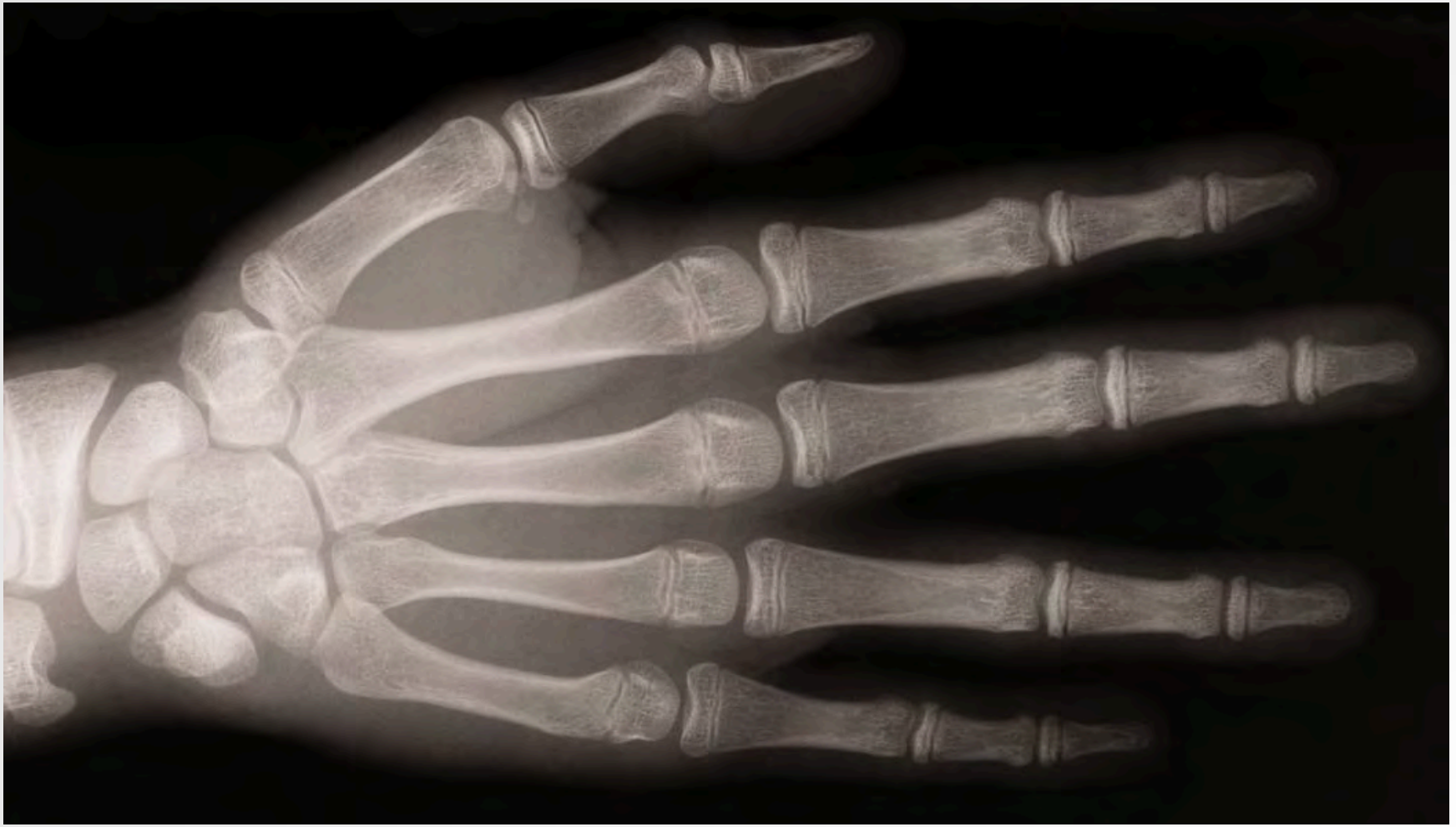
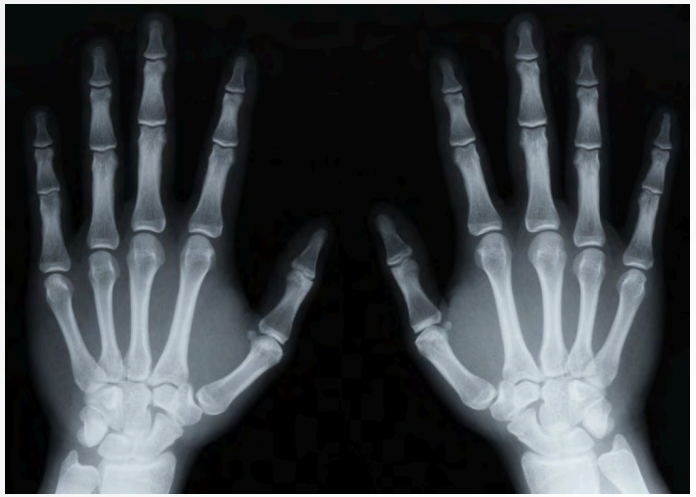
History of Research Abuses



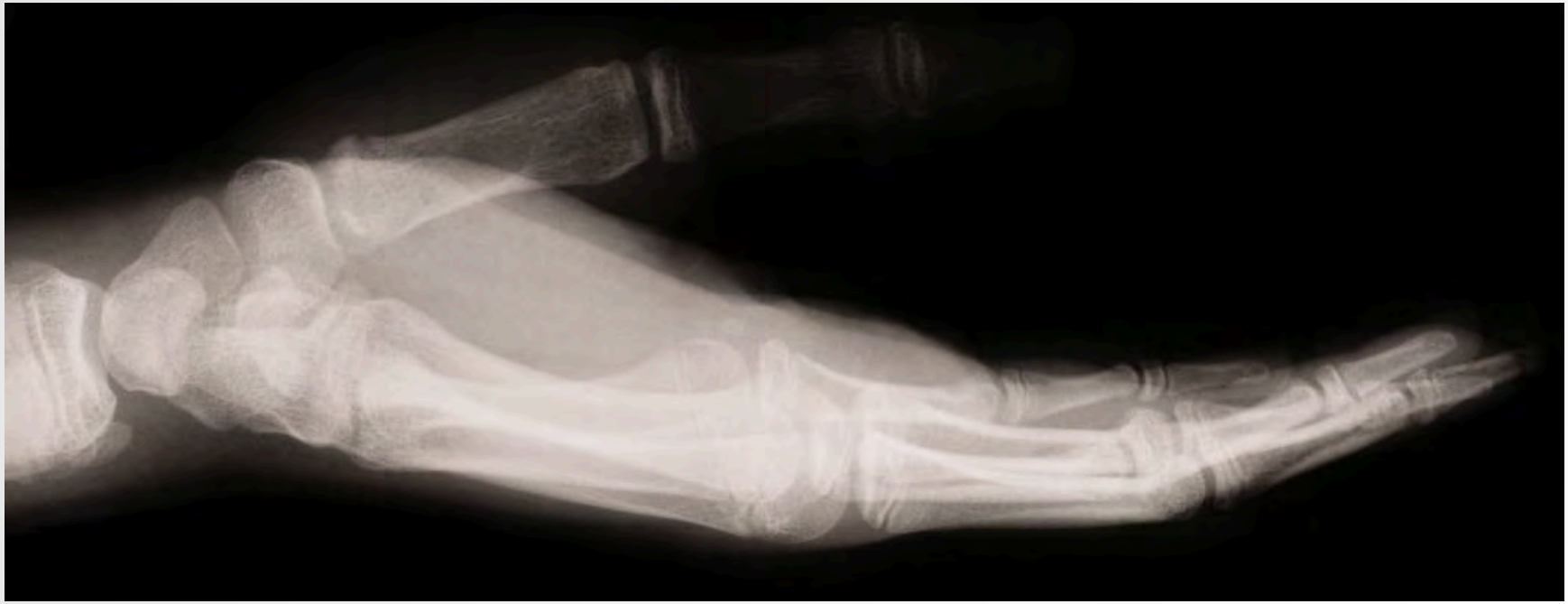
Historical Perspectives

- There are many examples throughout history of research causing harm:
  - Exploiting disadvantaged populations without benefit
  - Experimenting on people without their knowledge
  - Dangerous research
  - Violations of privacy



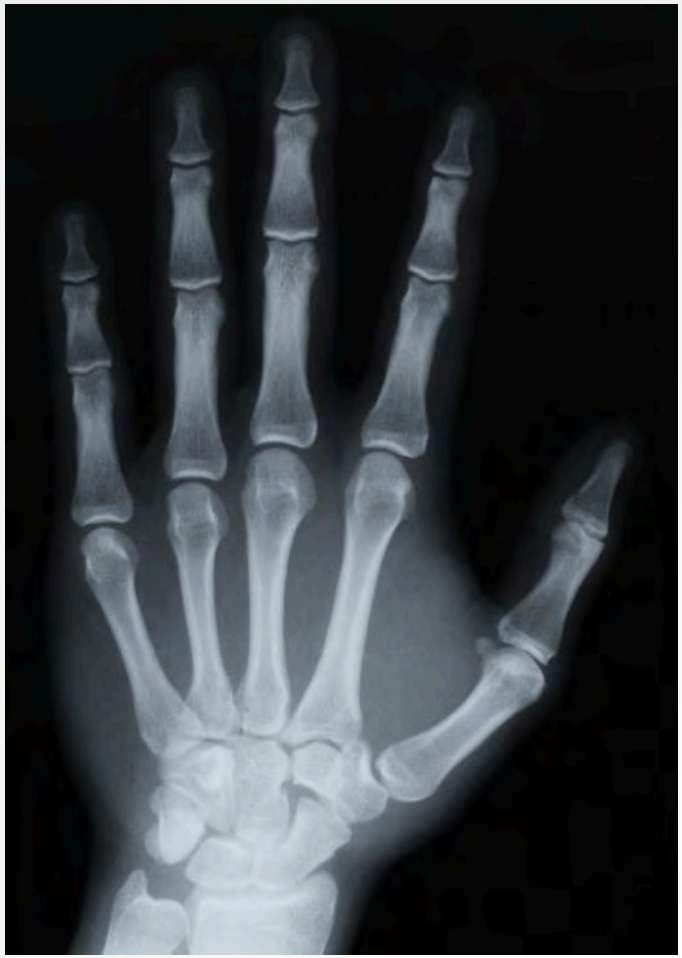
Take Home Message

- Public outrage over research abuses led to increased government involvement and regulations for research



Nazi Experiments

- Conducted by Nazi doctors in concentration camps during WWII
- Involved thousands of prisoners
- Involved purposely infecting prisoners, exposing them to dangerous conditions
- Trial of Nazi doctors resulted in 1st formal ethical guidelines for medical research

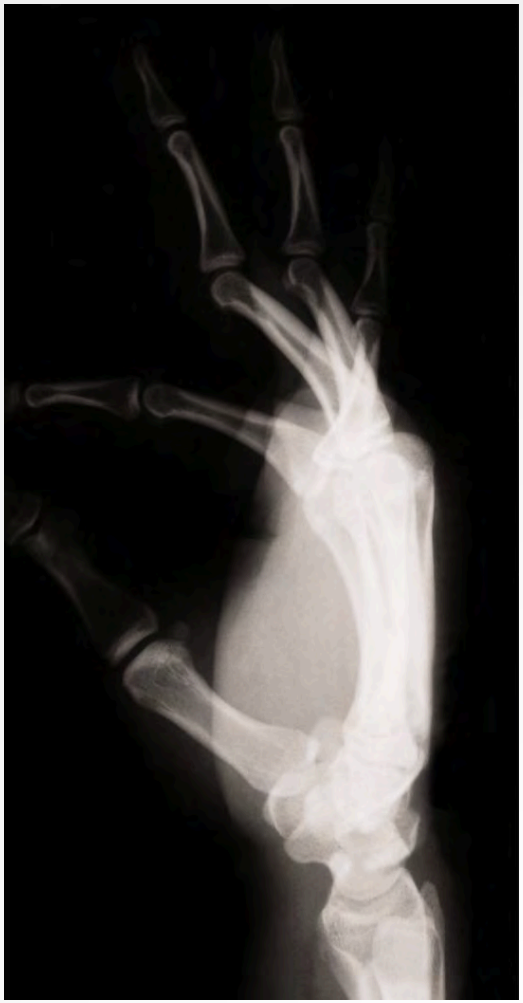


Willowbrook School for Mentally Retarded Children

- Staten Island, NY; 1956-1971
- Residents purposely infected with hepatitis through injection
- Experimental vaccines administered
- Risks not fully explained to parents
- For a time, study participation required of all new students in order to be accepted into the school

Milgram Obedience Studies (1960s)

- Stanley Milgram, social psychologist
- Wanted to see how far "obedience" would go
- Did not reveal whole truth about the experiment
- Participants told to give electric shocks to an unseen individual in another room
- Shocks were not real, but many people did not stop despite protests
- Caused anxiety, embarrassment, and discomfort for participants
- Not enough debriefing

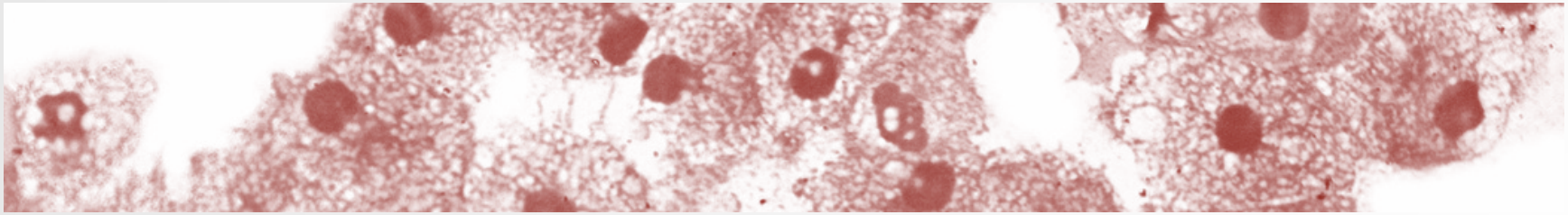


Tearoom Trade Study (1960s)

- Laud Humphreys, sociology PhD student in St. Louis
- Observed men having sex in public restrooms
- Concealed identity as a researcher
- Wrote down license plate numbers
- Later went to men's homes pretending to be conducting general health study
- Invasion of privacy

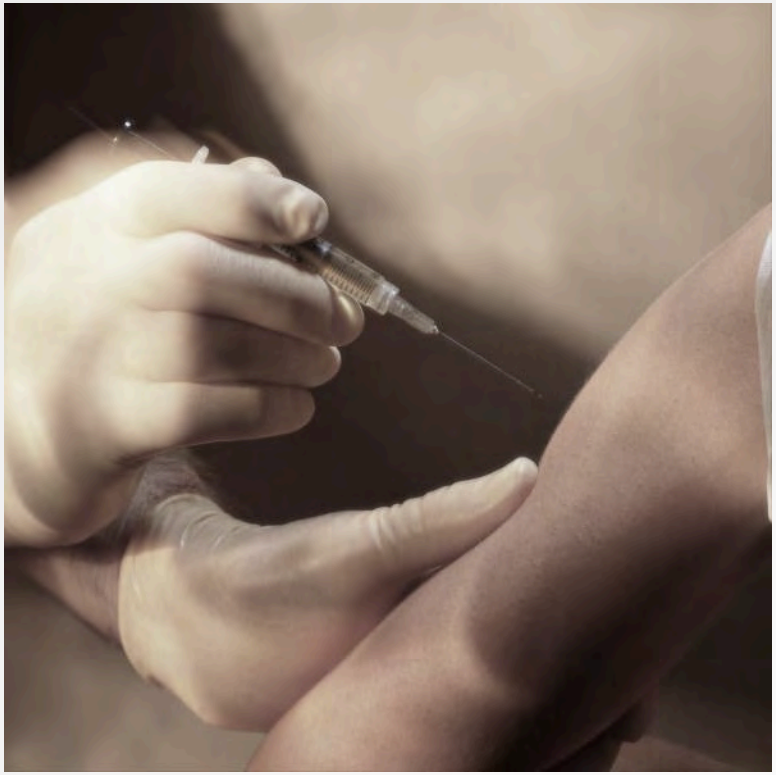
Havasupai Tribe (1990s)

- Live in Grand Canyon in Arizona
- Researcher from University of Arizona collected blood samples from tribe members to study type II diabetes
- Researcher also used samples to study schizophrenia
- Shared samples with other researchers
- Tribal leaders would not have agreed to this
- No information from diabetes study shared
- Privacy violations



Public Health Service Study of Untreated Syphilis in the Negro Male (Tuskegee)

- Government-funded
- Macon County, Alabama, 1932-1972
- What happened when syphilis left untreated?
  - increased disability and early death – already known!
  - Recruited black men only
  - Men tested for syphilis but not told they had it
  - Infected men kept from getting treatment even though treatment (and later cure) available



Public Outrage Over Tuskegee

- Many scientists knew about the Tuskegee syphilis study – it was NOT a secret!
- But once it was reported in Washington, DC newspaper, **the public demanded government action**
- A federal commission was formed to address protection of research participants and develop federal guidelines

Ethical Principles, Regulations, and Institutional Review Boards

Ethical Principles for Research

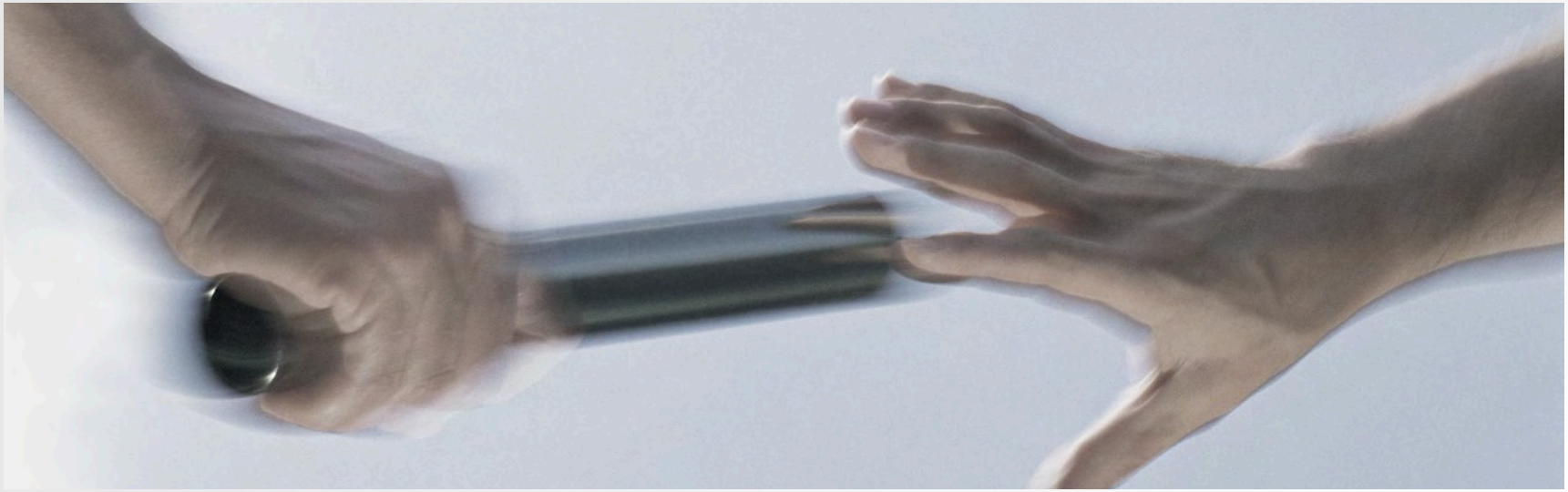
- 3 “golden rules”
  - Respect for persons
  - Beneficence (Do good, not harm)
  - Justice (Fairness)
- Federal research regulations are based on these three rules

Research Rule #1: Respect People

- Everyone deserves to be treated with respect
- People should make their own decisions
- Good decisions require truthful, accurate information
- Researchers show respect for participants through the informed consent process
- Agreement to participate in research must be freely and voluntarily given
- Those with diminished capacity (vulnerable) require extra protections

Research Rule #2: Do Not Harm

- Avoid known risk of harm to participants
- Do not risk harm to participants regardless of potential benefits to society, future patients
- Minimize potential harms whenever possible
- Maximize potential benefits to participants



What are Some Risks of Research?

- Different types of harm
  - Physical (you are injured)
  - Social (someone finds out something about you that you don't want them to know
  - Psychological (you get upset)
  - Legal/Economic (you can't get a job)

- Big or small

- Unknown risks
  - New medications=side effects?

Research Rule #3: Be Fair

- The benefits (good) and burdens and risks (bad) of research should be shared by all people
- People should not be used out of convenience
- Certain groups or participants should not be excluded out of convenience either
- The safety and welfare of some groups should not be risked for the benefit of others

Research Regulations

- The federal government has made laws for how research should be done
  - Protecting participants
  - Informing participants
  - Reviewing research before it starts

- Everyone doing research must follow these rules

- Review boards called "IRBs" enforce these rules at the local level in order to protect the rights and welfare of participants

The Institutional Review Board (IRB)

- Main goal: Protect participants from harm!
- Before a project starts, the IRB:
  - Weighs risks and benefits
    - Reviews all forms and procedures
    - Recruitment of participants
    - Informed consent procedures
    - Privacy and confidentiality protection
- Requires changes – big and small
  - Research cannot start until the IRB approves it

Who Serves on the IRB?

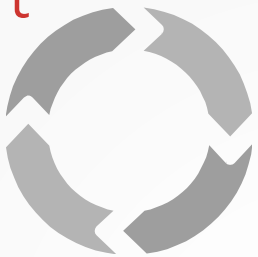
- Required at institutions that conduct research
- Made up of:
  - At least 5 members with different backgrounds
    - At least 1 member who is a scientist
      - At least 1 member who is **NOT** a scientist
        - At least 1 member who is not an employee or related to an employee of the institution

Community Representation on IRBs

- Many IRBs meet the requirements:
  - At least 1 member who is NOT a scientist
  - At least 1 member who is not an employee or related to an employee of the institution with **one or more "community member" representative(s)**
- GOALS:
  - Transparency
  - Represents local community(ies) interests
  - Protects vulnerable populations
  - Lay perspective, language

As Research Continues…

- Any changes that a researcher wants to make must be reviewed & approved by IRB
- Researchers must provide annual (or more often) updates to IRB
- Problems ("adverse events") must be reported
  - When proper procedures are not followed
  - If participants complain
  - If harms occur that were not anticipated
- If rules aren't followed, appropriate forms aren't used, then researchers are "non-compliant"– that is, they are violating federal regulations



Research with Communities

What is Different about CEnR?

- Builds on community strengths & resources
- Collaboration in all phases of research
- Commitment to local health issues
- Academics & community learn together

What Defines a Community?

- Geography
- Race/ethnicity
- Religion
- Health concerns
- Other shared interests or experiences

Unique Issues: Research with Communities

- Community or group-level harms
  - Stereotyping

- Privacy and confidentiality
  - Access to information about known individuals
  - Difficult to keep anonymous
  - Gossip!

Unique Issues:
Research with Communities (continued)

- Biases
- Competing goals

Your Important Role in Research

- Know the rules for research
- Know your study
- Ask questions about things you do not understand
- Raise issues with your team if you think something about the research is not right

Informed Consent Overview

Informed Consent

- What it is:
  - An ongoing dialogue
  - Mutual understanding of the requirements of the study
  - Voluntary agreement
  - The cornerstone of research
  - Necessary for trust

- What it's **NOT:**
  - Just a piece of paper
  - a one-time thing
  - a contract

Informed Consent Basics

- Information
  - You have to give all the information
- Understanding
  - The potential participant needs to have the right idea
- Voluntariness
  - The participant's agreement can't be forced

Recruitment

- Finding and inviting the right people to participate in a study
- Based on “eligibility criteria” (inclusion/exclusion)
- Defined requirements for participants: age, sex, health, zip code, etc.
- Only people who meet criteria should be invited
- Ensures fairness and usefulness of information

The Consent Form

- Written document summarizing a research study
- A tool to help recruit participants in a way that is ethical and fair
- Explains participants' rights
- Written in language understandable to participants
- No leading language or false promises
- Must be approved by the IRB

Key Elements of IC

- This is an invitation to be in RESEARCH
- Purpose, procedures involved, length of time
- Known risks/benefitsWhat will be done to keep information confidential
- Who to contact with questions
- Participation is voluntary

IC with Special Populations

- Some people are not able to look out for their own interests
  - Prisoners – not free to make own decisions
    - Children –can't legally make decisions, not fully mature
      - Cognitive or intellectual limitations – may not understand
        - Mentally or physically ill–not able to care for themselves
- Special practices for informed consent
- Should be protected from influence
- Should not be excluded from benefits of research

The Consent Form

Basic Study Information

University of Anywhere
Research Information and Consent for Participation in Research
Community Diabetes Study

You are being asked to take part in a research study. Researchers are required to provide a consent form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you make an informed decision. Please feel free to ask any questions you may have.

This study is being conducted in partnership by researchers at the University of Anywhere (UA) and the North Side Community Health Partnership (NSCHP).

Principal Investigator Name and Title: Anne Smith, Professor
Department & Institution: School of Public Health, University of Anywhere
Address & Contact Information: 101 Main Street, Anytown, Anystate, USA, (555) 123-4567
E-mail: annesmith@usomewhere.edu
Sponsor: National Institutes of Health

Why Am I Being Asked?

You are being asked to participate in this research because: you are a resident of the North Side community; you are between the ages of 18-64; you have been diagnosed with Type II diabetes within the last year; and your doctor has recommended that you lose 10 or more pounds.

Why are certain individuals asked to participate? What makes someone qualify?

Your participation in this research is voluntary. Your decision whether or not to take part will not affect your current nor future relationships with the UA or the NSCHP. If you decide to take part, you are free to stop at any time without affecting these relationships.

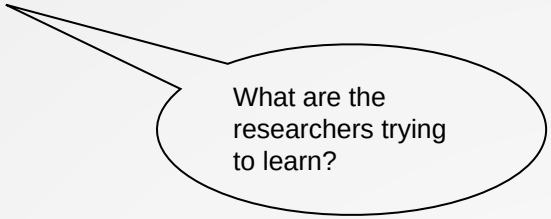
A clear statement that research participation is voluntary and that refusing to participate will not have negative consequences

Approximately 100 participants may be involved in this research.

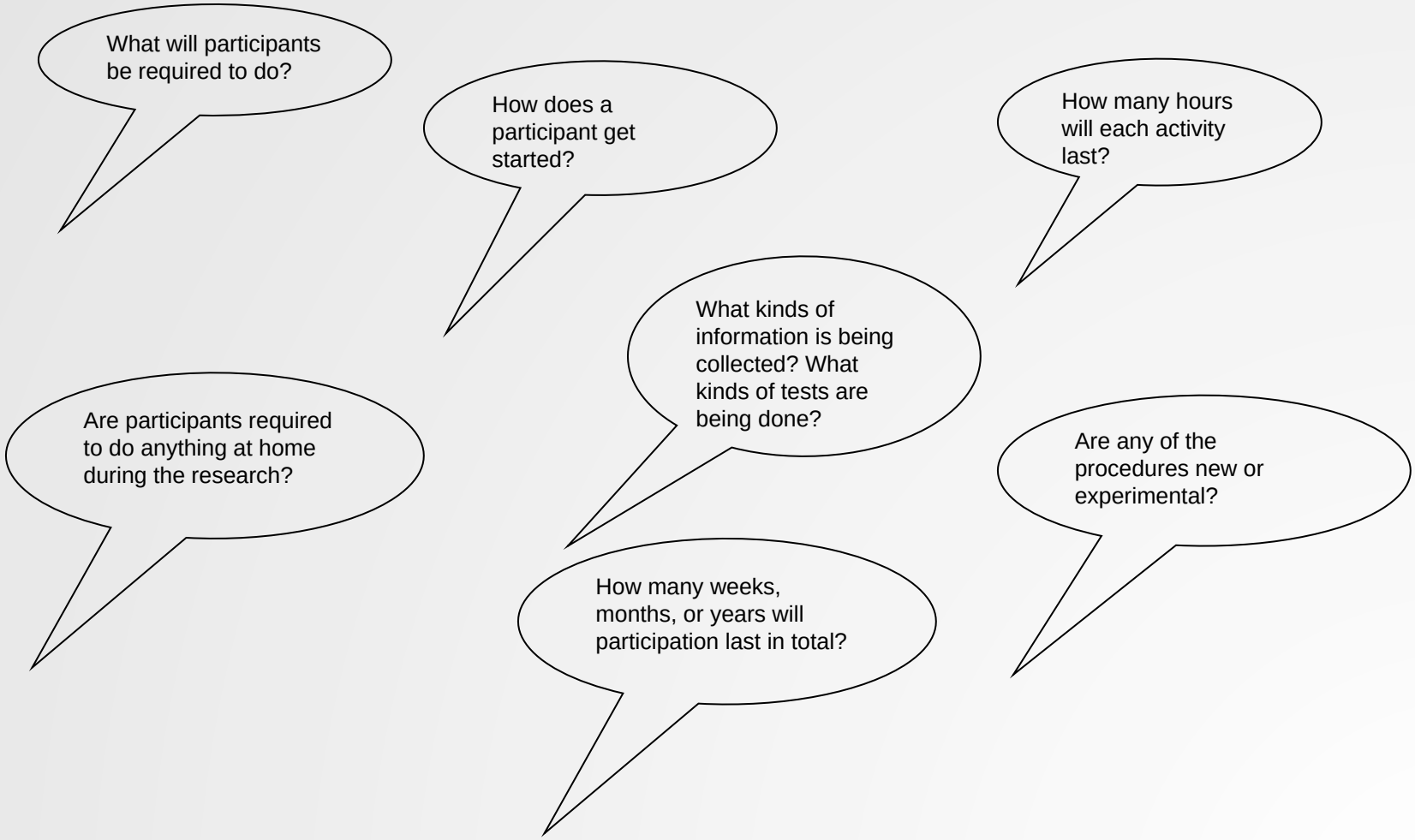
How many participants are going to be in the study?

Why Is this Research Being Done?

The purpose of this research study is to find out if the "Shape Up, Slim Down" program can help people who have recently been diagnosed with Type II diabetes lose weight. "Shape Up, Slim Down" was created especially for adults who live in large cities who might not be able to find other programs such as gyms or exercise classes. This program will show you ways to exercise at home and give you tips for making healthy meals. "Shape Up, Slim Down" is considered research because we do not know yet if it will really help.



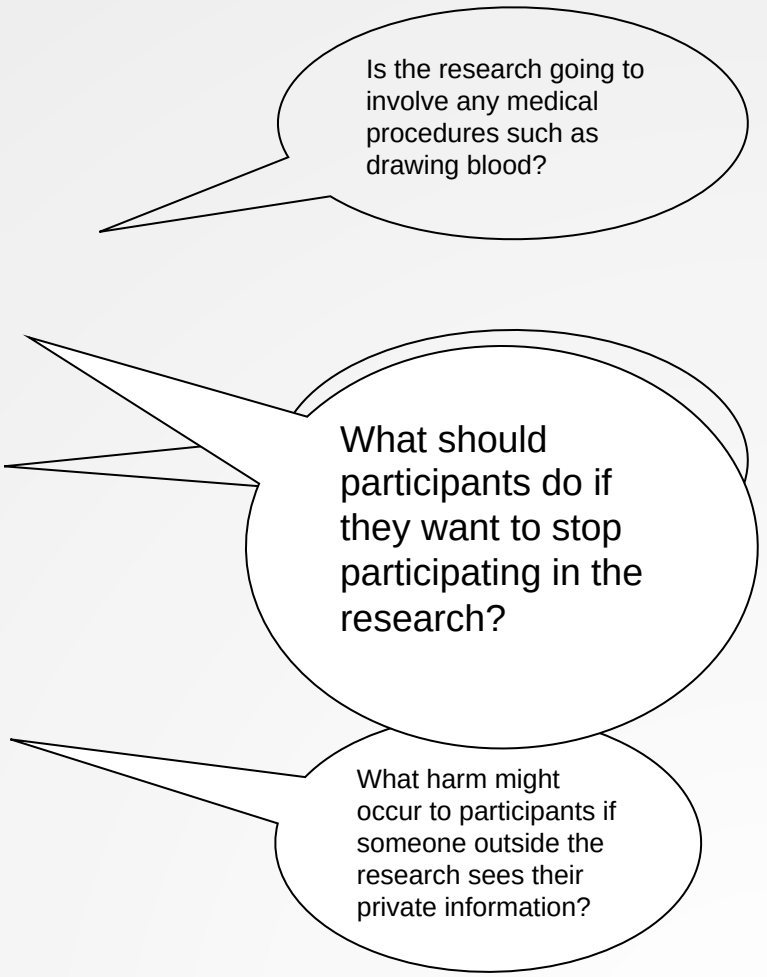
What Procedures are Involved?



Potential Risks and Discomforts?

You may feel uncomfortable discussing food, exercise, or your weight or being weighed. If you feel uncomfortable at any time, you can choose not to answer a particular question that we ask on a survey. You may also experience some minor discomfort when blood is drawn. You may get bored filling out all the surveys. You may not like the exercises we show you. To the best of our knowledge, the things you will be doing in this research have no more risk of harm than you would experience in everyday life.

Another risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not been given permission to see this information). We take special care to protect your information.



What About Privacy and Confidentiality?

The only people who will know that you are participating in research will be the North Side Health Expert who comes to your home and other members of the research team. No information about you that is provided by you during the research will be disclosed to others without your written permission except if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the UA Institutional Review Board monitors the research or consent process) or if required by law.

You will be assigned an identification number that will be kept separate from confidential information like your survey answers and results of your blood tests. The number will appear at the top of all your study materials. Only the North Side Health Expert and the Project Coordinator will have access to the list that links that number to you. This list along with all other study information will be kept in a locked file cabinet in a locked office at the NSCHP office. This list will be destroyed once the study ends. Electronic data files will be stored in databases that are protected by passwords. When the results of the research are published or discussed at conferences, no information will be included that would reveal your identity.

Benefits, Payment, Costs, and Options

Are there benefits to taking part in the research?
You may or may not benefit from this research. We may find out information that will help type II diabetics lose weight in the future.

Are there any direct benefits to participants? If there are no direct benefits to participants, is this stated clearly? How might society benefit?

What other options are there?
You have the option to not participate in this study.

If the study involves a new treatment, are participants told what other treatments exist for their illness or condition?

What are the costs for participating in this research?
There are no costs to you for participating in this research.

Are there any additional costs that might result from participation in the research, such as costs for medical treatment billed to an insurance company?

Will I be paid for my participation in this research?
You will receive a $20 at the end of the first meeting. Each time the North Side Health Experts visits your home, you will receive $5 (9 visits x $5=$45). If you cancel a visit, you will not receive compensation. You will also receive small items throughout the course of the program to help you make changes such as cookbooks, inexpensive exercise equipment (such as stretchy bands), and other health education materials. At the end of the 6 month program, when you are asked to return to one of our community sites for questionnaires, you will receive $20. At the final in-home visit, 6 months after the program is over, you will receive $40. Overall, you may be paid up to $125 in cash if you complete all research activities.

Are participants going to receive any payment incentive for participation, for their time, for inconvenience, for travel?

Can I Withdraw or Be Removed?

You can choose whether to be in this study or not. If you volunteer to be in this study, you may withdraw at any time without consequences of any kind. You may also refuse to answer any questions you do not want to answer and still remain in the study.

You may change your mind and stop taking part at any time. If you want to stop, we ask that you please call us to let us know. We will also want to ask a few questions about why you are stopping. This will be very brief. It is important to help us learn about the program. Please call: Mary Jones, Project Coordinator, at (555) 555-5555.

Questions? Rights?

You may ask any questions now. You may also call Mary Jones, Project Coordinator, at (555) 555-5555 at any time. During the study, you will always be able to call the North Side Health Expert who visits your home at any time. Dr. Anne Smith is the Principal Investigator of the study. You may contact Dr. Smith at (555) 123-4567 at any time.

Who should participants contact if they have general questions about the research?

If you feel you have not been treated according to the descriptions on this form, or if you have any questions about your rights as a research participant, including questions, concerns, complaints, or to offer input, you may call the Office for Protection of Research Participants at (555)765-4321 or (800)765-4321 (toll-free).

Who should participants call if they have not been treated as described in the informed consent form, or if they have complaints or concerns, or believe they have been injured as a result of the research?

Signature Page

Remember:

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current nor future relationship with the UA or the NSCHP. If you decide to participate, you are free to withdraw at any time without affecting this relationship. ***You will be given a copy of this form for your information and to keep for your records.***

Signature of participant

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research.
I will be given a copy of this signed and dated form.

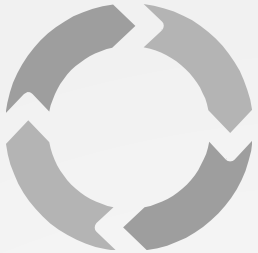
Your signature indicates that you are providing consent to participate in the research study.

Signature of Research Participant	Date
Printed Name	
Signature of Person Obtaining Consent	Date (must be same as Subject's)
Printed Name of Person Obtaining Consent	

Obtaining Informed Consent

Remember…

- Informed consent is a process
  - Discussion
  - Opportunities for questions and answers



- No pressure

- Obtain IC before any study activities start

- Obtain IC at a time and place that
- respects participants' time and privacy
- gives participants the opportunity to think more about their decision or discuss study participation with others

Ensuring Understanding

- Materials should be
  - written clearly
  - written at an appropriate reading level
  - translated for non-English speakers if they are to be included in research
- Participants should be encouraged to ask questions
- Person obtaining IC can ask questions to ensure understanding

Ensuring Voluntariness

- Participants should not be:
- Pressured
- Made to feel bad
- Threatened (with loss of services, for example)
- Offered lots of money to do risky things

Documenting Consent

- **When is a signature required?**
  - For authorization to access medical or other records
  - If the research involves more than minimal risk (including risks due to disclosure of personal information)
- The person obtaining consent also signs the document
- Include dates for record keeping

- **When is a signature NOT required?**
  - The research is anonymous
  - Signing a document would pose risks to confidentiality
  - If participation is brief and involves minimal risk
- Keep a log noting when each participant provided consent and to whom

Challenges to Informed Consent

- Consent forms contain a lot of information
- Many Americans read at grade school level
- It is difficult to explain complicated procedures in simple language
- It is difficult to explain how research is different from health care services
- People may exaggerate benefits in their mind even if you do not
- You cannot force people to read or listen

Your Responsibilities

- Know the study procedures very well
- Do not rely on participants to read the form
  - Discuss it or read it to them
- Encourage participants to ask questions
- Maintain participants' privacy
- Don't rush
- Spend more time with those who seem to not have read or understood
- If you think someone might not understand, ask them to explain the research to you

Being Careful with Research Information

Why Collect So Much Data?

- Each piece of information collected is necessary for the research
- Each piece of information may provide an answer to a particular question
- Research records must reflect what actually happened and is true

The “Don’ts”

- Do not write on forms that are supposed to be filled out by participants
- Don’t guess what a participant’s answer to a question might be – let them tell you
- Don’t rush participants through the research
- Don’t skip informed consent
- Don’t be sloppy

The “Do’s”

- Use the required forms
- Keep track of what you are doing
- Pay attention to codes and numbers
- Store data safely
- Be especially careful when transporting data to and from different locations
- If you don’t understand something –ask!

Research Should Be Worthwhile

- Failure to properly collect and protect research information may result in:
  - Not showing the real picture of the problem or issue being studied
    - Wasting valuable resources, including participants' time and effort
      - Violating confidentiality (for ex., if data are lost)
      - Any deviation from the research protocol must be reported to the IRB
- Any deviation from the research protocol must be reported to the IRB

Privacy and Confidentiality

The Basics

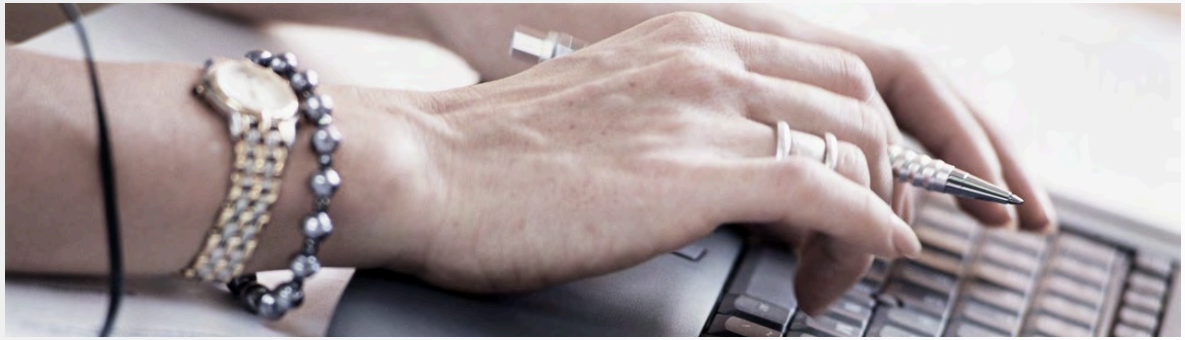
- Nobody likes their business to be shared with others!
- Confidentiality is central to the researcher-participant relationship
- Participants' personal information should not be disclosed to others
- Different people have different ideas about what is and is not private
- In research, it is ALL private!
- Everything should be kept safe and protected

Privacy (Who sees participants?)

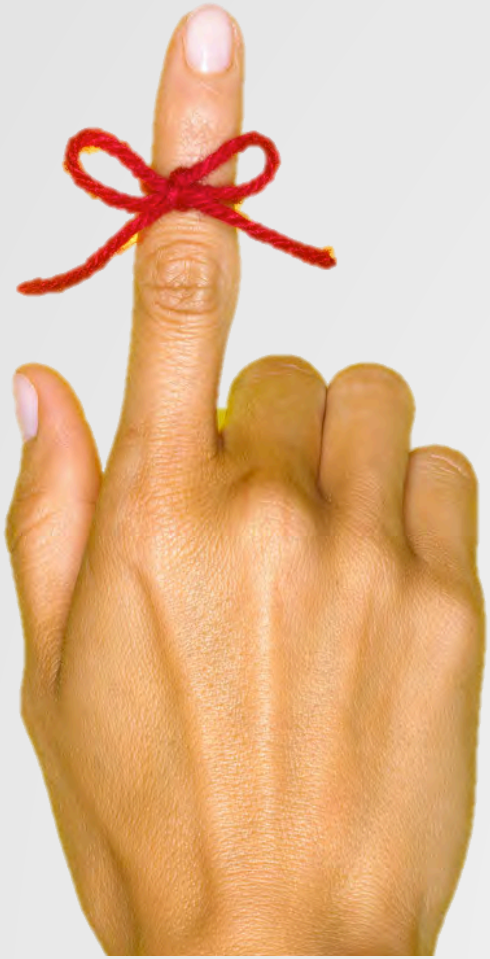
- It is a rule in research that people are allowed to decide if and when they are going to talk to researchers and share information about themselves
- Think about where research is being conducted and who might see participants

Confidentiality (Who sees information?)

- Security of information
- It is a rule in research that information about participants should not be shared with any people outside the research project
- Think about where you keep participant contact information and survey answers (on paper and on the computer)



EVERYTHING Is Confidential



- Name and contact information
- The fact that someone is a research participant, no matter what the study is about
- Health problems and diseases (Example: cancer)
- Health habits (Example: smoking)
- Other sensitive information
  - Drug use, arrests, pregnancy history
  - Different people are sensitive about different things (e.g., weight, income)

What Could Happen?

- Social harm
  - Neighbor learns research participant is HIV+; rumors start, causing participant to feel unsafe in their home
- Economic harm
  - Employer learns research participant is in treatment for alcoholism; fires participant
- Legal harm
  - Police learn research participant uses cocaine; follow participant, arrest during drug purchase

The “HIPAA” Privacy Rule

- Protects patient data from medical records
- Gives patients control over how their personally identifiable health information is used in research
- Affects what health information researchers can access without patient permission
- Fines for breaches

Every study should have a plan to keep participant information safe

- Only people who are allowed to see participant information should see it
- Activities involving participants should happen in private areas
- Don't discuss participants in the hall, elevators, cafeteria, etc.
- Don't leave computer screens open
- Don't leave surveys or participant information where others can see it