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Geisinger IRB Member Orientation – Session 2

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Associate Director, Research Compliance

How does the IRB make decisions?

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How does the IRB make decisions?

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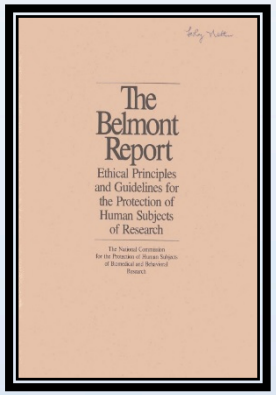
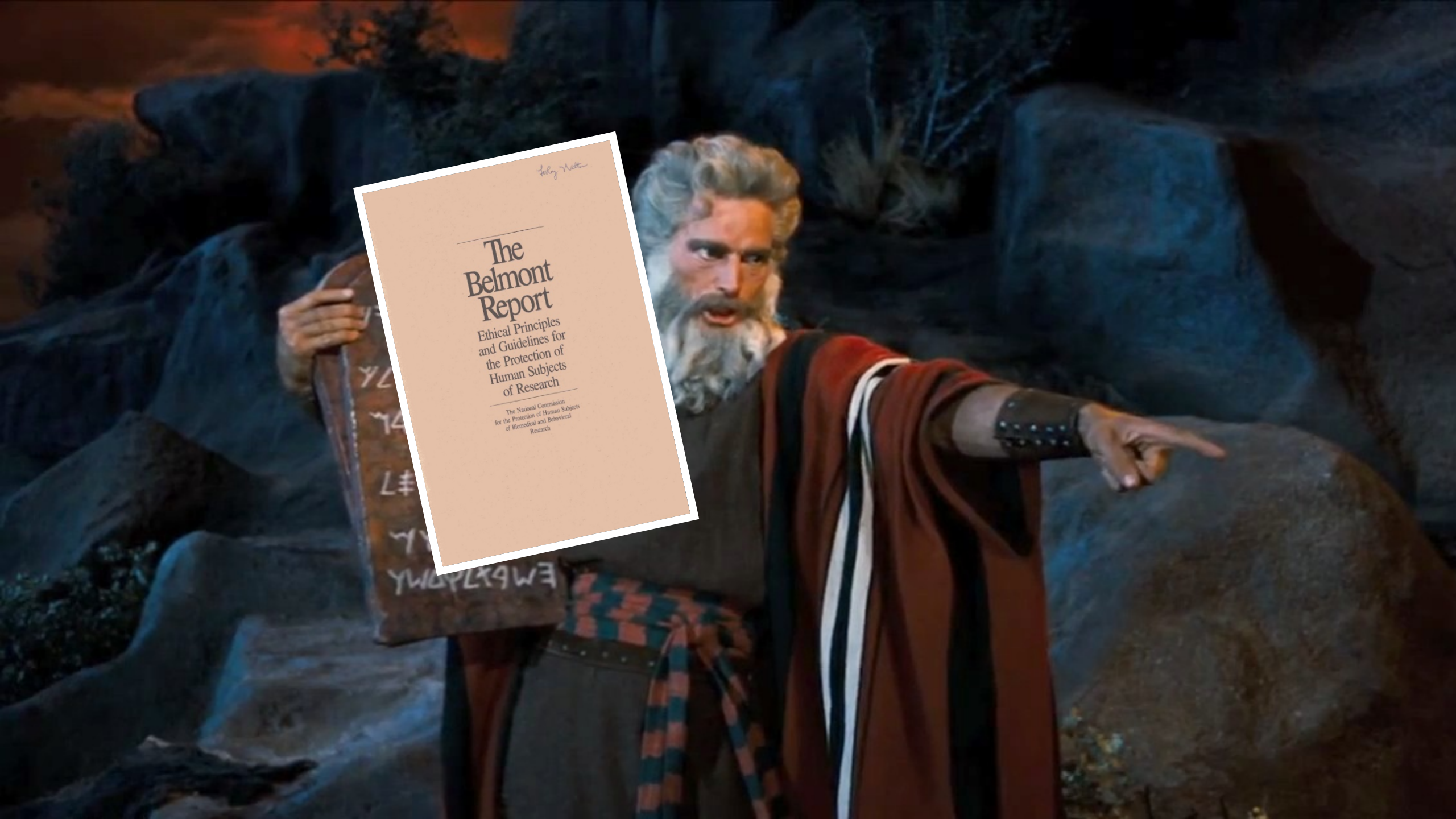
abuse and scandal

National Research Act + National Commission, 1974

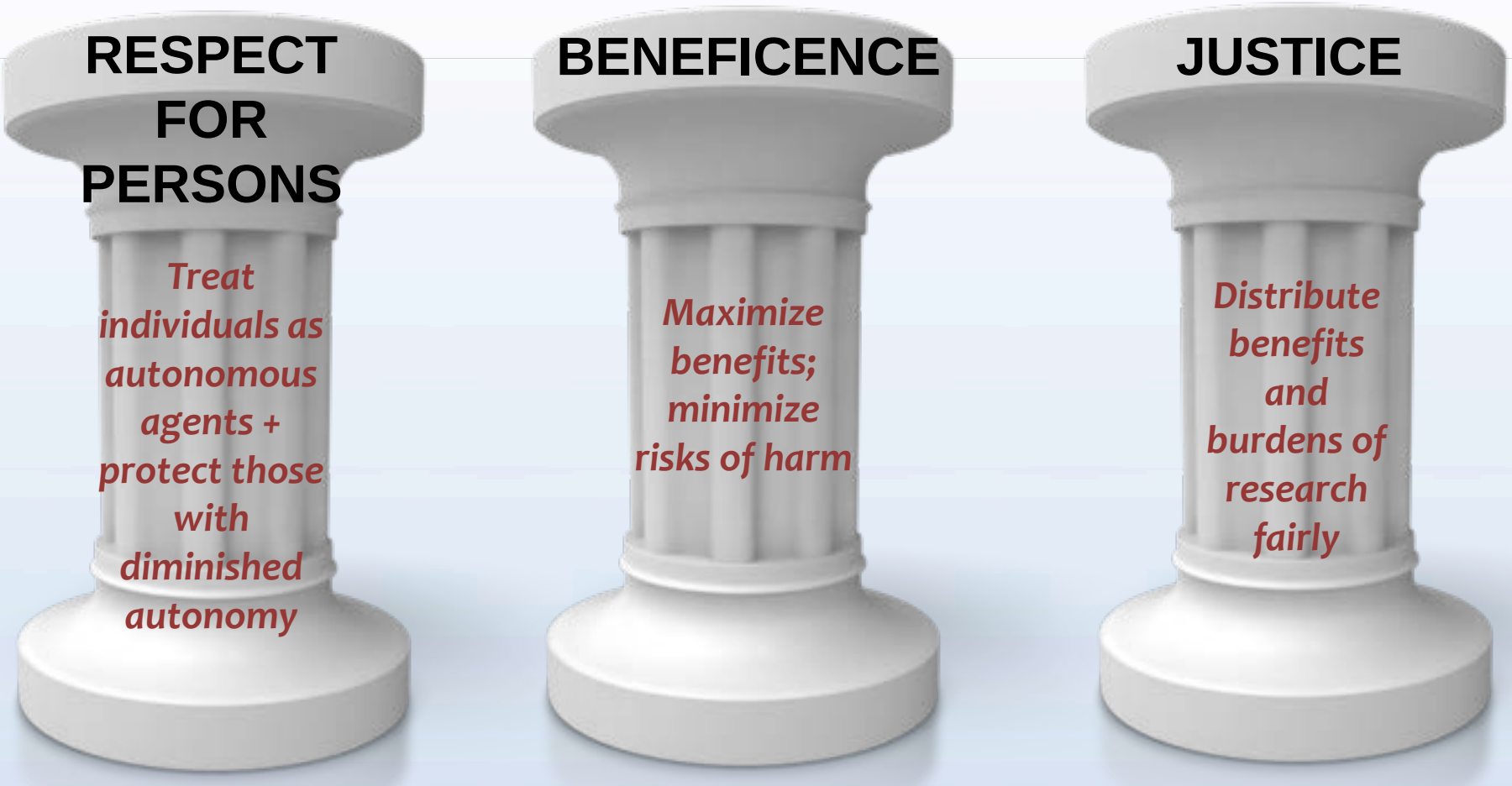


The Common Rule 1991

Author: F. Daniel Davis, PhD, 2016


The
Belmont
Report
Ethical Principles
and Guidelines for
the Protection of
Human Subjects
of Research
The National Commission
for the Protection of Human Subjects
of Biomedical and Behavioral
Research

Belmont Principles & Applications



Obtain voluntary informed consent

Systematically analyze risks and benefits; minimize risks

Select subjects fairly; distribute benefits and burdens of research fairly

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Author: F. Daniel Davis, PhD, 2016

How does the IRB make decisions?

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The Common Rule 1991

BELMONT PRINCIPLES	APPLICATIONS	COMMON RULE (HHS) 45 CFR 46
Respect for persons	*Informed consent* Information Comprehension Voluntariness	46.116: *informed consent requirements* 46.117: *informed consent documentation*
Beneficence	*Risk-benefit assessment*	46.111(a)(1): *risks are minimized* 46.111(a)(2): *risks are reasonable in relationship to benefits* 46.111(a)(6): *safety monitoring* 46.111(a)(7): *privacy & confidentiality*
Justice	*Selection of subjects*	46/111(a)(3): *equitable selection of subjects* 46.111(b): *additional safeguards for vulnerable populations*

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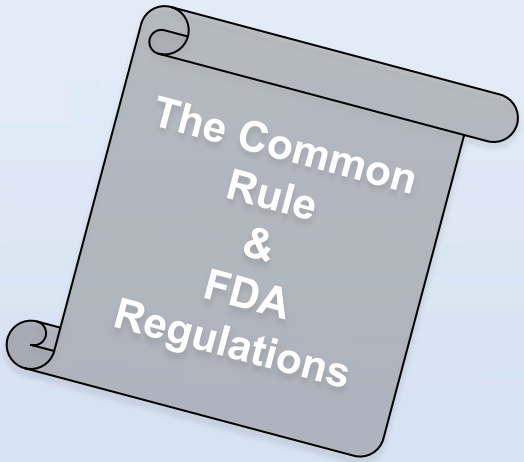
What criteria must be met for research to be approved?



Risks to participants are reasonable

- ✓ … in relation to anticipated benefits, if any, to subjects
- ✓ … and the importance of the knowledge that may reasonably be expected to result

Consider ONLY those risks and benefits that may result form the research … as distinguished from the therapies participants would receive even if not taking part in the research.

Risks to subjects are minimized

By using procedures …

- ✓ consistent with sound research design
- ✓ that do not unnecessarily expose participants to risk
- ✓ already being performed on the participants for diagnostic or treatment purposes, when appropriate

Risks to subjects are minimized

Research proposal …

✓ Addresses likelihood of harm and magnitude of harm

- Potential physical, psychological, social and/or economic risks to participants

✓ Research is likely to achieve its proposed aims

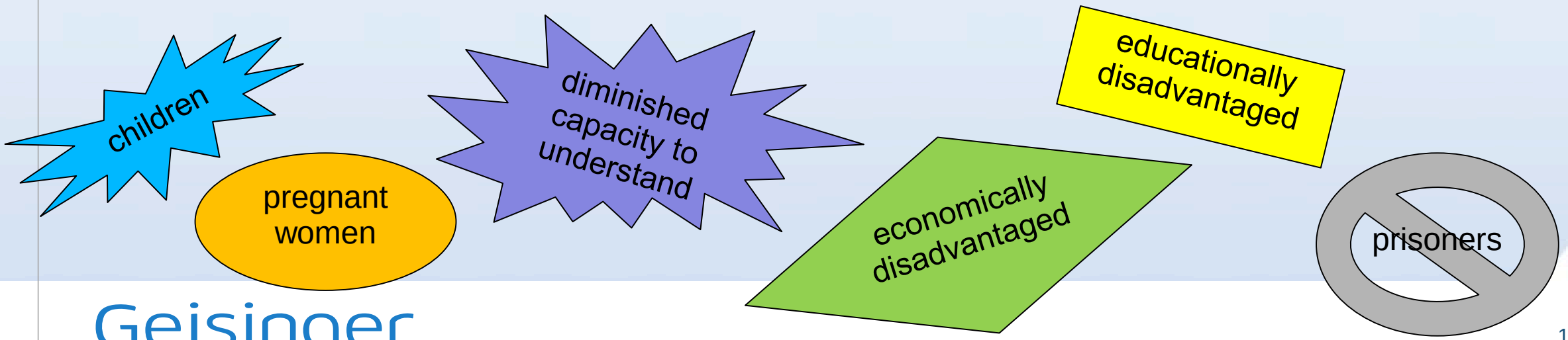
✓ The importance of the knowledge expected to result is clear

Risks to subjects are minimized

- ✓ Any potential conflicts of interest are minimized or managed
  - ✓ Management plan (disclosure in consent; limits who can obtain consent, etc.)
- ✓ Credentials and/or qualifications of investigators and research staff are appropriate to perform their responsibilities in the study
- ✓ The research setting supports adequate safeguards for protection of participants
  - ✓ Location of research
  - ✓ Facilities
  - ✓ Drug/device controls & accounting

Selection of subjects is equitable, taking into account …

- ✓ Purposes of the research
- ✓ Setting in which the research will take place
- ✓ Recruitment methods & participant payments
- ✓ Inclusion/exclusion criteria
- ✓ Special problems of research involving vulnerable populations



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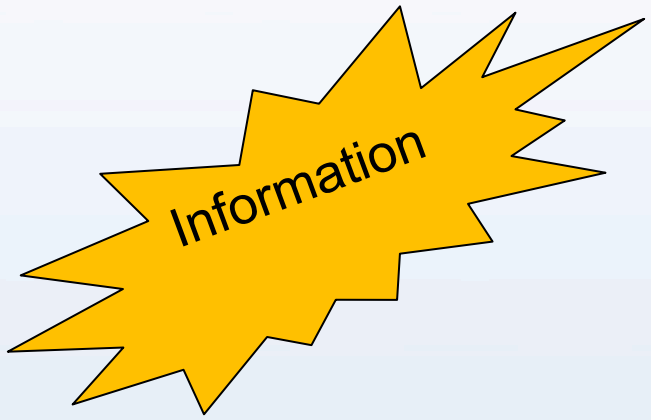
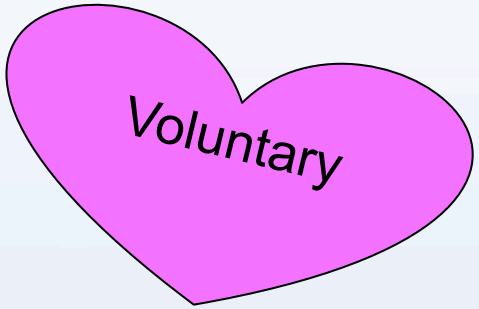
Informed consent will be sought from each prospective participant or his/her legally authorized representative (LAR)

- ✓ Adequate plans for seeking informed consent
- ✓ Proposed consent process
  - ✓ Provides participants/ participant's LAR with sufficient opportunity to consider whether to participate
    - ✓ Adequate information
    - ✓ Adequate time
  - ✓ Minimizes possibility of coercion or undue influence
- ✓ Information relayed during consent process
  - ✓ Is understandable - language, comprehension
  - ✓ Does not include exculpatory language that appears to:
    - ✓ Waive any of participant's legal rights
    - ✓ Release the investigator, sponsor, institution from liability or negligence

Informed consent will be sought from each prospective participant or his/her legally authorized representative (LAR)



Comprehension



... to the extent required by federal regulations

- consent
- assent
- parental permission
- waiver

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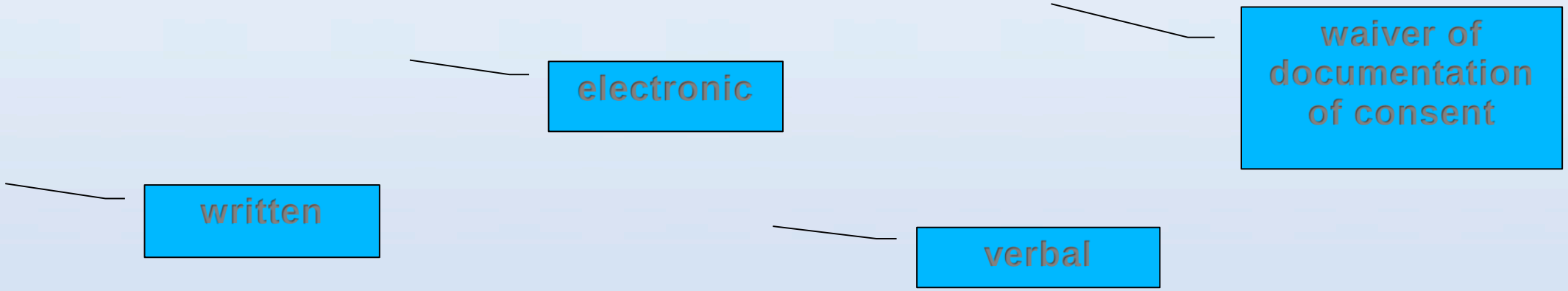
Informed consent will be appropriately documented

… in accordance with, and

… to the extent required by federal regulations



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Study includes plan for monitoring data to ensure participant safety

- ✓ When study is greater than minimal risk
- ✓ When NIH-funded clinical research
- ✓ When FDA-regulated clinical trial

Study includes plan for monitoring data to ensure participant safety

Consider:

- ✓ Is plan appropriate for nature, size, complexity of research and degree of risk?
- ✓ Include plan for promptly detecting harm & mitigating potential injuries?
- ✓ What safety information is collected? How collect? How often?
- ✓ What data will be monitored & who will monitor?
- ✓ What is frequency of review or analysis of cumulative safety data to determine whether harm is occurring?
- ✓ Are there procedures for ensuring appropriate reporting of findings to IRB?
- ✓ Are there any conditions/criteria that could trigger immediate suspension/termination of research & procedures for reporting same?
- ✓ Is establishment of independent data safety monitoring board (DSMB) warranted? If so, is there a plan for providing DSMB reports to IRB?

Study includes adequate provisions to

… protect privacy of participants

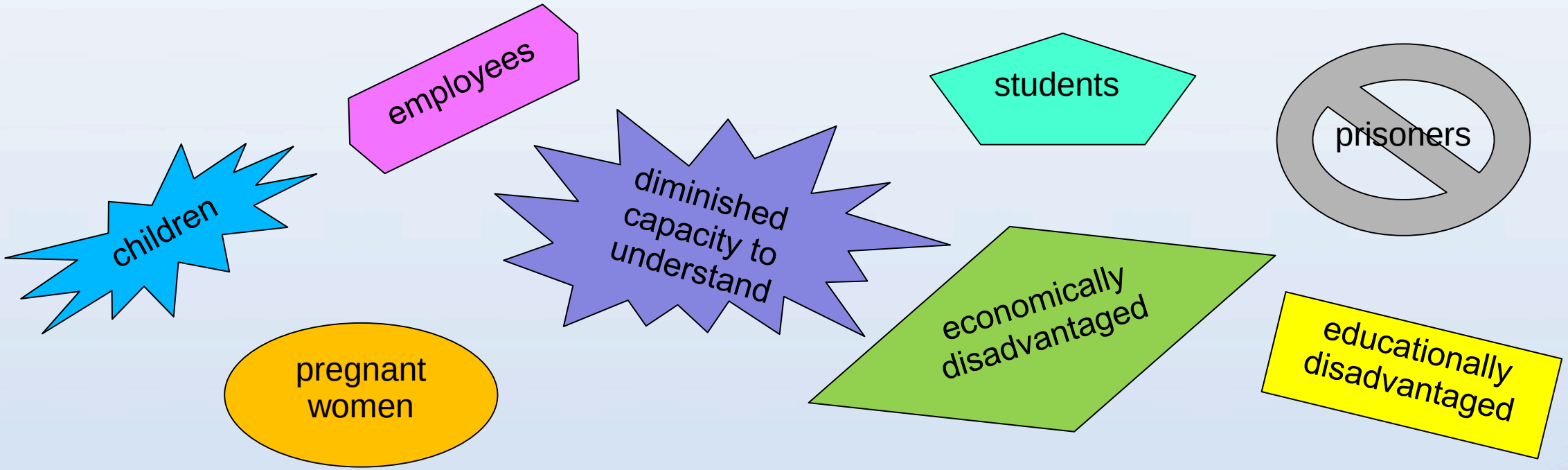
- ✓ How are potential participants identified & contacted?
- ✓ Where is consent obtained? Where do study activities take place?

… maintain confidentiality of data

- ✓ Data elements? Data sources? Who obtains data? How?
- ✓ Where & how is data stored? When & how destroyed?
- ✓ How is data transported?
- ✓ Is data disclosed outside of Geisinger?
  - ✓ Is data transferred and stored securely? Encryption?

Where any of the participants are likely to be vulnerable to coercion or undue influence …

…additional safeguards have been included in the study to protect participants



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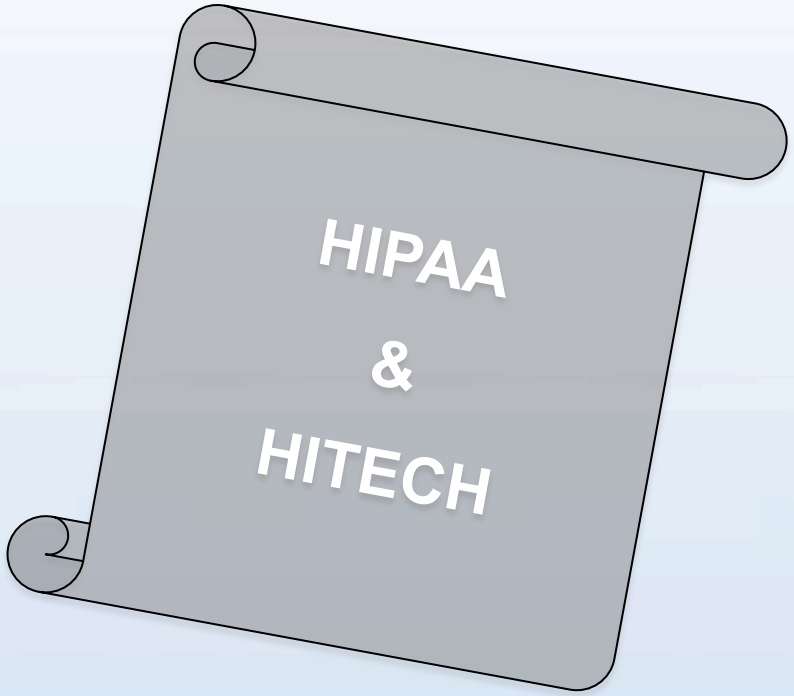
IRB must determine that ALL criteria are met prior to Issuing IRB approval

HIPAA Privacy Rule – Geisinger is a covered entity



HIPAA Identifiers

•Name	•Account Numbers
•Street address, city, county, precinct, zipcode	•Certificate/license numbers
•Dates	•Vehicle identifiers and serial numbers
•Telephone Number	•Device identifiers and serial numbes
•Fax Number	•Web addresses (URL)
•Electronic mail address	•Internet addresses (IP)
•Social Security Number	•Biometric identifiers including fingerprints and voiceprints
•Medical record number	•Full face photographic images and comparable images
•Health plan identification numbers	•Any other unique identifying number, characteristic or code

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Use vs. Disclosure of PHI

Use: accessing, using, or sharing of PHI within Geisinger

Disclosure: the sharing of PHI outside of Geisinger

(i.e., with another institution or even with Geisinger Health Plan)

HIPAA Regulations

Outside of treatment, payment and healthcare operations (TPO), the *permitted* use and disclosure of PHI requires:

PHI *Personal Health Information*

	Use	Disclosure	Accounting for Disclosure
Authorization	√	√	
Waiver of authorization	√	√	√
De-identified			
Review Preparatory to Research	√		
Decedent Research	√		

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How does the IRB make decisions?

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Institutional Requirements for IRB submissions

- ✓ Research Education requirements
- ✓ Research Financial Conflict of Interest requirements
- ✓ Principal Investigator requirements
- ✓ MCA & Billing Determination
- ✓ Investigational Pharmacy
- ✓ Radiation Safety Committee
- ✓ Institutional Biosafety Committee
- ✓ Information Security Office (ISO)
- ✓ Clinic/Provider/External Institution Approval for Recruitment
- ✓ Psychiatry Review for use of mental health data with identifers
- ✓ Nurse Research Council (nurse researchers)
- ✓ MyCode Governing Board (use of MyCode data/samples)
- ✓ Geisinger Health Plan Proposal (use of GHP data)

Objectives

Human Research Protection Program
&
IRB Resources

HRPP Webpage

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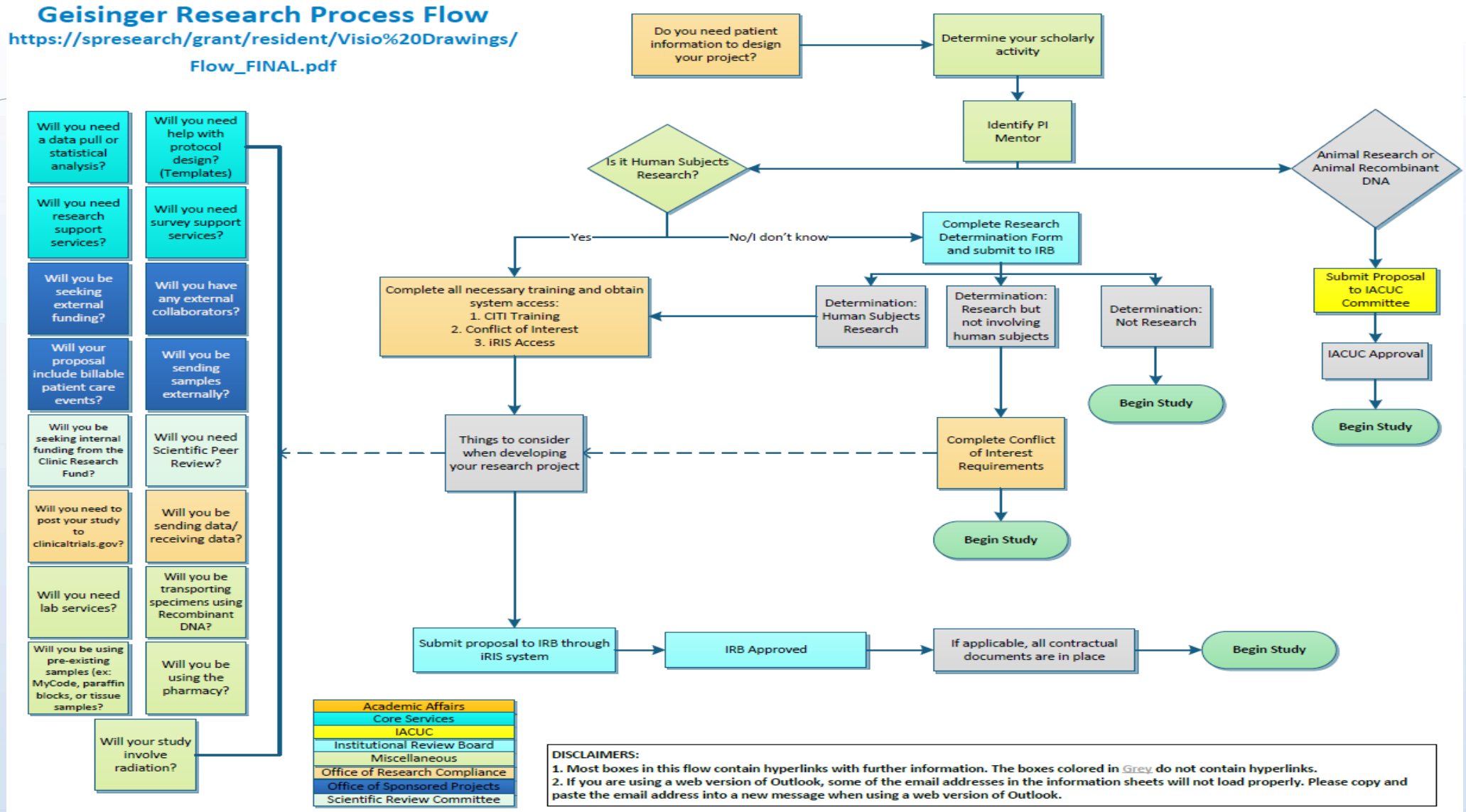
Geisinger Research Process Flow



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Geisinger IRB Information

NAME:	Geisinger Institutional Review Board
IRB REGISTRATION #:	00008345
INSTITUTION:	Geisinger Clinic
FWA ASSURANCE:	FWA00000063
ACCREDITATION:	Geisinger Health System is accredited by the Association for the Accreditation of Human Protection Programs, Inc. (AAHRPP)
ADDRESS:	Geisinger Institutional Review Board 100 North Academy Avenue Danville, PA 17822-3069
TELEPHONE:	570-271-8663 or 844-542-3299

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QUESTIONS??