



**HOW DO WE TREAT THE
ASYMPTOMATIC PATIENTS THAT ARE
NOT ELIGIBLE FOR ACST-2 OR TURN
DOWN ENROLMENT ?**

”PATIENT’S CHOICE”

GUIDING ETHICS

INCREASING LEVEL OF EVIDENCE

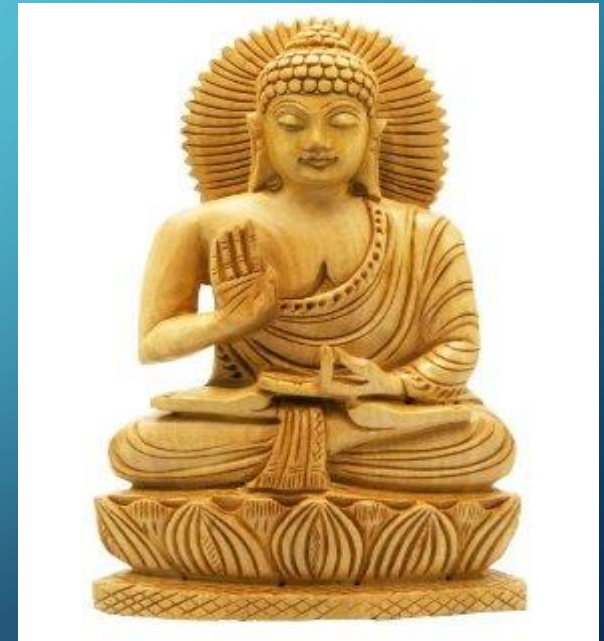
1. OPINIONS OF (VERY) RESPECTED AUTHORITIES
2. CONSENSUS COMMITTEE REPORTS
3. NON-EXPERIMENTAL STUDIES

SIDDHARTA GAUTAMA

SOMETIMES BETWEEN THE SIXTH AND FOURTH CENTURIES BC

”DAIJI” = mercy

”SOKUIN” = sympathy

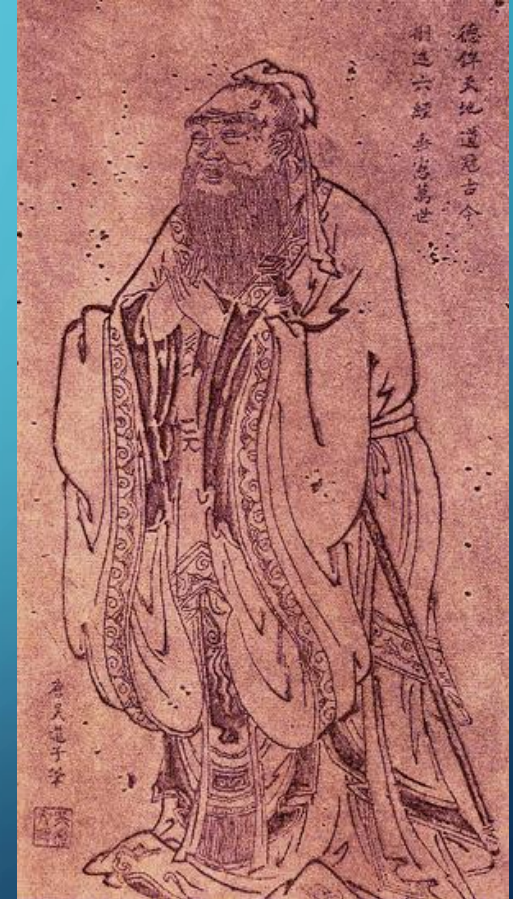


CONFUCIUS

551 – 479 BC

Tell me, and I will forget.
Show me, and I may remember.
Involve me, and I will understand.

— Confucius, 450 BC



NUREMBERG CODE 1947

”CONSENT OF RESEARCH SUBJECTS MUST BE VOLUNTARY, INFORMED, AND WITHOUT COERCION”

RIGHT TO WITHDRAW

DECLARATION OF HELSINKI

1964-2013

The investigator must respect the right of each individual to safeguard his...

“PERSONAL INTEGRITY”



BELMONT REPORT, 1979

**ETHICAL PRINCIPLES AND GUIDELINES FOR HUMAN SUBJECTS
RESEARCH
COMMISSIONED BY U.S. CONGRESS**

MAIN PRINCIPLE

PEOPLE ARE AUTONOMOUS



OFFERING PATIENTS ENTRY IN CLINICAL TRIALS

Corbett et al. J Med Ethics; 1996:22

TRADE-OFF BETWEEN AUTONOMY AND BENEFICIENCE

- **Modern opinion would give more weight to the former**
- **Some scepticism with process of randomisation**

PATIENT'S PREFERENCES FOR PARTICIPATION IN CLINICAL DECISION MAKING

Benbassat et al. BehavMed; 1998

- PATERNALISTIC MODEL –

EMPHASIZES DOCTOR'S AUTHORITY

- ALTERNATIVE MODEL –

ALLOW PATIENTS TO EXERCISE THEIR

"RIGHT TO AUTONOMY"

SHARED DECISION MAKING - A MODEL FOR CLINICAL PRACTICE

Elwyn et al. for the Cochrane institute; JGIM; 2012

SDM – An approach where clinicians and patients share the best available evidence when faced with making decisions, and where patients are supported to consider options, to achieve...

"INFORMED PREFERENCES"

IMPORTANCE OF CLARIFYING PATIENT'S DESIRED ROLE IN SHARING DECISION MAKING ...

Politi et al. BMJ; 2013:347

- "We suggest clinicians start by acknowledging equipoise..."
- Once patients are informed, they can decide whether they would like more (or less) ...

"RESPONSIBILITY FOR THEIR HEALTH DECISIONS"

THE ETHICS OF RCTs...

Edwards et al. BMJ; 1998:317

- A review of ethics for RCTs
- 61 studies on attitudes to trials
- Patients preferred...

A THREE-WAY CHOICE !!!

Treatment A, Treatment B, or Trial: (A vs B)