RESEARCH ETHICS
DURING COVID-19
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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

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!
“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?
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
FDA COVID-19 Response At-A-Glance Summary (updated periodically)
https://www.fda.gov/media/137005/download

OHRP Guidance on COVID-19

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

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

Why the Coronavirus is so Confusing, Ed Yong

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

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/