev Clin Oncol, 2011

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Vulnerable Populations: Children & Research Biopsies

Title 45 CFR 46 Subpart D

- Risk level of research
- Type of biopsy, site, accessibility, etc.
- Risk-benefit analysis
- Opportunities to obtain information in another way – 'liquid' biopsies, imaging, etc.
- Dual role of clinician, researchers

IRB Discussion

- Consultation with IRB
  [Very little guidance published on topic]

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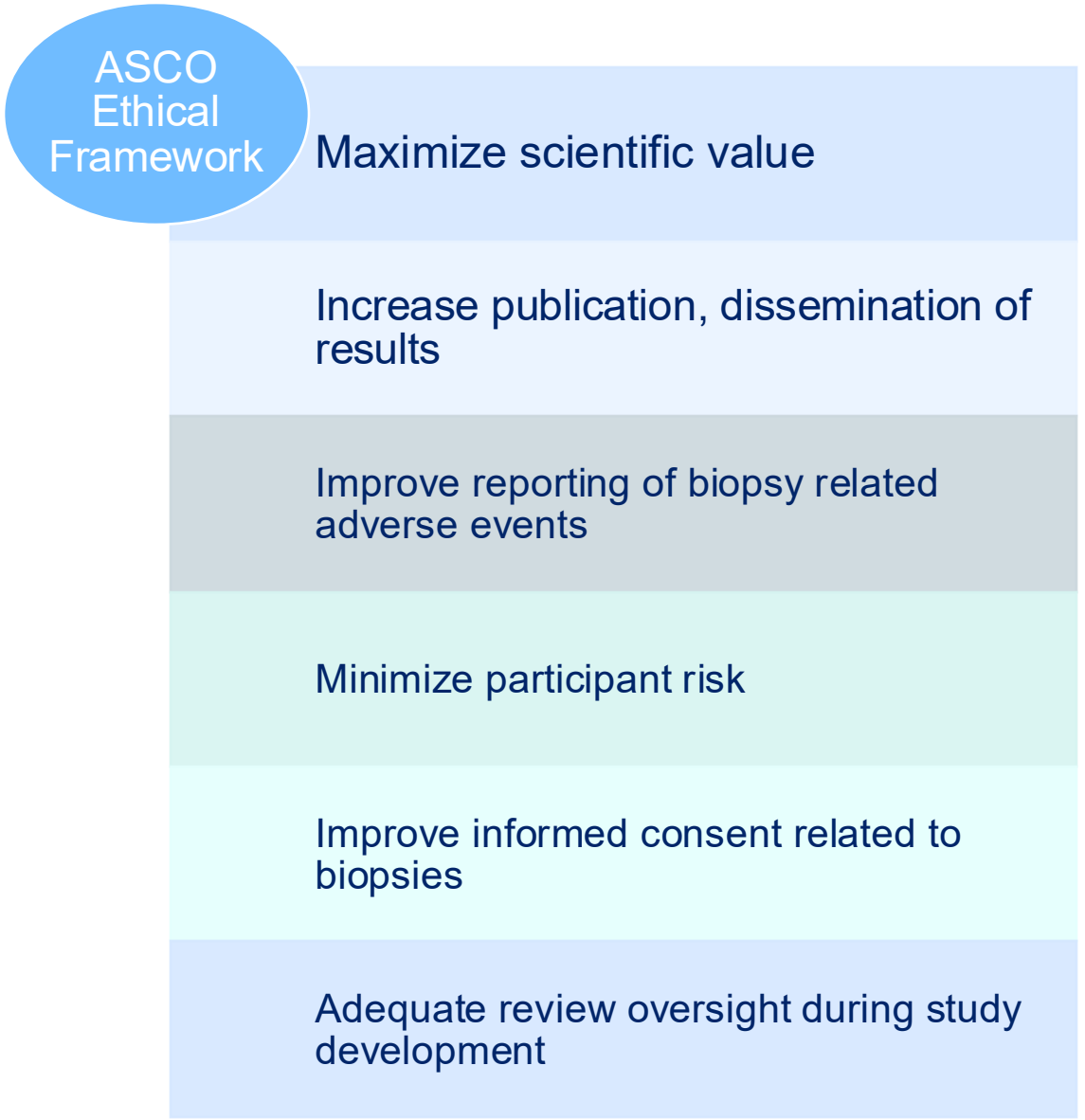
Research Biopsies Recommendations

ASCO Position Statement



Overman, MJ. J Clin Oncol, 2013

Research Compensation

Research Payments: Background, Context

- Practice is long-standing
- Issue of substantial debate, contention, legal, ethical concerns – coercion, undue influence?
- Little guidance on topic, including regulatory oversight

- **'Research exceptionalism'**
  Concerns about payment to research participants differs to payment in other situations
  Is research meaningfully different from other contexts in life where risk assumed?

- Largent et al argue:
  Against research exceptionalism
  Recommend: definitions, regulatory oversight, whether participants are paid enough?
  Encourage default position: Favor research compensation

Largent, EA…Fernandez-Lynch, H. Yale J Health Policy Law Ethics, 2017

Research Compensation

Case Example: Research Participant Payment

Phase I, first-in-human BIA 10-2474 (anxiety, motor disorders in Parkinson's disease, chronic pain)

N= 6 men enrolled; 1 RIP

€1,900 ($2,500), travel expenses, inpatient stay x 2 weeks, extensive blood tests (> 40 samples), medical tests, etc

- Was it acceptable to offer this level of compensation? If not, why not?

Chan, Sewell, NY Times, 2016. Brosky, J. Bioworld, 2016. Butler, D. Nature, 2016

Research Compensation: Why, Which, When, How Much?

Why Payment is Ethically Concerning?

- Important, perhaps essential tool to complete enrollment?
- Evil or legitimate compensation for services?
- Minority advocate: research altruism – no compensation
- Most agree acceptable, reasonable:
  Concerns – amount, timing, context
- Coercion vs inducement and render consent invalid?

Which Particpants Receive Payment? When?

- Research participants – selected via inclusion, exclusion strategies
- Healthy volunteers vs individuals with health concerns – should these be considered separately?
- Should payment be permitted if potential for benefit?
- Receipt during, on completion, bonus?

Why Payment? How Much?

- Reimbursement for research related expenses
- Compensate for time/effort
- Recruitment incentive
- Gesture of appreciation
- Benefit to research partipant – risks to participation reasonable relative to benefits?
- 2005: 467 studies $0- 2,000; Most < $250

Largent, EA…Fernandez-Lynch, H. Yale J Health Policy Law Ethics, 2017

Research Compensation: Default to ‘Yes’

Rationale

- Changing default to favor payment – remove ‘research exceptionalism’
- Little evidence that undue inducement is credible concern in practice
- Little evidence that payments lead to irrational choices by research participants
- Promotes wider inclusion of participants – under-represented minorities, diversity

Furthering the argument….

- Perhaps real concern: Participants are undercompensated?
- Participants should not have to pay for making a contribution to societal good
- Compensate similar to what would be expected outside of a research setting

Theoretic issues

- Harms from overpayment typically overstated
- Harms from underpayment typically understated, ignored

Largent, EA…Fernandez-Lynch, H. Yale J Health Policy Law Ethics, 2017. FDA Guidance to Improve enrollment from diverse ethnic, racial groups, 2022
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations

Research Compensation: Regulatory Oversight

- Belmont Report

- The Common Rule: Federal Policy for Protection of Human Subjects (45 CFR 46 ‘111 criteria’)
  FDA equivalent
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects
  IRB Members, investigators

  …minimize ‘**coercion** or **undue influence**’…

  Common Rule: Does not define either term, or directly address payment

- OHRP Office Human Research Protection (2000)
  Provides clarification, guidance, develops educational programs, materials, maintains regulatory oversight, provides advice on ethical, regulatory issues in biomedical, behavioral research
  https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html

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Conclusions: Ethics and Early Phase Clinical Research

- Large body of literature; many ethical challenges exist (research payments, etc.)
- Tensions – expedient drug development vs safety, optimal dosing, risk/benefit
- Collaboration: Participants, oncologists, biostatisticians, regulatory environment (IRB, FDA, other), social scientists, bioethicists, psychologists
- Thoughful oversight, discussion and review

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Resources & Websites

1. Ethical and Regulatory Aspects of Clinical Research; Ezekiel J. Emanuel, et al
2. Ethics and Regulation of Clinical Research; Robert J. Levine
3. Institutional Review Board Management and Function; Robert Amdur & Elizabeth Bankert
4. Protecting Study Volunteers in Research – A Manual for Investigative Sites; Cynthia Dunn & Gary L. Chadwick

FDA www.fda.gov

NIH www.nih.gov

OHRP https://www.hhs.gov/ohrp/

FDA IRB Guidance www.fda.gov/oc/oha/IRB/toc.html

Code of Federal Regulations www.access.gpo.gov/nara/cfr/cfr-table-search.html

Thank you!

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Questions?