IRB: EVERYTHING YOU WANTED TO KNOW BUT WERE AFRAID TO ASK

KENNETH BIELAK

CYNTHIA LANGLEY

ANTHONY WILSON

OCTOBER 24, 2018

LEARNING OBJECTIVES

BY THE END OF THIS SESSION PARTICIPANTS WILL BE ABLE TO:

- Give examples of unethical historical research which led to the formation of IRBs
- Determine the level of IRB review needed based on the risk to subjects
- Complete an IRB application using iMedRIS, the IRB's online application system
- Avoid common pitfalls that delay IRB approval

LEARNING OBJECTIVES (CONTINUED)

BY THE END OF THIS SESSION PARTICIPANTS WILL BE ABLE TO:

- Review basic guidelines regarding the ethical conduct of research
- Review the history of human subject protection
- Discuss issues of informed consent
- Discuss the ethics of and use of incentives for recruitment and participation of human subjects in research studies
- Discuss QI vs Evaluation vs Human Subjects Research

DIRECT AND INDIRECT NEEDS **FOR HUMAN SUBJECTS PROTECTION**

- There are a number of challenges to ethical conduct in research!
- Whether conducted in an academic setting or a healthcare institution, by an agency or a private organization, research involving human subjects often raises ethical concerns as study participants may experience risks and inconveniences primarily to benefit others by advancing knowledge.
- Ethical questions may arise at any time during the research process – from the design phase to subject recruitment to data collection to analyses and dissemination of study results.

DIRECT AND INDIRECT NEEDS **FOR HUMAN SUBJECTS PROTECTION**

- Institutions engaged in research using human subjects are required to provide written assurance of compliance with regulations (including documentation that the IRB reviewed the research project) to funding sources. For federally funded research this means a Federalwide assurance or FWA.
- There may be times when multiple IRBs must approve the study (e.g., for multi-center trials, for collaborative projects between two agencies, etc.). Studies conducted at multiple sites may pose additional IRB concerns (e.g., maintaining confidentiality of data held at multiple sites; ensuring consistency of protocols between sites, etc.).

WHAT IS AN IRB?

(Institutional Review Board, aka: Ethics Committee)

A federally mandated committee, governed by federal law, that oversees research at an institution that receives federal funds to conduct research

Membership must include:

- Scientists: physicians, pharmacists, nurses, other scientists
- Non-scientists
- At least one member unaffiliated with the institution

Purpose:
To protect human subjects involved in research

WHAT DOES IT DO?

An IRB shall review and have authority to:

- Approve, require modifications in, or disapprove all research activities
- Suspend or terminate research that is not being conducted as approved or that has been associated with unexpected serious harm to subjects
- Any suspension or termination shall be reported promptly to the investigator, appropriate institutional officials, OHRP and/or FDA.

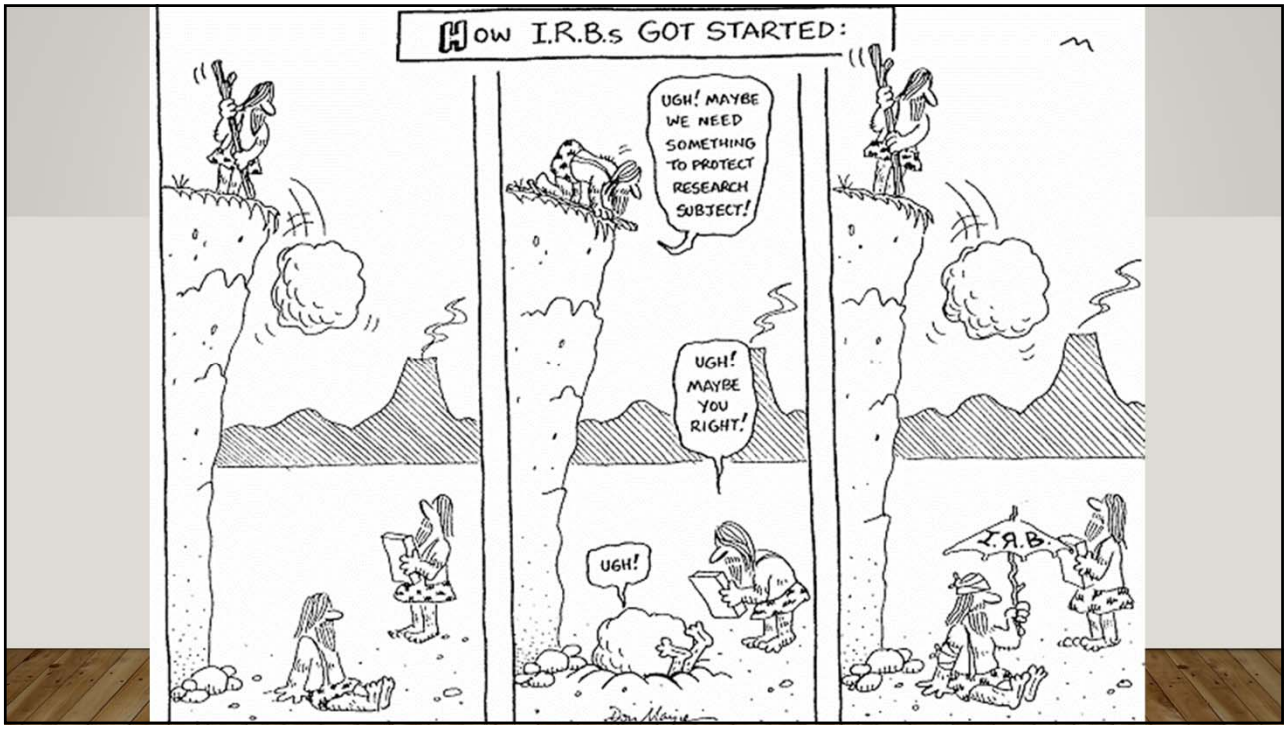
- If the IRB approves a study, institutional officials can overrule IRB's decision
- If the IRB disapproves a study, institutional officials cannot overrule IRB
- PI has the right to appeal IRB's decision but IRB has final say

INSTITUTIONAL REVIEW BOARD (IRB)

- The goal of the IRB (aka Human Subjects Committee or Committee for the Protection of Human Subjects Research) process is to protect the rights and welfare of those individuals who contribute to the research process by participating as subjects.
- In protecting the rights of subjects, the IRB also **protects the institution and the researcher** from the potential consequences of an inadequate consent process or the exposure of the subject to a negative risk.
- "The ultimate responsibility for protecting human subjects must be borne by the institutions that perform the research."
  - (Shalala, D. Protecting research subjects - what must be done. New Engl J Med 2000;343:808-10)

HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

How IRBs got started…



HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

- The modern story of human subjects protections began with the *Nuremberg Code* (of 1947), developed for the Nuremberg Military Tribunal as the standard by which to judge the human experimentation conducted by the Germans.
- The Code captures many of what are now taken to be the basic principles governing the ethical conduct of research involving human subjects.
- The first provision of the Code states that "*the* ***voluntary consent*** *of the human subject is absolutely essential.*"
- Freely given consent to participation in research is the ***cornerstone* of ethical experimentation** involving human subjects.

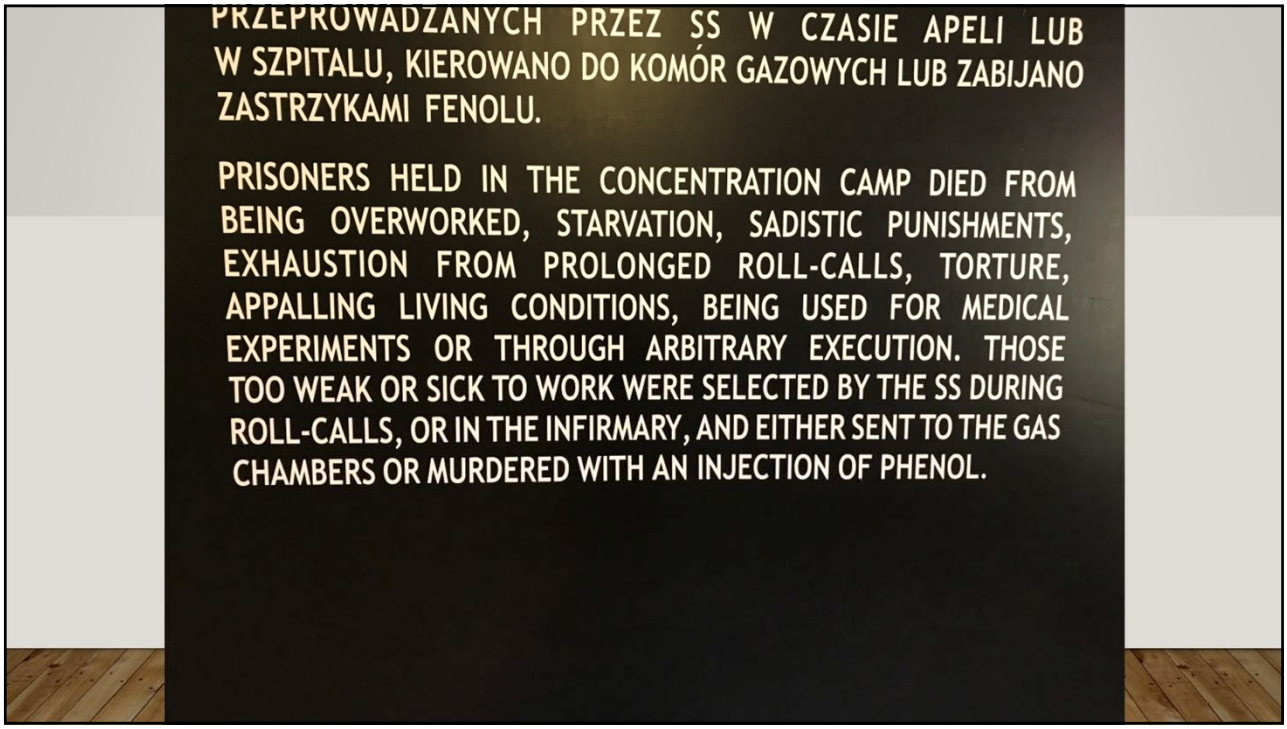

MEMORIUM
NÜRNBERGER PROZESSE
МЕМОРИАЛ
НЮРНБЕРГСКИЕ ПРОЦЕССЫ

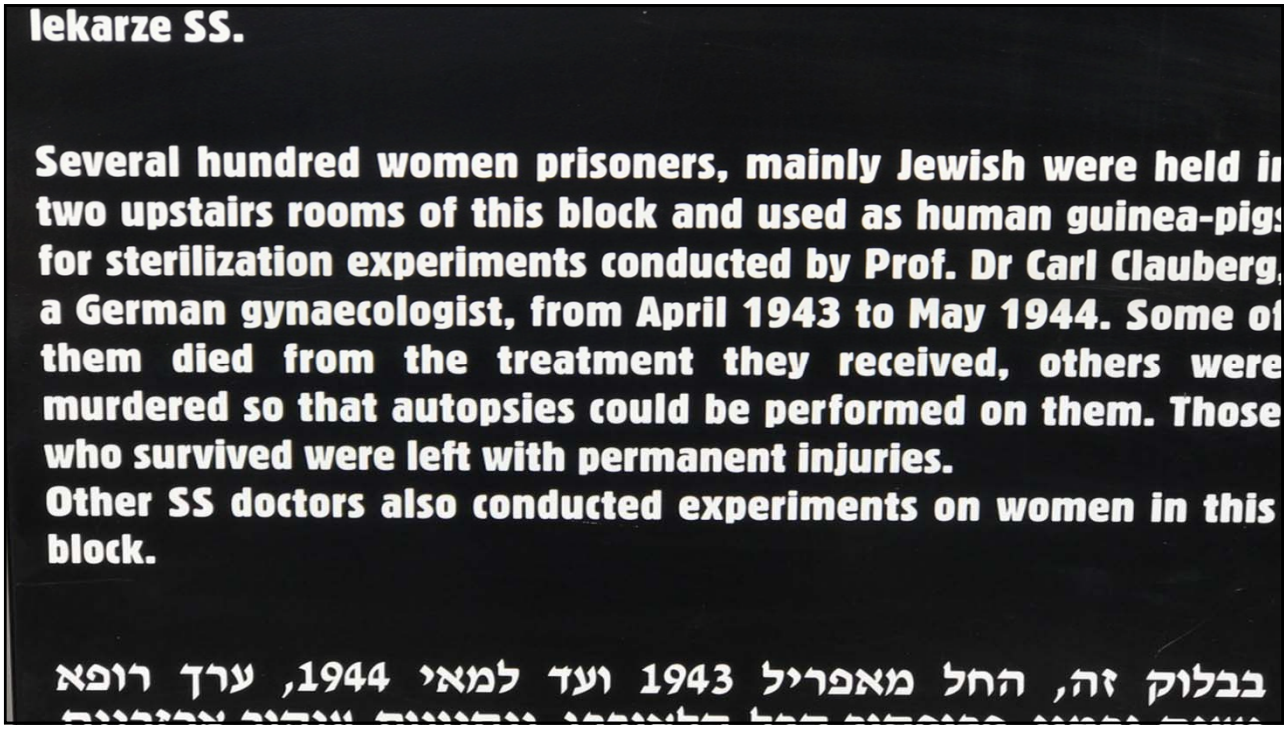

HALT


KL AUSCHWITZ II BIRKENAU 1944 - PRZYBYCIE TRANSPORTU ŻYDOW Z WĘGIE
- ARRIVAL OF JEWS FROM HUNGARY

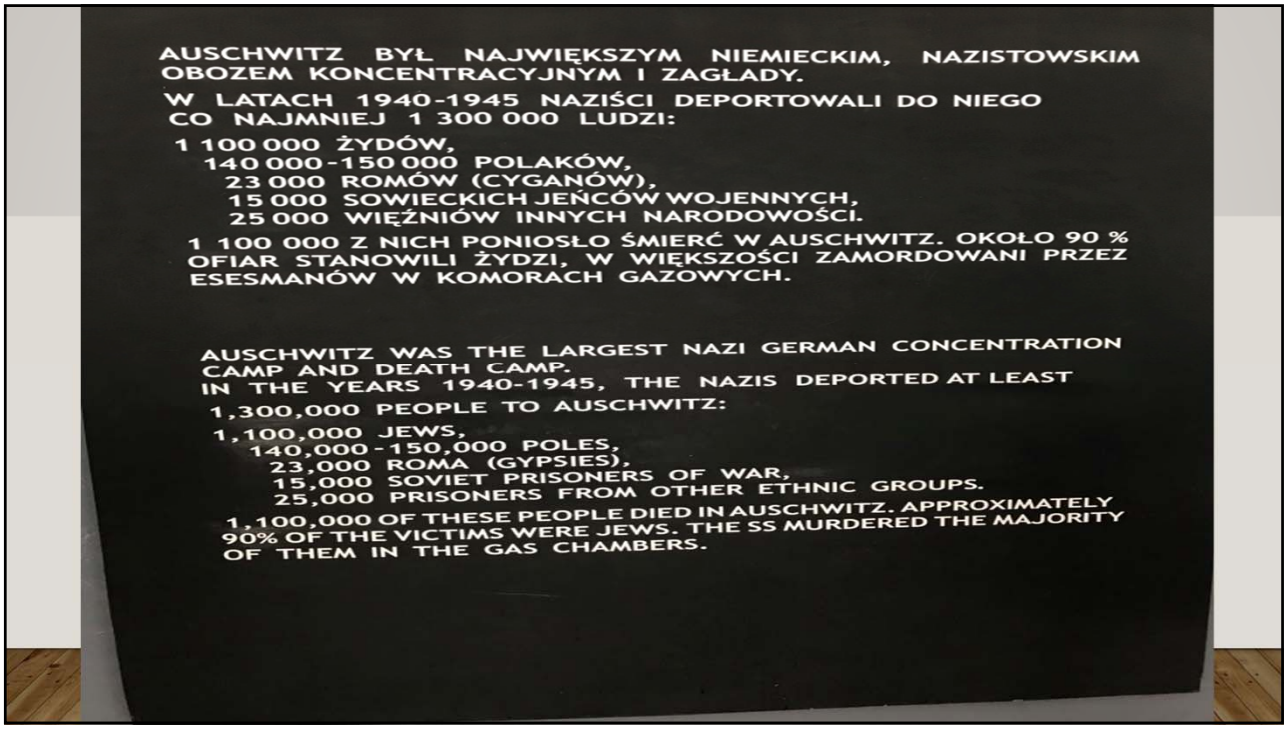

KL AUSCHWITZ II BIRKENAU 1944 - PRZYBYCIE TRANSPORTU ŻYDÓW Z WĘGIER
- ARRIVAL OF JEWS FROM HUNGARY


BIRKENAU 1944 - PRZED SELEKCJĄ
- BEFORE THE SELECTION


PRZEPROWADZANYCH PRZEZ SS W CZASIE APELI LUB W SZPITALU, KIEROWANO DO KOMÓR GAZOWYCH LUB ZABIJANO ZASTRZYKAMI FENOLU.
PRISONERS HELD IN THE CONCENTRATION CAMP DIED FROM BEING OVERWORKED, STARVATION, SADISTIC PUNISHMENTS, EXHAUSTION FROM PROLONGED ROLL-CALLS, TORTURE, APPALLING LIVING CONDITIONS, BEING USED FOR MEDICAL EXPERIMENTS OR THROUGH ARBITRARY EXECUTION. THOSE TOO WEAK OR SICK TO WORK WERE SELECTED BY THE SS DURING ROLL-CALLS, OR IN THE INFIRMARY, AND EITHER SENT TO THE GAS CHAMBERS OR MURDERED WITH AN INJECTION OF PHENOL.


lekarze SS.
Several hundred women prisoners, mainly Jewish were held i
two upstairs rooms of this block and used as human guinea-pig
for sterilization experiments conducted by Prof. Dr Carl Clauberg,
a German gynaecologist, from April 1943 to May 1944. Some o
them died from the treatment they received, others were
murdered so that autopsies could be performed on them. Those
who survived were left with permanent injuries.
Other SS doctors also conducted experiments on women in this
block.
בבלוק זה, החל מאפריל 1943 ועד למאי 1944, ערך רופא


POLKA - 31 LAT, W KL AUSCHWITZ OD MAJA 1943 R. PRZED OSADZENIEM W OBOZIE WAŻYŁA OK. 75 KG, PRZY 160 CM WZROSTU.
W MOMENCIE WYKONANIA FOTOGRAFII WAŻYŁA 25 KG.
A 31-YEAR-OLD POLISH WOMAN, IMPRISONED IN K. AUSCHWITZ IN MAY 1943. BEFORE SHE WAS SENT TO THE CAMP SHE WEIGHED APPROXIMATELY 75KG AND WAS 160CM TALL. AT THE TIME THIS PHOTOGRAPH WAS TAKEN, SHE WEIGHED 25KG.
PHOTOGRAPHS OF WOMEN TAKEN IN MAY 1945 SHOW LIBERATED PRISONER
INTENSIVE FOUR-MONTH -LONG MEDICAL CARE. THE PHOTOGRAPHS OF C
WERE TAKEN IMMEDIATELY AFTER THE LIBERATION.


AUSCHWITZ BYŁ NAJWIĘKSZYM NIEMIECKIM, NAZISTOWSKIM OBOZEM KONCENTRACYJNYM I ZAGŁADY.
W LATACH 1940-1945 NAZIŚCI DEPORTOWALI DO NIEGO CO NAJMNIEJ 1 300 000 LUDZI:
1 100 000 ŻYDÓW,
140 000-150 000 POLAKÓW,
23 000 ROMÓW (CYGANÓW),
15 000 SOWIECKICH JEŃCÓW WOJENNYCH,
25 000 WIĘŹNIÓW INNYCH NARODOWOŚCI.
1 100 000 Z NICH PONIOSŁO ŚMIERĆ W AUSCHWITZ. OKOŁO 90 % OFIAR STANOWILI ŻYDZI, W WIĘKSZOŚCI ZAMORDOWANI PRZEZ ESESMANÓW W KOMORACH GAZOWYCH.
AUSCHWITZ WAS THE LARGEST NAZI GERMAN CONCENTRATION CAMP AND DEATH CAMP.
IN THE YEARS 1940-1945, THE NAZIS DEPORTED AT LEAST
1,300,000 PEOPLE TO AUSCHWITZ:
1,100,000 JEWS,
140,000-150,000 POLES,
23,000 ROMA (GYPSIES),
15,000 SOVIET PRISONERS OF WAR,
25,000 PRISONERS FROM OTHER ETHNIC GROUPS.
1,100,000 OF THESE PEOPLE DIED IN AUSCHWITZ. APPROXIMATELY 90% OF THE VICTIMS WERE JEWS. THE SS MURDERED THE MAJORITY OF THEM IN THE GAS CHAMBERS.

NUREMBERG CODE (OF 1947)

- The Code provides details implied by such a requirement:
  - capacity to consent;
  - freedom from coercion;
  - and comprehension of the risks and benefits involved.
- Other provisions require:
  - the minimization of risk and harm;
  - a favorable risk / benefit ratio;
  - qualified investigators using appropriate research designs;
  - and freedom for the subject to withdraw at any time.

HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

- Similar recommendations were made by the **World Medical Association in its *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*** – first adopted in 1964.
- In the U.S., regulations protecting human subjects first became effective in 1974. The regulations established the IRB as one mechanism through which human subjects would be protected.

HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

- The **National Research Act**, passed in 1974, led to the issuance of reports and recommendations identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and recommending guidelines to ensure that research is conducted in accordance with those principles – known as ***The Belmont Report*** *(submitted in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research – the commission established by the National Research Act)*.

HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

- **The Belmont Report** set forth the basic ethical principles of respect for persons, beneficence, and justice – *the quintessential requirements for the ethical conduct of research involving human subjects.*
- **Respect for persons** involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. This principle underlies the need to obtain *informed consent*.

HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

- **Beneficence** entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle underlies the need to engage in a risk / benefit analysis and to *minimize risks*.
- **Justice** requires that the benefits and burdens of research be distributed fairly. This principle requires that subjects be *fairly selected*.

HISTORICAL CONSEQUENCES OF NOT HAVING IRB OVERSIGHT

- **Tuskegee Study** of untreated syphilis in African American men, 1932-1972
- **Walter E. Fernald State School**, 1946-1953
- **Thalidomide**, 1957-1961
- **Jewish Chronic Disease Hospital**, 1963
- **Willowbrook Hepatitis Study**, 1963-1966
- **Holmesburg Prison**, 1964-1968
- **Stanford Prison Experiment**, 1971
- **Johns Hopkins Study of Lead Paint Hazards**, 1990s – 2001 (after IRBs were estab.)

DEFINITIONS

Research - means a systematic investigation, including research development, testing, and evaluation designed to develop or contribute to generalizable knowledge.

DEFINITIONS

Human Subject - means a living individual about whom an investigator (whether professional or student) conducting research:

- Obtains **information or biospecimens** (data) through intervention or interaction with the individual, **and uses, studies, or analyzes the information or biospecimens;** or
- Obtains, **uses, studies, analyzes, or generates** identifiable private information **or identifiable biospecimens**.

*Bold print within the definition indicates a Common Rule Revision

DEFINITIONS

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

THE IRB PROCESS

- The purpose of the IRB is to review research and determine if the rights and welfare of human subjects involved in research are adequately protected.
- It has the authority to approve, require modification, or disapprove all human subjects research activities.
- Research approved by the IRB may be subject to review/ approval or disapproval by officials of the institution.

THE IRB PROCESS

- Office for Human Research Protections (OHRP), overseen by the U.S. Department of Health and Human Services (DHHS), oversees all IRB functions at academic institutions and performs periodic audits of these institutions and the IRB applications approved.
- **OHRP can halt ALL HUMAN SUBJECT RESEARCH at an institution found not to be in compliance.**

THE IRB PROCESS

- The type of IRB review that is required typically depends on the level of risk presented by the study.
- The primary focus of IRBs is on the safety and well-being of research participants.
- The IRB office is a valuable resource in determining whether a research project requires a **full** or **expedited review** or whether the project may be **exempt** from review.

TYPES OF HUMAN SUBJECT REVIEWS

- IRB reviews are qualified as one of three types: **full, expedited, or exempt**.
- The level of review is determined by the risk to subjects
- The IRB office staff, in consultation with the Chair or other Board members, determines whether or not a study is greater than minimal risk
- **Full IRB Reviews**:
  - Studies that are greater than minimal risk: Examples: **new drug or new device trials**, **vulnerable populations (children*, prisoners, pregnant women*)**.

* May qualify for expedited review depending on the research

TYPES OF HUMAN SUBJECT REVIEWS

Full Board Review

- Reviewed at a convened meeting
  - Monthly on the third Tuesday, submission deadline is the 1st working day of the month
- 1 – 3 primary reviewers who present the project to the Board for discussion and make recommendations on revisions/approval
- All Board members have access to the entire submission and can ask for clarification, make motions or request revisions.

TYPES OF IRB REVIEW

Expedited Review

- Minimal risk to subjects
- 7 Pre-defined categories for initial research – may choose more than one category
- Continuing Review every year*
- IRB submission deadlines do not apply
- Reviewed by IRB Chair or by one or more experienced reviewers designated by the Chair from among the members of the IRB

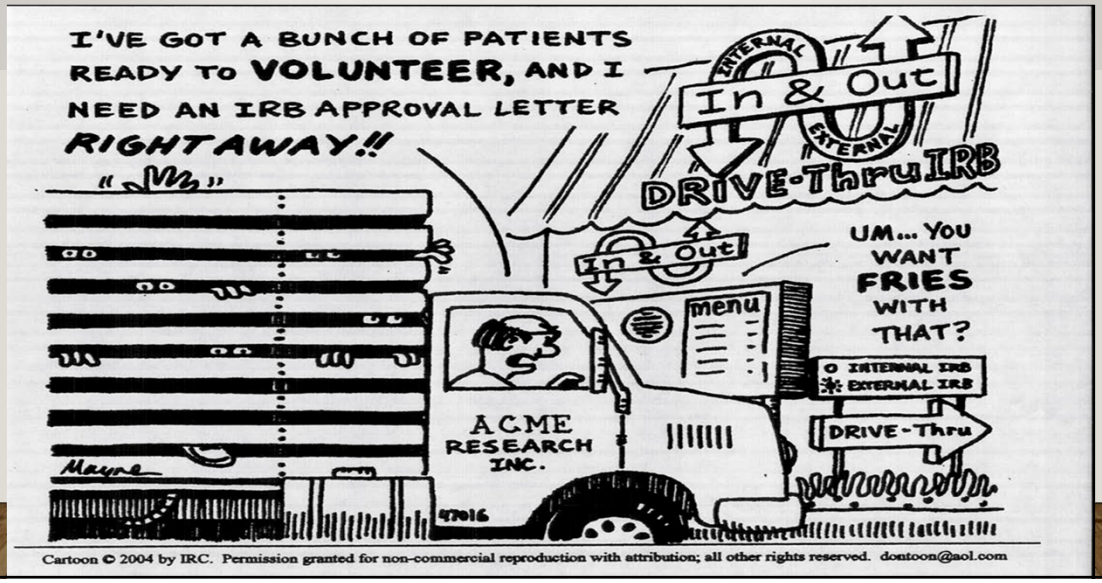
*Changing with Revised Common Rule 1/19/2019

TYPES OF IRB REVIEW

Expedited Review (continued)

- The reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by the full Board.
- Each IRB that uses an expedited review procedure must notify members of research proposals that have been approved by expedited review.

EXPEDITED REVIEWS – NOT…



EXPEDITED REVIEWS

- Expedited review does not mean "fast". It means that the study **qualifies as minimal risk** and **does not need the approval of the entire review board**.

  The most commonly used exempt category at GSM/UTMC is

  - **Category 5:** Research involving data, documents, records or specimens that have been collected or will be collected solely for **non-research** purposes (e.g., medical/school record reviews, discarded tissue from surgical/pathology procedure, registry studies)

EXPEDITED REVIEWS

- **Category 4:** Collection of data through noninvasive procedures routinely employed in the clinical practice, excluding procedures involving x-rays (e.g., sensors attached to the skin, body composition assessment, moderate exercise).
- **Category 7:** Research on individual or group characteristics and behavior or research using surveys, interviews, focus groups, program evaluations, and quality assurance methodologies (see additional handouts on QI projects and program evaluations).

REVIEWS RECEIVING EXEMPT STATUS

- Research involving prisoners does not qualify for exemption, nor can a project be exempt if the funding agency prohibits this.
- **Category 1:** Research conducted in an established or commonly accepted educational setting, involving normal education practices such as instructional strategies, research on effectiveness, or comparison among instructional techniques, curricula or classroom management.

REVIEWS RECEIVING EXEMPT STATUS

- **Category 2:** Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior as long as the information obtained is recorded such that the human subject cannot be identified directly or through identifiers linked to the subjects.
  - However, if there's a possibility that any disclosure of human subjects' responses outside of the research could reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation, the study will not qualify for an exemption.

REVIEWS RECEIVING EXEMPT STATUS

- **Category 4:** Research that involves only the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens. **Existing means** existing before the research is proposed or initiated; existing at the time of request.
  - The data, documents, records, etc., to be used must be publicly available OR recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

REVIEWS RECEIVING EXEMPT STATUS

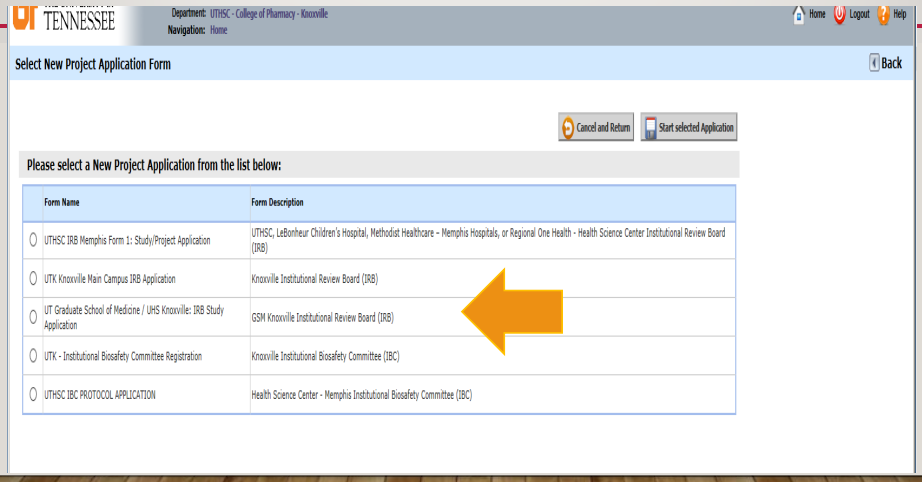
- Exemption from regulations does not necessarily mean that there is no IRB oversight. Many institutions (including GSM) do not allow investigators to determine exempt status themselves. (Though this is not forbidden by federal regulations, OHRP guidelines suggests that someone other than the investigator make the determination.)
- Because journals are increasingly requiring evidence of IRB review, it would be wise to consult with the IRB about exempt status, even if the project does not require formal review.

COMMON PITFALLS THAT DELAY APPROVAL

Before it reaches the IRB:

- Choosing the wrong IRB
  - This gives you the wrong application!

COMMON PITFALLS THAT DELAY APPROVAL

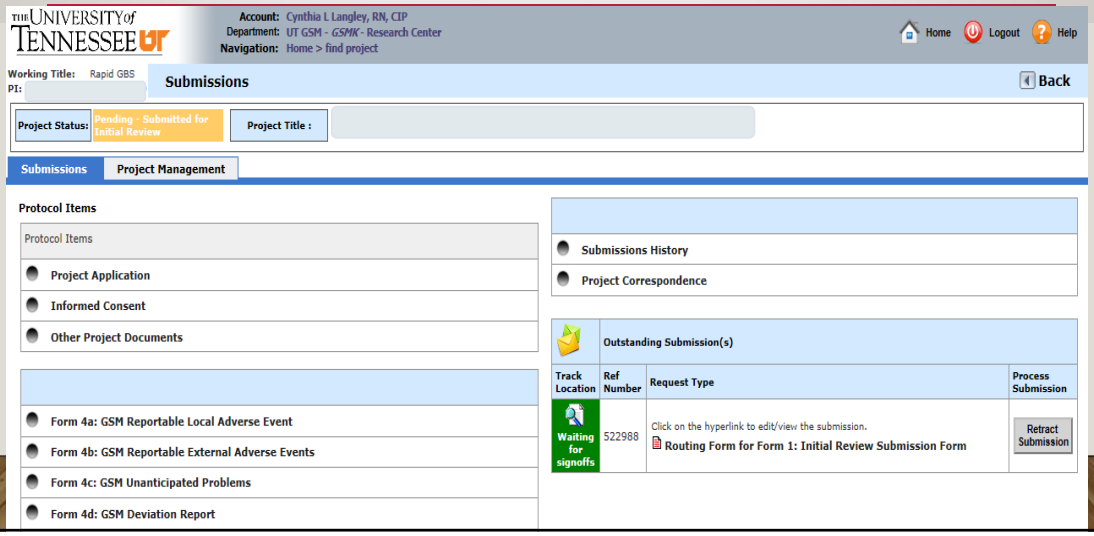


COMMON PITFALLS THAT DELAY APPROVAL

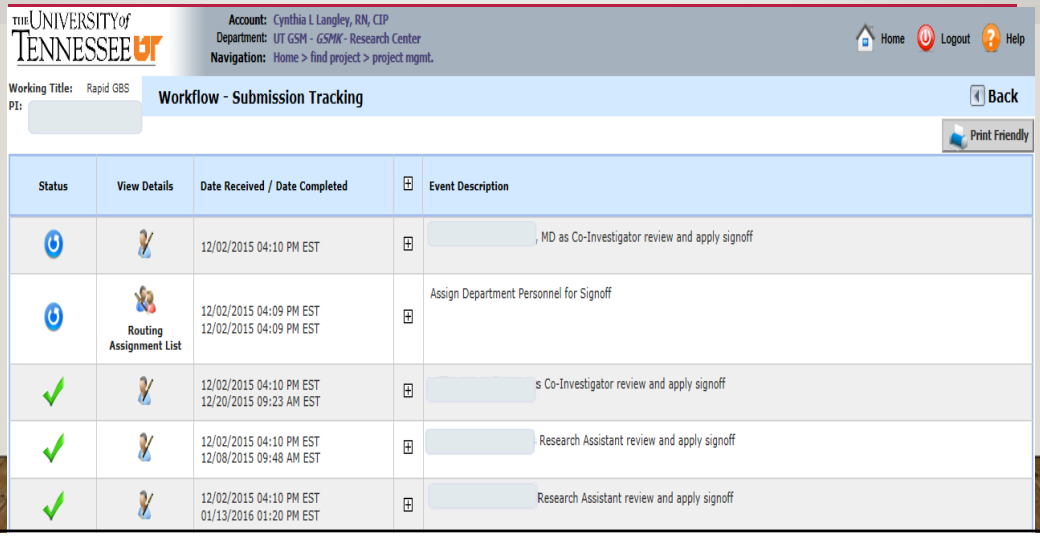
Before it reaches the IRB:

- Failure to submit the application after you finish it.
  - If you have any doubt, CALL US!
- Failure to follow-up on the submission: until everyone signs off, the IRB doesn't know about your submission.

COMMON PITFALLS THAT DELAY APPROVAL



COMMON PITFALLS THAT DELAY APPROVAL



COMMON PITFALLS THAT DELAY APPROVAL

When the IRB receives your submission, it undergoes a pre-review by the IRB staff.

We look for:

- Sign off by all members of the study team and the PI's Dept. Chair
- Current GSM or UTK CITI training for all Key Study Personnel (iMedRIS notifies you)
- A complete application: no obvious incorrect answers (such as the wrong review type, wrong exempt or expedited category, answering "No" to Use of PHI when submitting a retrospective chart review, etc.)
- Required attachments (consents, surveys, etc.) to insure they are attached

COMMON PITFALLS THAT DELAY APPROVAL

After pre-review, we may send it back for:

- Failure to route for signatures

  All members of the study team AND the Department Chair of the Principal Investigator must sign the initial application

- Incomplete information
  - Not listing a Faculty Advisor or Department Chair
  - Missing information about who will obtain consent (if applicable)
  - "Answers" that don't answer the question

COMMON PITFALLS THAT DELAY APPROVAL

After pre-review, we send it back for: (continued)

- Inconsistent information
  - The number of subjects in the consent, protocol and application don't match
  - The Inclusion/Exclusion criteria in the protocol and application don't match
- Consents that are missing required elements
- Consents or other documents intended for the research subjects that are not lay-reader friendly.
  - The goal for research consents is 7th grade reading level or below.

RESOURCES

The GSM IRB Website: **http://gsm.utmck.edu/irb/** contains:

- Forms (Case Report, QI, NHS, Collaboration Forms, etc.)
- Fee and Meeting schedules
- The link to iMedRIS https://ris01.uthsc.edu/
- IRB Standard Operating Procedures
- General Information

RESOURCES

The IRB Staff – Call us! x9781 or x6892

The OHRP Human Subject Regulations Decision Charts:
https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html

INFORMED CONSENT

- **Informed consent** requires documentation ensuring that research subjects have voluntarily accepted to participate in the research and have been properly informed of each step in the research process.
- **Informed consent** should include: an invitation to participate in the research study; the purpose of the research; the selection criteria; the research procedures; the description of the benefits and risks; an alternative treatment if an experimental procedure is offered; the possibility to have questions answered by the study team; and an assurance of confidentiality.

INFORMED CONSENT

- **Informed consent** ensures the privacy (and sometimes the anonymity) of research subjects.
- Issues of **informed consent** are particularly important for vulnerable populations (e.g., the disabled, inmates, those with cognitive impairments or mental illness, children, pregnant women, and the elderly) where comprehending information and making voluntary choices isn't always possible.

INFORMED CONSENT

- Under federal guidelines, there are 2 circumstances in which informed consent is **not** required:
  - when the research is **exempt** from the regulations;
  - and when the research meets the requirements for waiver of consent:

INFORMED CONSENT

Requirements for waiver and alteration. In order for an IRB to waive or alter consent, the IRB must **find and document** that:

- (i) The research involves no more than minimal risk to the subjects;
- (ii) The research could not practicably be carried out without the requested waiver or alteration;
- (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format (Revised Common Rule);
- (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

*CFR 45**§46.116**(f)(3)

INFORMED CONSENT

- A retrospective chart /record review that collects any of the18 **Health Insurance Portability and Accountability Act (HIPAA) identifiers does not qualify as exempt.**
- Research that poses minimal risk but does not qualify as exempt may be eligible for review under the expedited process and may qualify for a waiver of consent and a waiver of HIPAA Authorization.

HIPAA - THE FOLLOWING 18 IDENTIFIERS ARE CONSIDERED **PROTECTED HEALTH INFORMATION**

- Names
- Geographic subdivisions smaller than a state (addresses, zip codes, etc.)
- Telephone numbers
- Fax numbers
- Email addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers (including license plate numbers)
- Device identifiers and serial numbers
- Web URLs
- Internet protocol (IP) address numbers
- Biometric identifiers (finger and voice prints)
- Full face photographic images
- Any other unique identifying number, characteristic or code

INCENTIVES FOR PARTICIPATION

INCENTIVES FOR PARTICIPATION

- With many research projects, study subjects are 'paid' for participating in research.
- Gone are the days when internal incentives – i.e., 'wanting to help', were sufficient to recruit subjects.
- Some incentives are monetary.
- Sometimes, other 'rewards' are offered in lieu of money (e.g., free medical care, free medications, gift certificates to local stores, movie tickets, raffle 'tickets' – a chance to win a bigger prize, offers to donate money to a local charity, etc.)

INCENTIVES FOR PARTICIPATION

- Regardless of the external incentive, IRBs must consider whether 'paid' participants in research are recruited fairly, informed adequately, and reimbursed appropriately.
- Taking into consideration the subjects' medical, employment, and educational status, as well as their financial, emotional, and community resources, the IRB must determine whether incentives for participation in research constitute ***undue inducements* or *coercion***.
- Federal regulations governing research with human subjects contain no specific guidance for IRB review of payment practices

INCENTIVES FOR PARTICIPATION

- One of the primary responsibilities of the IRB is to ensure that a subject's decision to participate in research is **truly *voluntary***.
- Clear cases of coercion may seem obvious, but 'undue inducement' is sometimes more difficult to recognize.
- Undue inducements may be problematic because:
  - Offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment;
  - and they may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling – or continuing – as participants in the research project

THE IRB CITI PROCESS

- The Collaborative Institutional Training Initiative (CITI) program is the vehicle for ensuring comprehensive education in bioethics and human subjects protection.
- The CITI program is a 13-module program created by 'IRB experts' (experienced researchers and IRB personnel) and is used by many academic health centers across the country. Certification via the CITI exam can be transferred to another academic institution.
- The complete set of modules may take up to 4 hours to complete, but they *do not* have to be completed at one sitting. Recertification is required every three (3) years.

IS IRB OVERSIGHT REQUIRED?

- In order for a project to require IRB review, it must involve human subjects and qualify as research.
- A ***Human Subject*** is defined as "A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information." (45 CFR 46, subpart A, section 46.102)

IS IRB OVERSIGHT REQUIRED?

- *Research* is defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (45 CFR 46, subpart A, section 46.102)
- **NOTE**: Intent to publish, by itself, is *not* a reason to go to the IRB for review/oversight. It must be human subjects research (HSR) at the start of the study

IS IRB OVERSIGHT REQUIRED?

- IRB Rules – Guided Project Analysis
  https://redcap.wright.edu/surveys/index.php?s=EEAC49MY4D
- https://is.gd/GuidedProjectAnalysis_IRBRules
- Designed to help analyze research projects according to the Human Research Subjects Protections regulations that Institutional Review Boards must follow.

IS IRB OVERSIGHT REQUIRED?

- The IRB asks: is it HSR?
  - If yes, does it meet any of the exemption categories?
    - If no, does it meet any of the expedited review categories?
      - If no, requires full Committee review

IS IRB OVERSIGHT REQUIRED?

- Quality Improvement Activities FAQs: http://answers.hhs.gov/ohrp/categories/1569
  - What is the purpose of the activity? Is it research?
  - Are you using QI data to answer a research question?
  - Remember: Intent to publish isn't, by itself, a rationale for IRB review – it must be human subjects research at the start of the study.
- How to Distinguish Research from Quality Improvement.
  - J of Empirical Research on Human Research Ethics 2015; 19(2):209-201

IS IRB OVERSIGHT REQUIRED?

- Program Evaluations:
  - http://oregonstate.edu/research/irb/does-evaluationrequire-irb-review
  - When does evaluation require IRB review?
  - https://compliance.vpr.okstate.edu/IRB/documents/IRB_toolbox/Program_Evaluation.pdf
  - Program Evaluation: When is it Research?

NEW TOOL TO HELP DETERMINATION

- Based on current OHRP Human Subjects Decision Charts.
- Provides a user-friendly evaluation of an investigator's specific project according to Decision Charts. Requirements may change as OHRP provides new information for the **New Common Rule**.
- Helps investigators determine whether their project meets the definition for 'Research' – informs you on whether IRB review is likely required.
- If 'Research', determines whether the project likely meets criteria for Exempt status or qualifies for Expedited Review.
- Includes information on requirements for vulnerable populations and for waiver/alteration of consent.

NEW COMMON RULE

- Changes to the Federal Code of Regulations for the Protection of Human Subjects
- Original roll-out: January 19, 2018 (did not happen)
- New roll-out: July 19, 2018 (still did not happen)
- Potential (probable) new roll-out: January 21, 2019
- Some changes are specific to research that is FDA-regulated or funded/supported by the Department of Justice.

NEW COMMON RULE

- Changes to the Federal Code of Regulations for the Protection of Human Subjects
- Examples of some upcoming changes:
  - New definition of 'human subjects'
  - New consent template (the GSM Template has already been updated to include this)
    - Provides information a reasonable person would want to know, creating opportunity to discuss
    - Begins with concise and focused presentation of key information most likely to aid in understanding why someone might or might not want to participate
  - Indicates whether clinically relevant research results - including at the individual level - will be disclosed, and if so, under what conditions

NEW COMMON RULE

- Additional exemption categories that do not require Continuing Review
  - Uses of secondary data and biospecimens that are already subject to HIPAA
  - Research involving benign behavioral interventions with adults
  - Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior, even if identifiers are recorded and disclosure may pose a confidentiality risk to research participants

NEW COMMON RULE CHANGES (CONTINUED)

- New periodicity for some expedited research
- Automatic Certificate of Confidentiality (for NIH funded studies with identifiable sensitive information)
- Public posting of clinical trial consent forms (for studies conducted/supported by federal agencies)
- Changes to criteria for waiver of informed consent

SELECTED BIBLIOGRAPHY AND RESOURCES

- DHHS.gov web site: http://ohrp.osophs.dhhs.gov/irb/irb_introduction.htm. NOTE: This website has an abundance of historical information about conducting research using human subjects, plus dozens of useful and interesting references and links to other pertinent information.
- Aita M, Richer MC. Essentials of Research Ethics for Healthcare Professionals. Nursing and Health Sciences 7:119-125, 2005.
- Grady C. Payment of Clinical Research Subjects. The Journal of Clinical Investigation 115(7):16811687, 2005.
- Grant RW, Sugarman J. Ethics in Human Subjects Research: Do Incentives Matter? Journal of Medicine and Philosophy 29(6):717-738, 2004.
- Wolf LE, Walden JF, Lo B. Human Subjects Issues and IRB Review in Practice-Based Research. Annals of Family Medicine 3(Supp 1):S30-37, 2005.