

Simplifying Research: Observations and Advice from a Chaplain Who Chairs an IRB

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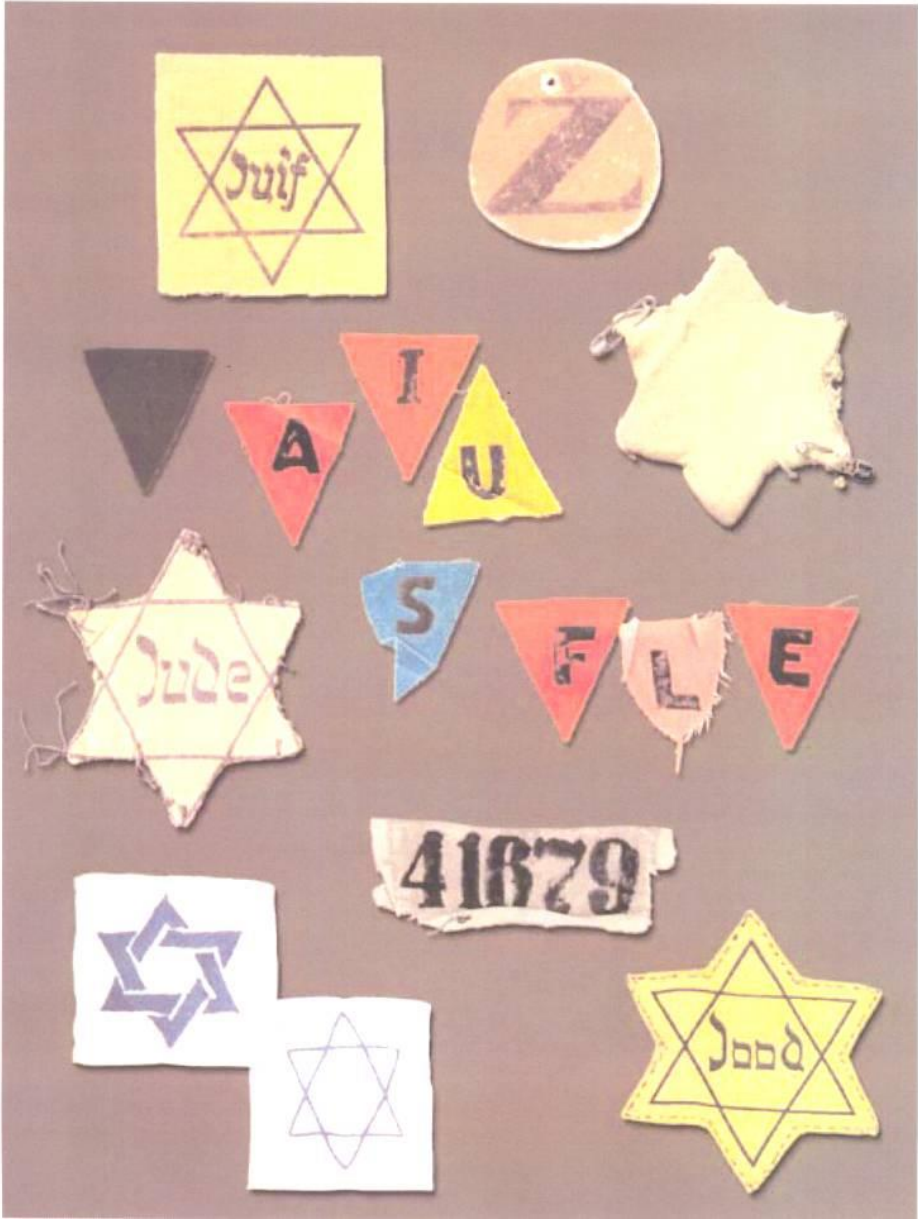
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Objectives

- Participants will review the history of human subjects research and the mandated establishment of Institutional Review Boards.
- Participants will understand the basic inner-workings of an Institutional Review Board.
- Participants will strategize how to overcome some of the basic barriers to research that many chaplains face.







1.5 Million Children Died in the
Holocaust (Shoa)

Nazi Experiments

- Experimental group injected with vaccine for typhus while control group injected with typhus-infected blood
- Bones transplanted from one prisoner to another to evaluate regeneration of nerve, muscle and bone
- Prisoner shot in order to study ballistics
- Prisoners starved to study physiology
- Prisoners submerged in tubs of freeze water till death to evaluate how long a downed pilot could survive
- Prisoners were put in to pressure chambers and subjected to lethal extremes of atmospheric pressure

Nuremberg Trials

- 23 Nazi physicians and bureaucrats placed on trial
- 16 convicted of war crimes
- 7 sentenced to death

Research in the United States

- Many thought we did not need any externally imposed ethics codes.
- Hence there were many harmed individuals as a result of research.

Human Radiation Experiments 1944-1974

- 74 male residents of Fernald School belonging to “Science Club”
 - Fernald was a residential institution for mentally retarded
 - Fed radioactive iron and calcium in cereal
 - Parental Permission
 - *“We are considering the selection of a group of our brighter patients . . .to receive a special diet rich in the above mentioned substances for a period of time . . .”*
 - Special diet did not mention radio isotopes or risks
 - Final Report
 - *“in some non-therapeutic tracer studies involving children, radioisotope exposures were associated with increases in potential lifetime risk of developing cancer that would be considered unacceptable today.”*

Willowbrook Studies

- Dr. Saul Krugman, 1950-1960
- Willowbrook—institution for mentally retarded children
- Wanted to study natural history of hepatitis
- Infected new arrivals with virus
- Established a special unit
 - Less crowded, better nutrition, cleaner
- Long waiting list except if parents enrolled
- Did not enroll wards of state

Willowbrook (con't.)

- Krugman justified this harm by stating:
- Greater than 90% would eventually become infected
- Thought that induced infection with attenuated strain may protect against severe effects of hepatitis
- Expedited entry represented a benefit to those participating
- His results helped develop a vaccine
- He did create a consent process
 - Parents interview a social worker and attended a group meeting introducing project
 - Encouraged to talk with private physician before consent
 - Could not sign consent for 2 weeks to allow ample time for consideration

Code of Federal Regulations: 45 CFR 46

- Research must be reviewed by IRB
- Only human subjects research requires review by IRB
- “a living individual about whom an investigator conducting research obtains:
 - (1) data through intervention or interaction with the individual
 - (2) identifiable private information”

IRB at Children's Mercy

- One IRB with two “panels.”
- Two co-chairs (ID doc, chaplain).
- Board members are classified as “scientist” or “non-scientist.”
- Members include physicians, surgeons, psychologist, nurses, pharmacist, social workers, IS specialists, and attorneys and clergy from the community.
- Everyone work with an alternate. To maximize our psychosocial presence, my alternate is a child life specialist.

ALL BOARD MEMBERS HAVE A GREAT
INTEREST IN THE PROMOTION OF
RESEARCH!

The IRB is an integral part of our research enterprise!



The IRB is the keeper of the **holy grail**, the gnosis, the eternal flame:

*Research, as defined by federal regulations, is categorized by its **intentions** rather than by its level of risk or its innovation. Research is any activity that has as its goal the creation of **generalizable knowledge**.* The activities that lead to this goal generally involve systematic collection of data and analysis of the data. Something is considered research if there is an **intention** to publish or share publically the results of new information that is being gathered by an investigator. Sharing the data publically is a necessary aspect of making it “generalizable.”

Sharing and Replication

The reason why data should be **shared** is that it allows others to try to **replicate** the study. This is an important component of the scientific method. The science behind research is designed to assure that the conclusions being suggested by an investigator can be repeated and thus that the data are generalizable and, therefore, valid. When results can be repeated they can be studied for their effectiveness, the results of which continue improvement of the quality of care and establishment of “**best practice**.” While the aim of internal quality improvement initiatives also seeks to define best practice, research has a broader and less defined audience.

Broader Definition of Research

- Adding to “generalizable knowledge.”
- INTENT to share information through publication or presentations.
- Systematic collection of data (numbers or narratives).
- Demonstration of validity through replication of research methods.
- Defining best practice.

Research vs. Quality Improvement

- External vs. Internal
- INTENT to publish or share.....vs.....
- INTENT only to improve products or processes
- QI often leads to Research

Activities outside of Human Subjects Research

- Animal research
- Deceased patients
- ***Unidentifiable samples or data***
 - More on this later

IRBs differ from HECs!

Most HECs engage in non-binding mediation.

IRBs have complete, protected authorization to approve, change, disapprove or stop any research protocol.

The chair, singularly, also has these powers!

Caveat investigador!

PRIMARY RESPONSIBILITIES of an IRB

- Review and analyze risk/benefit ratio.
 - Is there equipoise?
- Review scientific merit of protocol.
- Review qualifications of the study team.
- Review necessary resources.
 - Can the research be done?
- Review process of informed consent.
 - Can subjects and families understand the proposed research?
- Will subjects be informed of new information?
- What happens to identifiable data/tissues/blood?

Great focus on RISK AND BENEFIT

- The federal regulations require that the potential risk to research participants must be **identified and minimized**, the prospect of direct benefits to research participants must be maximized, and the potential benefits of participating in the research must compare favorably with the risks of participating in the research.

Research Categories

- With adults:
 - Minimal Risk or Greater than Minimal Risk
- With minors:
 - Category #1: Research not involving greater than minimal risk
 - Category #2: Research involving greater than minimal risk but with prospect of direct benefit to individual participants
 - Category #3: Research involving an increase over minimal risk with no prospect of direct benefit but likely to provide generalizable knowledge of the subject's condition or disorder that is vital to understand or ameliorate it

Research Categories

- Category #4: Research not falling into one of the categories cannot be approved by local IRB (think: research in futile situations with no identified benefit to the subject):
 - The local IRB finds that the research provides a reasonable opportunity to improve the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children
 - The protocol must be approved by the Secretary of Health and Human Services, after soliciting the opinions of an expert panel and providing for a period of public comment

Minimal Risk is Contextual

- Where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of a routine physical or psychological examination or tests
- Xray, blood draw
- When performed solely for research purposes—catheterized urine collection, lumbar punctures, many blood draws, sedation for radiologic procedure is greater than minimal risk
- Question: If both arms of a comparative protocol are minimal risk and both are standard of care, is there need for IRB review?

All elements of risk and possible or lack of benefit to the subject must be discussed.

Case: Jessie Gelsinger

Other Elements of Informed Consent

- Purpose of research
- Research procedures and how they differ from standard of care
- The risks and anticipated benefits of the research procedures
- Alternative to research participation
- Voluntariness

Informed Consent, Parental Permission and Child Assent should be thought of as a process not an event.

...and who benefits?

The language of consent:

- Subjects (competent adults as individuals) can only give **consent** for themselves.
 - The word “consent” has connotations of understanding in its origins.
- Legally authorized representatives (LARs) or parents give **permission** (not consent) for their charge or child.
 - The word “permission” has connotations of ownership, as to own land and allow some to cross it.
- Minors and incapacitated individuals **assent by agreeing or disagreeing** to the permission others have given.

Assent

- A child's voluntary affirmative agreement to participate in research
- When an IRB requires assent, the child's refusal is binding
- Most children can provide assent to participate in research by the time they reach seven years old.

Two reasons to waive assent

- “the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of children and is **available only** in the context of the research”
- Children below a certain age, in a certain situation or with a certain condition have **limited capacity** to participate in the decision about research participation that they cannot reasonably be consulted.


- Assent should not be equated with consent
- The purpose of assent is not to treat children as if they are capable of making informed, autonomous decisions
- It is to remind us that children should be treated with dignity and respect



Where does the current
research pathway take us?
Six important observations

The image shows five smooth, dark, rounded stones of varying shades of brown and black, resting on a coarse, textured brown surface. The stones are arranged in a loose cluster. The lighting creates soft shadows and highlights the smooth, polished texture of the stones.

I. All patients will be involved in research.




II. All practitioners will be involved
in clinical research!
Publish or perish!
Research or die!
Show me the article!



III. The cost of health care will be increasingly supported through research endeavors.

IV. Hospital ratings will increasingly be based on research initiatives.





V. Research protocols will generate large sums of money...and money talks.



VI. Centralized IRBs will take the place of hospital/university based IRBs.

New Frontiers

- Human Genome Research
 - Creation of DNA Repositories
 - Data Banks
 - **De-identified data**
 - Presumption of consent/permission/assent
 - Community awareness
 - Trademarks, copyrights, patents
 - Profit
 - Pharmaceutical influence



**“TREMENDOUS PRESSURES THREATEN
EXISTENCE OF INSTITUTIONAL REVIEW
BOARDS”**

Systemic barriers to research

- Not part of the culture.
- Lack of mentors.
- No infrastructure for learning about research.
- No designated time.
- Other priorities (productivity, efficiency,
- Too much on one's plate.
- Too much is being demanded from us.



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Cosmic Hesitation



The background is a complex, abstract painting. It features a central figure, possibly a woman, rendered in a light, almost white color, set against a dark blue background. The figure is surrounded by swirling, organic shapes in various colors, including yellow, red, and green. The overall style is expressive and somewhat chaotic, with visible brushstrokes and a rich, textured appearance. The text is overlaid on this artwork, with the word 'allow' highlighted in red.

Our identity as chaplains is
unique precisely because we
allow ourselves to live in
unclear, dialectic tension.

A vibrant, high-angle photograph of a tea plantation. The tea bushes are meticulously arranged in neat, undulating rows that create a rhythmic pattern across the landscape. In the center of the image, a small, traditional pavilion with a conical thatched roof stands on a small platform. The overall scene is bright and verdant, with the green of the tea leaves contrasting against the brown of the thatch.

Notions from Tillich (by which I live)

Freedom and Destiny

Dynamic and Form

Individuation and Participation

Spirituality is the dynamic dimension of human life that relates to the way persons (individual and community) experience, express and/or seek meaning, purpose and transcendence, and the way they connect to the moment, to self, to others, to nature, to the significant and/or the sacred.

Prior research

- “Unlike other health professionals, the chaplain has no agenda to explain, cure, or eliminate disease. The chaplain seeks only to engage the sufferer and to reframe his/her suffering in the context of life’s incongruities. The chaplain serves as witness to their story and attentively and diligently mirrors unconditional love.”

- Puchalski CM, Lunsford B, Harris MH, Miller T. Interdisciplinary Spiritual Care for Seriously Ill and Dying Patients: A Collaborative Model. *The Cancer Journal*, 2006; 12:398-405.



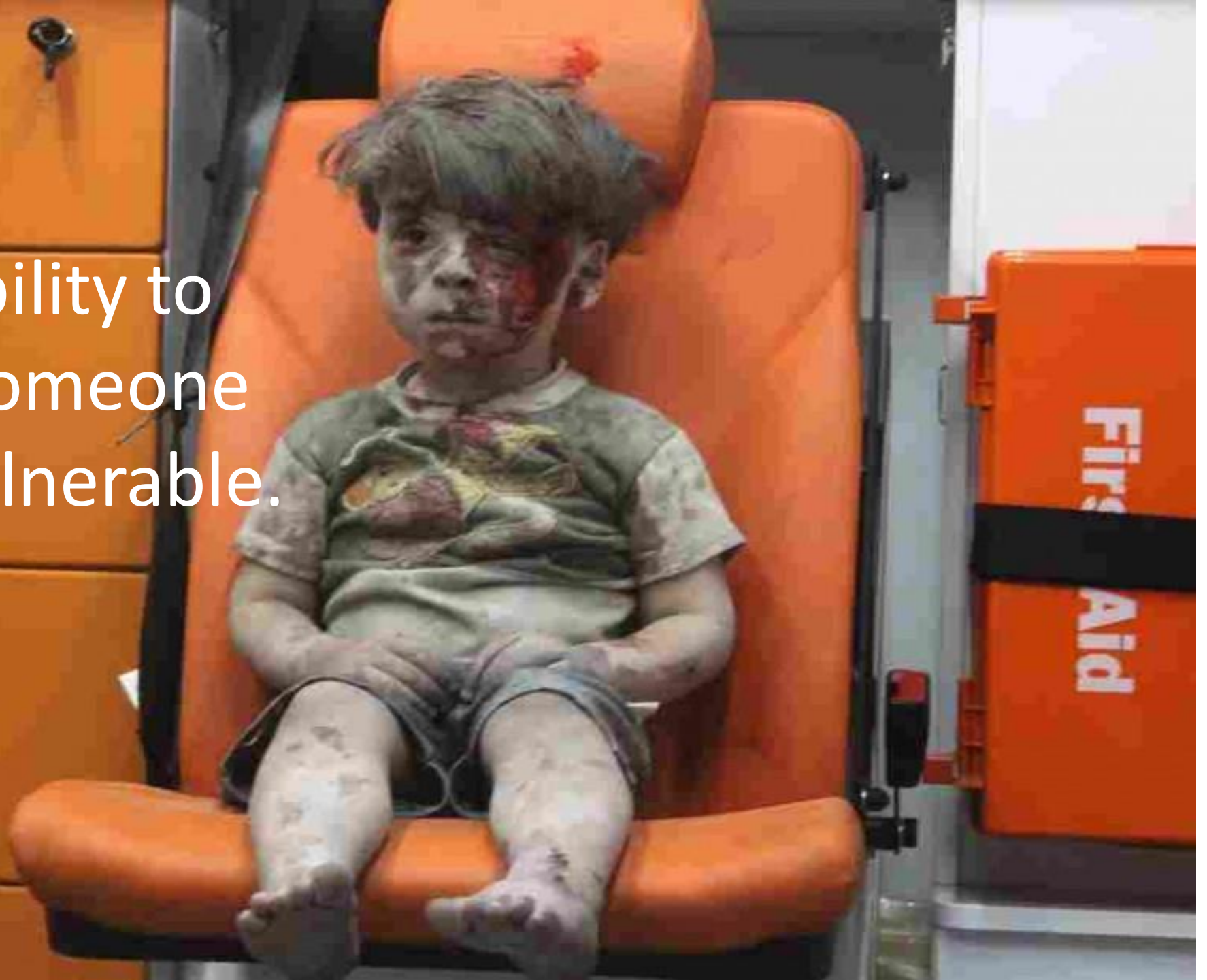
Can we research the
“ground of our being?”

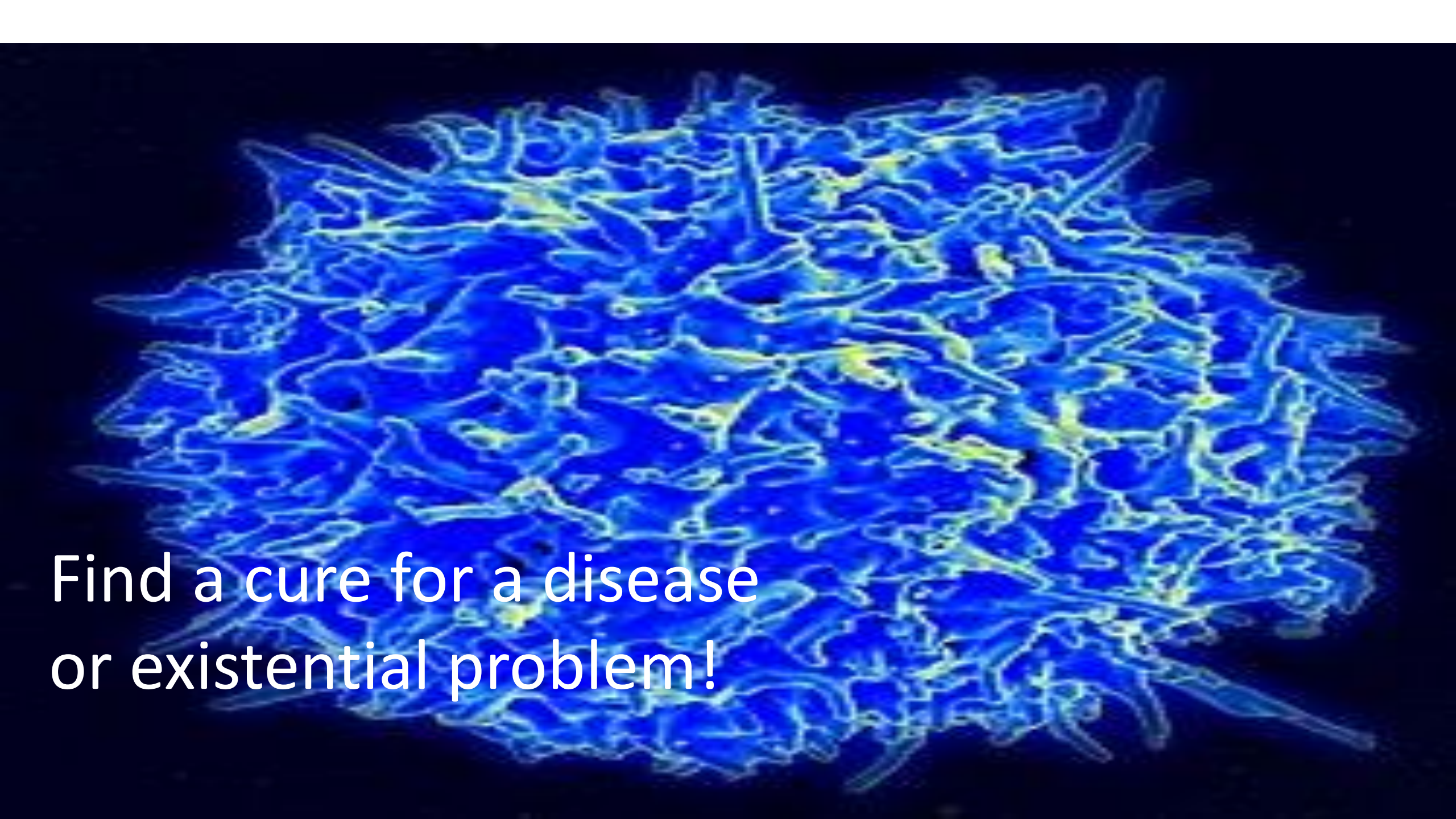
Of course we can!



Of course we can!!!

Claim the
responsibility to
protect someone
who is vulnerable.



A complex, glowing blue and yellow network structure, possibly representing a neural network or a complex system. The structure is composed of numerous interconnected nodes and edges, forming a dense, intricate web. The colors transition from deep blue to bright yellow, suggesting varying levels of activity or intensity within the network. The overall appearance is that of a highly interconnected and dynamic system.

Find a cure for a disease
or existential problem!

Overcoming the barriers

1. Find a research mentor.
2. Connect with an IRB member
 1. IRB members are experts in research!
3. Learn about qualitative or narrative research
 1. Chaplains have many stories to tell.
4. Become “fluent” in research.
5. Start with something that you believe makes a difference.
6. Start with something small.
7. Start slow and taper off.

Overcoming the barriers #2

- Connect with other Psych-social team members.
- Become familiar with APC standards for research.
- Start with your job description and leverage time.
 - (At CM) Chaplain managers have a 5% research requirement.
 - This translates to on day per month to reach, write and talk.
 - Build a workshop/publishing requirement into your work.
- Finally, boldly face the reality that research is our future!

We're all in this together!

Strangers passing in the street
By chance two separate glances meet
And I am you and what I see is me
And do I take you by the hand
And lead you through the land
And help me understand the best I can.