What is wrong with these studies?

Middle school students are asked to participate in an experiment to study the effects of bullying behavior.

Soldiers are asked to volunteer for a "medical study" in which they will "get a shot and have to visit the doctor twice for 15 minutes each time" and that they will get extra leave for participating.

Concentration camp prisoners are used for experiments.

Patients in a state mental health facility are asked to volunteer for a treatment study.

The hospital research group mailed study participants details of the next steps in the study using envelopes with a return address of "HIV Research Group at University Hospital"

An IRS employee wanting to study the reasons for charitable deductions finds tax filers with high deductions and calls them to ask questions.

Principles

Institutional review board (IRB)
- o Ensures the people conducting the research understand ethics
- o Review their proposed procedures, requiring approval
- o Creates procedures to ensure compliance

The IRB will ensure:
- Informed consent

- Confidentiality

At Southern:
- o I had to pass on-line course
- o My survey forms, procedures, every element of my contact with subjects needed pre-approval
- o I had to prove I had a secure, confidential way to back up all my data for X years (liability)

Informed, **freely given,** consent

The review board will ensure studies have this.

Informed:
You were given all the relevant information
You understood all the information

Freely given:
Nothing keeps you from saying, "No" if you wish

Consent:
You are capable of agreeing
You agreed

What informed consent issues might come up in testing a new ADHD drug?

- Minors:
Legal ability to consent
Intellectual capacity to consent
Ability to understand consequences

- Complexity of issues
Potential drug impact when you are young
list could go on for ever
real risks hard to understand
What is the harm in not participating?

Issues for researcher

Informed:

You were given **all** the relevant information

You **understood** all the information

- You can't give all, have to decide where to cut
- Your subjects must be able to understand
  - o Working on children and people with mental challenges
  - o The risks and issues might be hard to explain

Freely given:

Nothing keeps you from saying, "No" if you wish

- No coercion
  - o Prisoners
  - o People you or your institution of a relationship with.

Consent:

You are capable of agreeing

You agreed

- Minors: legal right to consent
- You have to take real care with a formal response

Confidentiality, why?

- Lack of secrecy could be effect results
- Even without harm from no people knowing, privacy is valued

Anonymity does not equal confidentiality

Anonymity => no one on the experimental team knows the subjects identity at any point.

Confidentiality => only members of research team, maybe a limited set, can connect data to identities.

Experiment only needs to defend confidentiality.
Anonymity, given documentation of consent and other practical considerations, is very difficult to arrange.

How is confidentiality maintained?:

1) Subjects are given numbers at the earliest stages, the document tying names to numbers is securely hidden, only numbers are used to refer to subjects.
(You need to keep names somewhere for record of consent and other issues.)

2) All data is kept securely and only seen by those who need to see it when they need to see it.

3) Mostly, only summary level data, statistics, are published or shown outside research group.
AN INDIVIDUAL DATA IS KEPT CONFIDENTIAL

4) Data for a particular subject is only revealed in special circumstance and only if the identity of the subject can not be figured out from the facts revealed.

Problem 3.44 discuss minimal risk

The study you would design without ethics:
- Is very different than an ethical study
- Will probably have fewer controls and comparisons

Ethics limit the strength of research results.

the interest of THESE subjects must always prevail

Is messing with people ethical at all?

the interest of THESE subjects must always prevail

- NO "sacrifice these people for the greater good" logic is allowed.
- If you would NOT consider it as a treatment for a patient outside the experimental context, then you CAN NOT consider it as a treatment in the study.

PUT ANOTHER WAY -
You must be able to say:
I have reason to believe each treatment will not put the subject at risk of harm.
I have reason to believe each treatment might not be the best treatment.

You ARE limited in the control groups in a study.
You can not give no treatment or a placebo when there is a proven/tested existing treatment.

In an experiment each treatment is **always instead of something else**.

A study could involve
- A new treatment
- Best known treatment
- No treatment
- **Placebo**

Would you expect to have a study with all four? No

- *The **placebo** is unethical if there is a **proven/tested** best known treatment in this circumstance WHY?*
- *No treatment is unethical if there is a **proven/tested** best known treatment in this circumstance WHY?*

An experiment testing a "best known treatment" that has not been tested in the test circumstance and a new treatment:
a) Should have **placebo** and/or no treatment controls
b) Is really testing two treatments.

Treatments must be pre-tested in some way.
In test-tubes
In petri-dishes
On non-humans

1) the interest of THESE subjects must always prevail

2) If you would not consider it as a treatment for a patient outside the experimental context, then you should not consider it as a treatment in the study.

Behavioral experiments have SLIGHTLY different standards

1) In a medical study the subjects are people who need healing,
one treatment versus the other is not a matter of possibly denying healing.
2) In a behavioral study the effects of participation in the study are ideas in the subjects head, not changes to their body.

But, psychological harm and suffering are still not allowed.

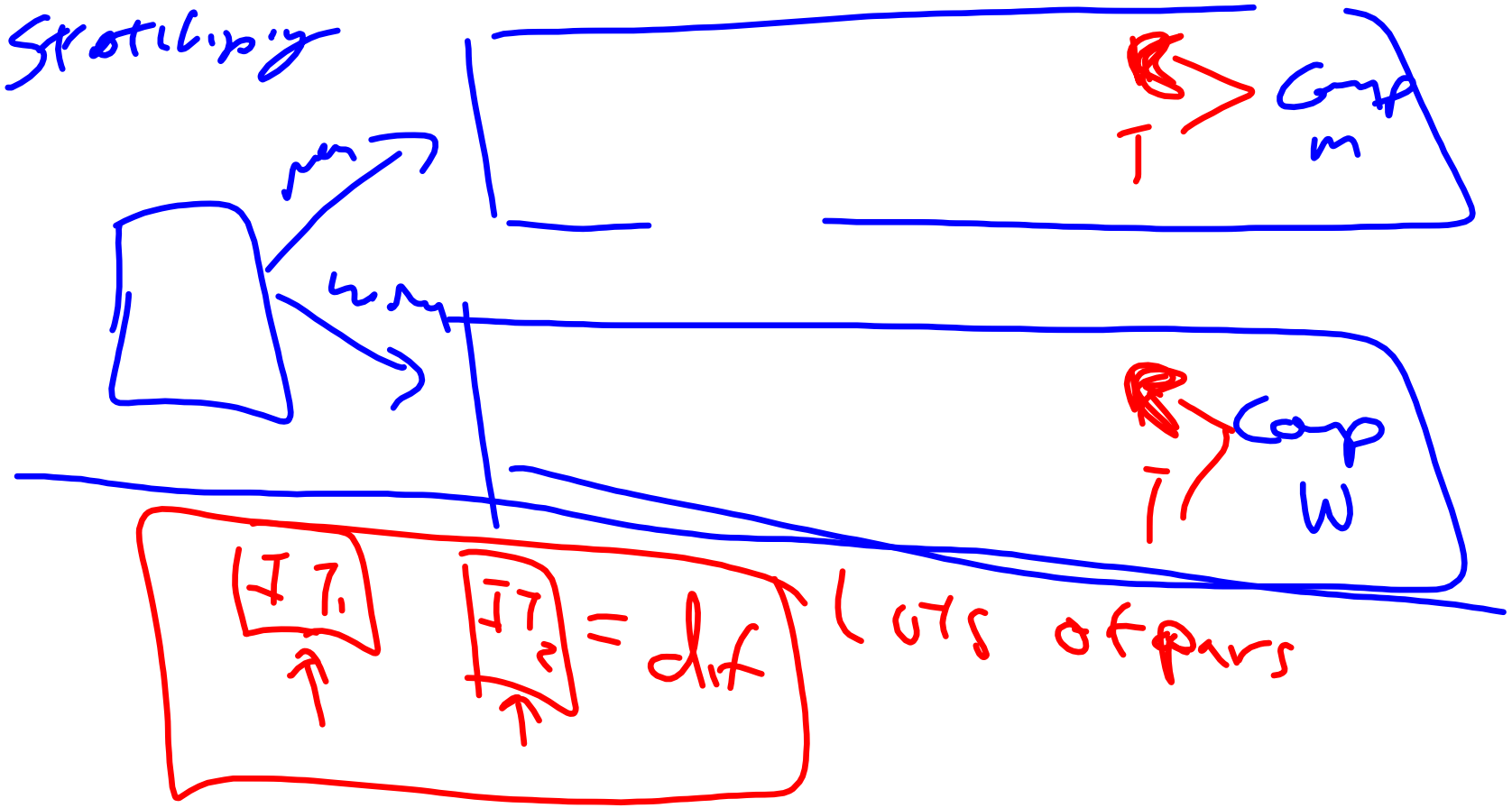
Informed consent generally required
- Exception for observation in a public place

"Informed" allows incomplete information, even some deception IF
- it is clear the misinformation or lacking information would not influence the subjects willingness to participate.

Standards/principles from 3.3:

1) Confidentiality: required, no room to avoid it
2) Fully informed consent:
    Medical studies: required, no room to avoid it
    Behavioral studies: Would the information change the subject's willingness to participate?
3) Minimal risk: How does the risk compare to risks of daily life or risks of routine examinations?
4) Interest of the subject must prevail.
5) Every treatment must be a valid treatment.

Match pairs
Uncooperative subjects
3.3
IRB
What is it?
Its job
The issues of ethics
Informed consent
Anonymity vs confidentiality
Principles
Minimal Risk
Interest of the subjects prevail
Valid treatments (Placebo, control, etc.)
Informed consent/deception exceptions
Principle: Would subjects be upset?
Medical studies
Behavioral studies


Stratifying
Comp
T
m
Comp
T
W
= df
Lots of pairs

M.P. Twins

⇒ Real Twins

⇒ Super person

⇒ Make match pairs