

# INDIVIDUAL AUTONOMY: WHAT IT IS & WHY IT'S HARD

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A History of Informed Consent in the U.S. & its Coming Frontiers

# **We've moved towards a much more individual-focused model of autonomy, but that's not without its problems.**

- A. Historically, definition of 'autonomy' has shifted from a deferral to doctors' opinions to a model that places the power of the decision in the subject
  
- B. Moving forward, there are two challenges with this model of autonomy:
  - 1) Potential infringement of value of beneficence regarding decisions
  - 2) Potential infringement on the autonomy of surrounding individuals

# Autonomy and consent currently stand as some of the cornerstone values in research ethics.

- *Nuremberg Code*: establishing and ensuring respect for the intrinsic rights and autonomy of subjects
- *Declaration of Helsinki*: 'potential participants should be treated as autonomous beings, capable of making an informed decision whether to participate in research'
- *Belmont Report*: basic ethical principles of research **include respect of persons, beneficence, and justice**

**But where do they come from, and how are they changing?**

**Preface to the History: Battery and negligence are the two core standards in informed consent cases.**

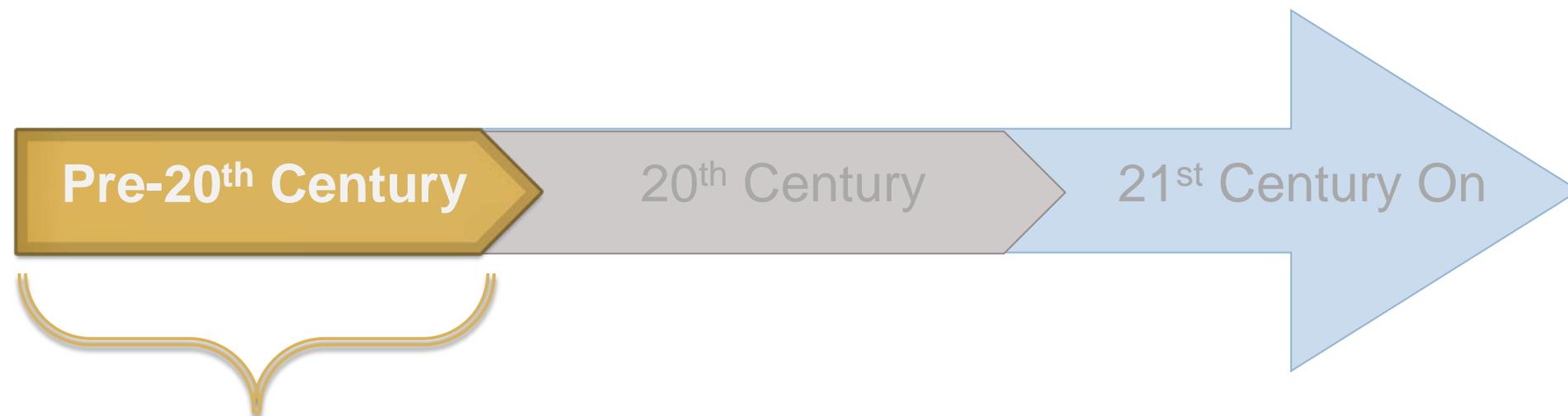
**Battery:**

Conduct with lack of consent (or against)

**Negligence:**

Conduct with inadequate consent

*Pre-20<sup>th</sup> Century Model*: Physician's autonomy should be maximized, since they're in the best place to make an ethical decision.



**RESULTING QUESTION:**  
**CONSENT**

Should subject autonomy count too, and if so how much?

# Pre-20<sup>th</sup> Century's Answer: Subjects should consent to what procedures are done to them.

## Schloendorff v. Society of NY Hospital

Case: subject expressly said not to conduct abdominal exam under anesthesia; doctor did anyway

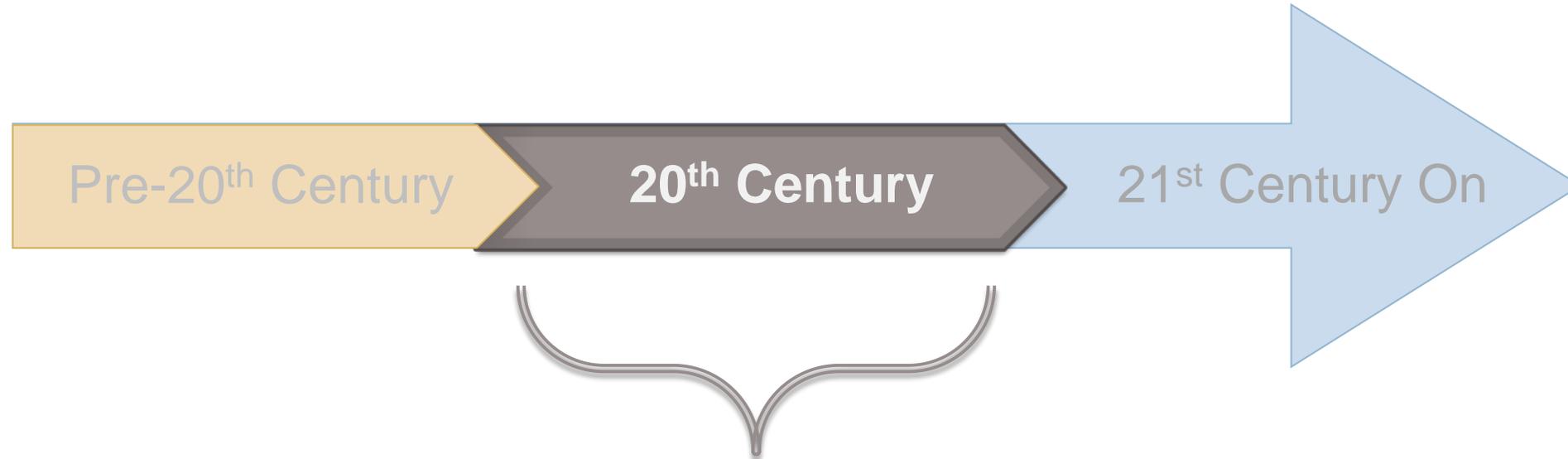
Result: **battery** (cannot conduct procedure without subject consent)

## Mohr v. Williams

Case: surgery conducted on incorrect ear of a subject

Result: **battery** (cannot conduct procedure without consent even if aligned intentions)

**20<sup>th</sup> Century Model**: Subjects should be asked first whether they would like a procedure to be conducted.



**RESULTING QUESTION:  
INFORMED CONSENT**

How much do subjects need to know (if anything) to make that decision?

## 20<sup>th</sup> Century's Answer: People must be apprised of anything that could 'reasonably change their mind.'

### Salgo v. Stanford

Case: administered an unconsented additional procedure and didn't apprise of all risks for original

Result: **battery** (need to be informed, but what to disclose is at physician's discretion)

### Natanson v. Kline

Case: administered procedure without telling person that there was a 'great risk of injury or death'

Result: **negligence** (must inform subjects of the potential risks associated)

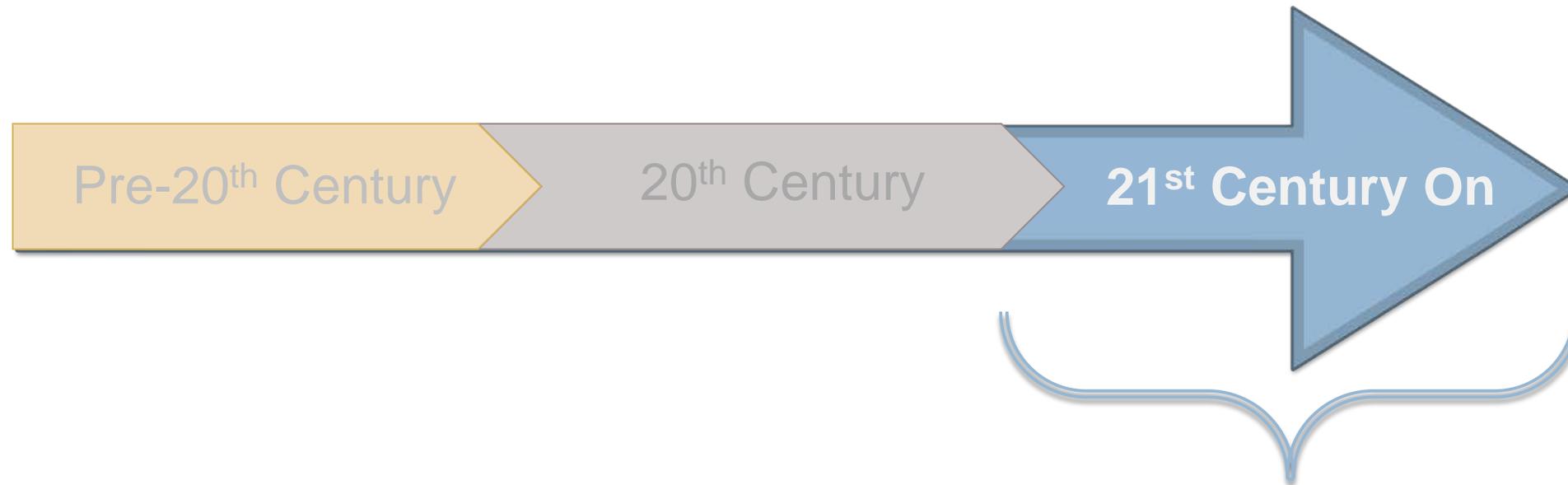
### Canterbury v. Spence

Case: did not disclose specifically the risk of paralysis prior to procedure

Result: **negligence** (establishment of standard of causation, or 'if it would change a person's mind')

**Current Model:** 'Subjects can and should have the opportunity to choose what can and cannot happen to them.'

–The Belmont Report



**RESULTING QUESTION:**  
**LIMITS OF CONSENT?**  
Are there any situations where it's morally better to limit subject autonomy?

## **Current Challenges to the Model:** Two core questions on limiting autonomy if infringing on other values

### **Beneficence:**

Is it okay to re-approach a subject if participation is 'in their best interest?'

### **Others' Autonomy:**

Should risks to people around the subject be factored into consent?

# Beneficence: is it okay to keep asking a subject who has refused if you think it's in their best interests?

**Dr. Forrow: The 'Green Eggs & Ham Problem'**

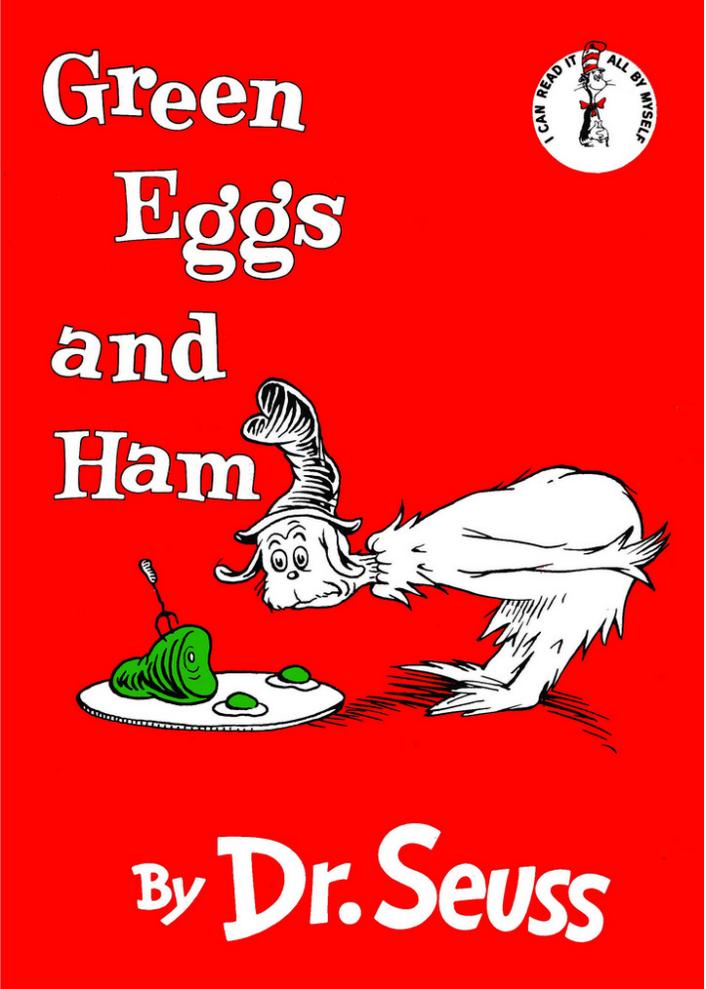
When a subject repeatedly refuses to do an unknown thing even if they may eventually like it

**Often a Result of Other Information**

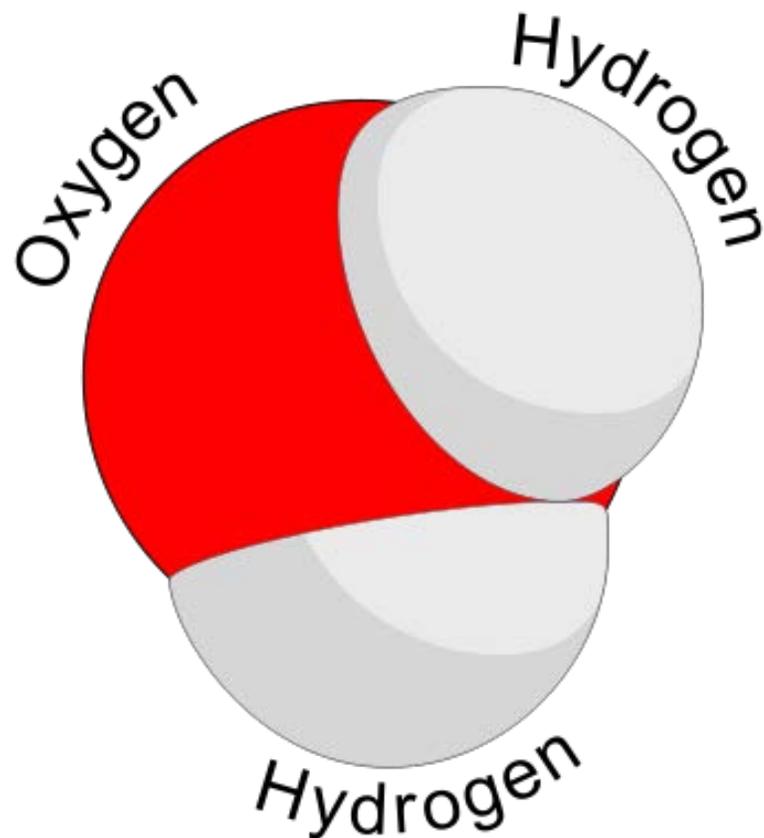
Can be from their perceptions of healthcare or research, unknown personal history, etc.

**Can It Contradict Beneficence?**

Is it against beneficence to not pursue the matter, or against autonomy to re-ask?



## Others' Autonomy: at what point do you bring others into a decision?



### Individual Doesn't Often Exist in Isolation

Dr. Forrow: like a water molecule – rarely just an oxygen atom alone; usually two little hydrogens attached

### Decisions Can Be Altered by or Impact Others

Person may change their mind based on impact to family, or decision may affect others close to them

### When (if ever) Do You Involve Others?

Is it infringing on others' autonomies to not include in an impactful decision, or infringing on the individual to not let them decide for themselves?

## *Common IRB Considerations for Vulnerable Populations.*

### **ASSENT:**

How much should a child know before assenting? Should they be continually updated with more information?

### **CONSENT WITH LAR:**

When is it appropriate to ask an LAR for consent? How much input should be sought from the potential subject?

### **CONSENT OF FATHER FOR A PREGNANT WOMEN TO ENROLL:**

Consent of father is required when direct benefit is solely to the fetus. When is this appropriate? When should father's decision be able to override the autonomy of the mother?

**Discussion Points: We've moved towards a more individual-focused model of autonomy, but that's not without its problems.**

- A. Historically, definition of 'autonomy' has shifted from a deferral to doctors' opinions to a model that places the power of the decision in the subject
- B. Are there times when the focus on individual autonomy should be limited?
  - 1) Potential infringement of value of beneficence regarding decisions
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# References

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