

LOYOLA BIOETHICS

Live!

RESEARCH ETHICS

DURING COVID-19

May 6, 2020



Emily E. Anderson, PhD, MPH

Associate Professor

Neiswanger Institute for Bioethics

Loyola University Chicago Stritch School of Medicine

COVID-19 and SARS- COV-2 Research

- About 200 trials in the U.S.
- Primarily treatment, primarily govt or non-profit sponsors
- >7500 scientific papers

<https://www.wcgclinical.com/covid-19/#dashboard>


NIAID Research Priorities

- Fundamental knowledge
- Diagnostics and Assays
- Treatments
- Vaccines

<https://www.niaid.nih.gov/sites/default/files/NIAID-COVID-19-Strategic-Plan-2020.pdf>

Impact on
Institutions,
Institutional
Review Boards,
and non-COVID
Research

- New FDA and OHRP guidance; varied institutional responses
- Prioritizing patient safety, continuing studies with greatest potential for direct benefit
- Some ongoing studies stopped, new studies postponed
 - Concerns about PPE, staff, supply chain
- Others providing treatment and collecting data while social distancing
- Innovation! and Flexibility!



COVID-19
Research
Narratives

- “Anything is better than nothing. What do we have to lose?”
- In times of crisis, it is reasonable and perhaps even necessary to relax ethical standards.
- Scientists are heroes!

Narrative #1:

What do we
have to lose?
Anything is
better than
nothing!

- “What do you have to lose? I’m not looking at it one way or another. But we want to get out of this. If it does work, it would be a shame if we didn’t do it early. What do I know? I’m not a doctor. But I have common sense. The FDA feels good about it, as you know they approved it.”
 - President Trump, April 5 White House Press Briefing

Narrative #2:

Shouldn't we
relax our usual
standards?
This is an
emergency!

- “Crises are no excuse for lowering scientific standards.”
 - Alex John London and Jonathan Kimmelman,
Science, May 1 2020

[this was actually the entire abstract]

Against Pandemic Research Exceptionalism
<https://science.sciencemag.org/content/368/6490/476.full>

Narrative #3:
Nothing says
“you’re a hero”
like having
Brad Pitt play
you on TV!



Challenges to Informed Consent

- Limited time to make a decision
- Increased uncertainty complicates risk assessment
- Increased risk of therapeutic misconception
- Decreased public acceptance of randomization to placebo
- Confusion re:
 - FDA approved vs.
 - can be prescribed through emergency use authorization vs.
 - what can be prescribed off label vs.
 - what is only available in the context of a trial

What if there are multiple trials at an institution competing for the same patients?

- “meta-randomization”
- Research triage by committee
- Patient choice
- Physician choice
- What if participation in a trial while moderately ill would exclude a patient from participating in a trial if they become severely ill?

When Clinical Trials Compete: Prioritising Study Recruitment, Gelinas et al., BMC Medical Ethics 2016

<https://jme.bmj.com/content/43/12/803.short?rss=>

What limitations of our ethical frameworks, regulatory systems, and research infrastructure have been exposed?

- “...our inability to start and run clinical trials faster — whether in normal times or in a pandemic — is a legacy of our decision not to develop the technologies and approaches that would make doing so easier.”

- Matthew Herper, STATnews, April 22

- <https://www.statnews.com/2020/04/22/people-are-dying-from-coronavirus-because-were-not-fast-enough-at-clinical-research/>

- Without coordination “prioritization is difficult, counterproductive competition is almost inevitable and, unfortunately, exploitation becomes a real risk.”

- Lane, Marston, and Fauci, 2016

- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4767673/>

Is it ethical to expose human volunteers to the virus to accelerate vaccine testing?

FDA to require antibody tes 1 Day Sooner

https://1daysooner.org/

COVID-19 Human Challenge Trials

Human challenge trials deliberately expose participants to infection, in order to study diseases and test vaccines or treatments. They have been used for influenza, malaria, typhoid, dengue fever, and cholera. Researchers are exploring whether human challenge trials could speed up the development of a vaccine for COVID-19, saving thousands or even millions of lives.

I am interested in being exposed to the coronavirus to speed up vaccine development.

[Volunteer For Challenge Trial](#)

Sign up here if you may wish to participate in a human challenge trial for COVID-19 if one were to occur, and, potentially, advocate for safe and rapid vaccine development.

I want to support COVID-19 challenge trials as an advocate (not as a volunteer).

[Support Advocacy Efforts](#)

Sign up here if you may wish to advocate for safe and rapid vaccine development and support coronavirus human challenge trial volunteers, but do not intend to volunteer at this time.

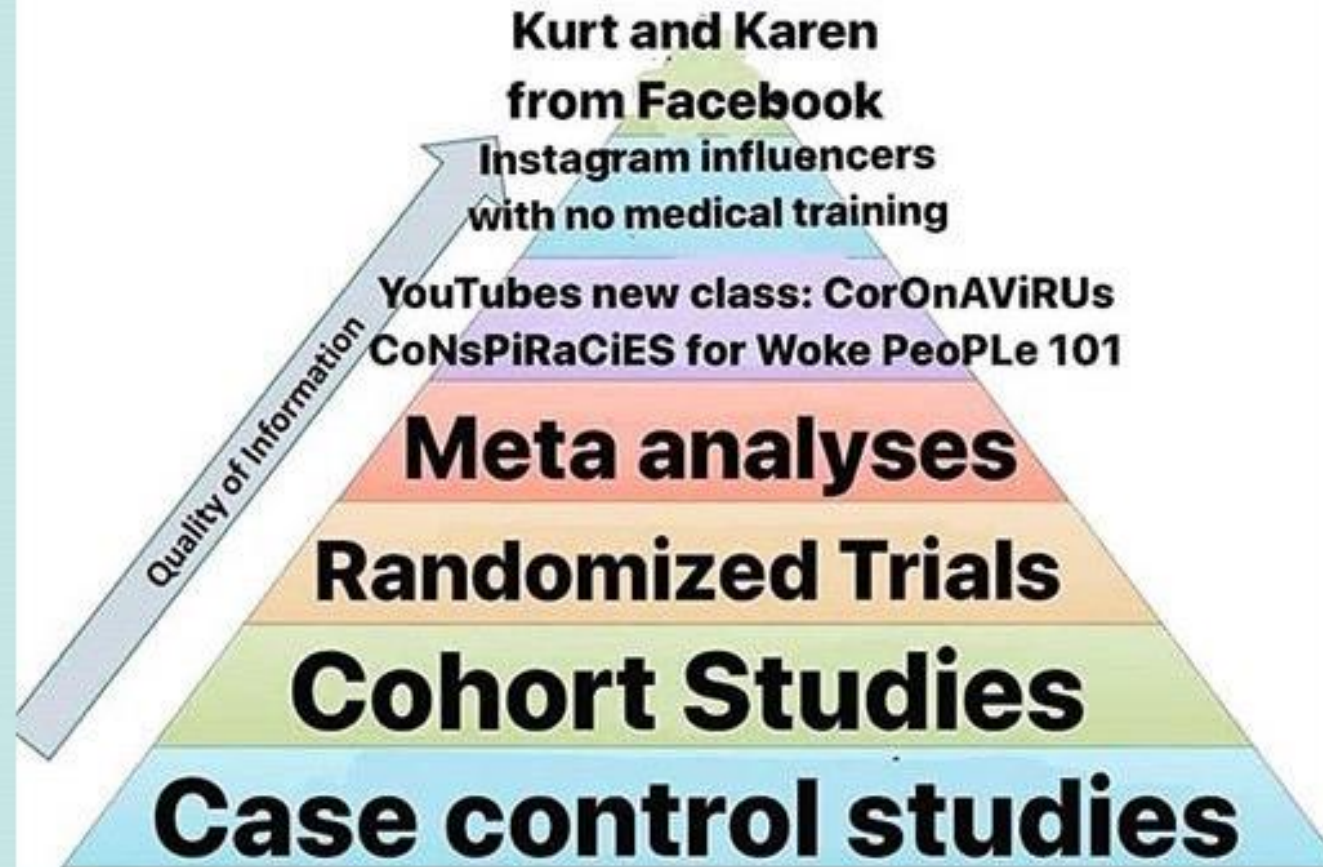
Type here to search

5:38 PM 5/4/2020

Some good news!

- The FDA has been acting fast
- We have a coordinated national strategy - finally
- The urgency of COVID-19 has nudged single IRB and e-consent
- Some have noted a “kinder and more creative” research culture
- The public is learning research vocabulary – and the importance of research

Levels of evidence for COVID-19 data



FDA COVID-19 Response At-A-Glance Summary (updated periodically)

<https://www.fda.gov/media/137005/download>

OHRP Guidance on COVID-19

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/ohrp-guidance-on-covid-19/index.html>

Preserving Clinical Trial Integrity During the Coronavirus Pandemic, McDermott and Newman

<https://jamanetwork.com/journals/jama/fullarticle/2763819>

Clinical Trials vs. Right to Try: Ethical Use of Chloroquine for COVID-19, Robert M. Veatch

<https://www.thehastingscenter.org/clinical-trials-vs-right-to-try-ethical-use-of-chloroquine-for-covid-19/>

New York Clinical Trial Quietly Tests Heartburn Remedy Against Coronavirus

<https://www.sciencemag.org/news/2020/04/new-york-clinical-trial-quietly-tests-heartburn-remedy-against-coronavirus>

Integrating Clinical Research in Epidemic Response: The Ebola Experience

<https://www.nap.edu/catalog/24739/integrating-clinical-research-into-epidemic-response-the-ebola-experience>

A Reminder to Reason, Ivry Zagury and Richard M. Schwartzstein

<https://www.nejm.org/doi/full/10.1056/NEJMp2009405?query=RP>

Why the Coronavirus is so Confusing, Ed Yong

<https://www.theatlantic.com/health/archive/2020/04/pandemic-confusing-uncertainty/610819/>

WHO Ethical Standards for Research During Public Health Emergencies: Distilling Existing Guidance to Support COVID-19 R&D

<https://apps.who.int/iris/bitstream/handle/10665/331507/WHO-RFH-20.1-eng.pdf?sequence=1&isAllowed=y>

People are dying from coronavirus because we're not fast enough at clinical research

<https://www.statnews.com/2020/04/22/people-are-dying-from-coronavirus-because-were-not-fast-enough-at-clinical-research/>