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FACULTY OF MEDICINE

RSCM

Penelitian Kesehatan non Covid-19 di Masa Pandemi: Perlukah Dihentikan?

Rita S. Sitorus

Komite Etik Penelitian Kesehatan

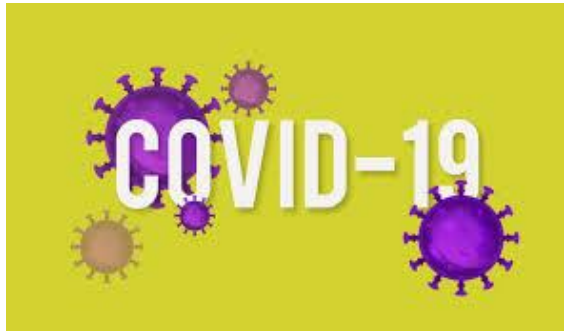
Fakultas Kedokteran Universitas Indonesia – RSUPN Dr Cipto Mangunkusumo

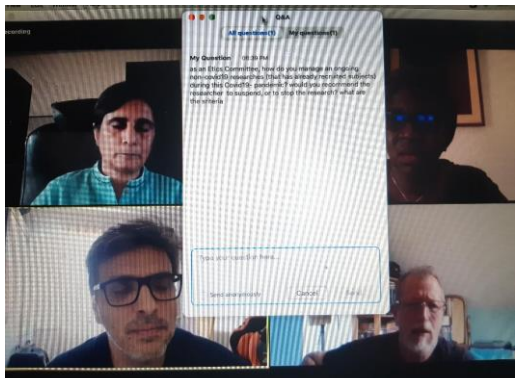
Disampaikan pada Webinar DRPM UI, "Tantangan, Solusi dan Harapan Penelitian di Masa Pandemi Covid-19.",
14 Mei 2020

Ethics in the research response to COVID-19

- The Nuffield Council on Bioethics, UK,* evidence gathered from around the world:

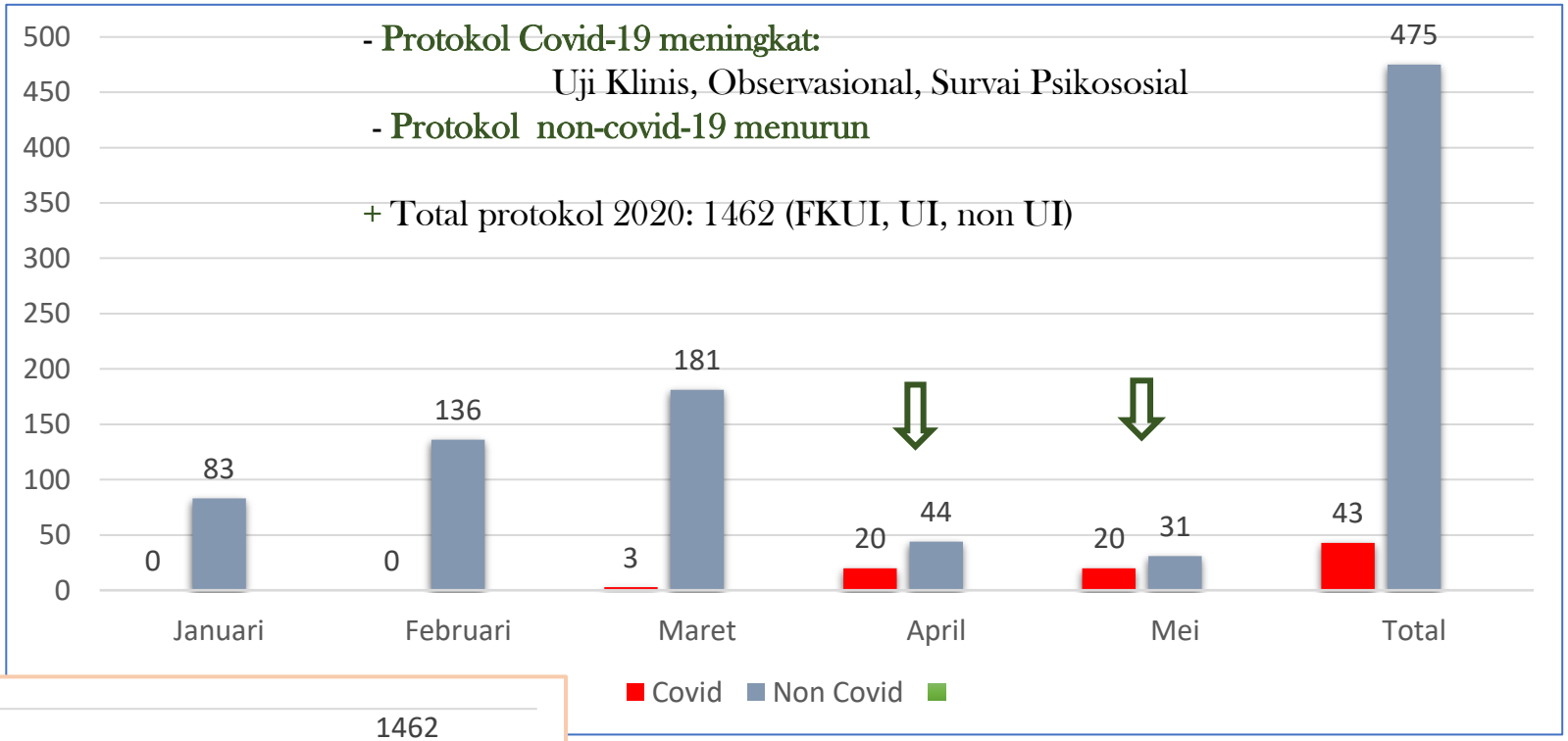
- Is an emergency a good time to conduct research.?
  - The answer was YES, research is a key aspect of the response to an emergency.
- Is ethical standards should be lowered in an emergency?
  - The answer was NO, and in fact ethical standards could be more important than ever at these times.

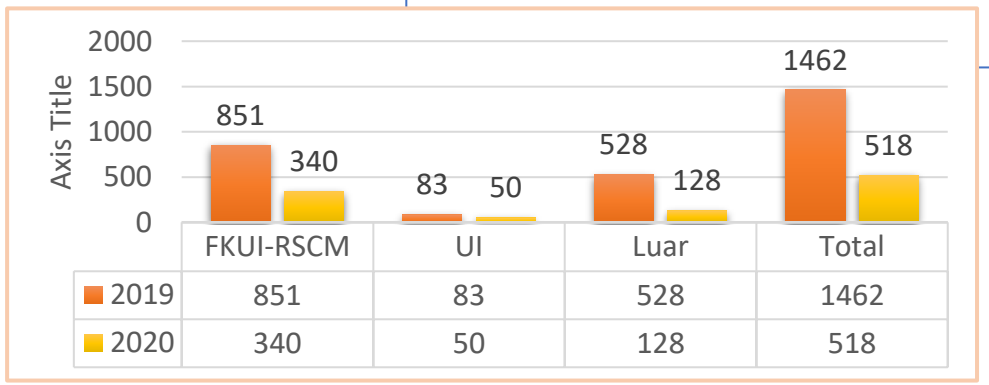




*WHO. Ethical standards for research during public health emergencies: **Distilling existing guidance to support COVID-19 R&D**

Jumlah Protokol Penelitian Januari – *Mei 2020 (*minggu 2)
Komite Etik Penelitian Kesehatan FKUI-RSCM





Data Mei s.d 11 Mei 2020

Ethical standards for research during public health emergencies: **Distilling existing guidance to support COVID-19**

(WHO Working Group on Ethics & COVID-19, 2020).

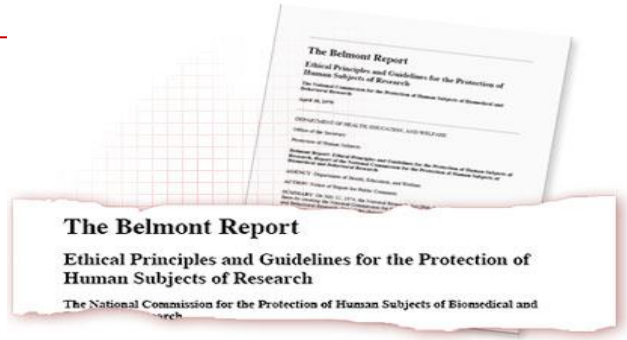
- Research is a key aspect of response to public health emergencies, yet it should never impede response efforts.
- Research projects should be coordinated nationally (and internationally) to avoid wasteful duplication and underpowered studies
- Ensure that research is responsive and sensitive to local realities, needs, values, and cultures,
- What are the requirements for informed consent in emergencies?

Penelitian di masa Pandemi Covid -19:

1. “Ongoing Research”: recruitment subjek penelitian sebelum masa pandemi
2. Protokol Penelitian Baru : -- Topik Covid-19

Fundamental Ethics Principles: (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974.)

- ***Respect for persons***
- ***Beneficence , non Maleficence***
- ***Justice***



Tantangan pelaksanaan penelitian yang sedang berjalan *(Ongoing)* di masa Pandemi Covid-19

- Karantina, *social distancing*, PSBB
- *Site closures*,
- Keterbatasan perjalanan,
- Gangguan rantai suplai produk/obat penelitian
- Risiko terjangkit infeksi bagi petugas peneliti atau subjek penelitian

Kesulitan mematuhi prosedur protokol Penelitian
- mengelola produk penelitian
- mematuhi protokol kunjungan
- uji laboratorium, pemeriksaan klinis

Tangguhkan?

√

LANJUT?

Ongoing Research: Continue or Suspend?

- Keamanan, Kesejahteraan dan Hak subjek penelitian yang **terbaik**
- Kepatuhan GCP
- Minimalisasi risiko yang mengganggu. integritas data penelitian

- Penyakit
- Desain
- Lokasi

The Principle of GCP no 3:

The rights, safety, and well-being of the trial subjects are the most important considerations and **should prevail over interests of science** and society.

FDA Guidance on

Conduct of Clinical Trials of Medical Products during Covid-19 Public Health Emergency. (March 2020, Updated April 16, 2020)

1. Unavoidable **Protocol Deviations** due to COVID-19 illness and/or COVID-19 public health control measures.
2. Protocol modifications may be required

- Apakah unavoidable **Protocol Deviations?**.

1. Unavoidable Protocol Deviation

- **Protocol Deviation**: Accidental or unintentional changes to, or non-compliance with the research **protocol** that does not have a **significant** effect on the subject's rights, safety or welfare; and/or on the integrity of the data.
  - Subjek tidak bisa datang ke lokasi kunjungan karena PSBB
  - Subjek tidak meminum produk susu yang diuji karena pindah ke kota lain, karena ayahnya tidak setuju
- **Protocol Violation** is a **deviation** that may affect the subject's rights, safety, or welfare, and/or the completeness, accuracy and integrity of the study data. M*ajor*, more serious than a deviation.
- The IRB requires reporting of Protocol Violations and Deviations

Prinsip GCP no.6:
Penelitian harus dilakukan sesuai dengan protokol yang telah disetujui sebelumnya oleh dewan peninjau kelembagaan (IRB) / komite etika independen (IEC)

2. Modifikasi Protokol: “do”

<u>Pertanyaan yang perlu dipertimbangkan</u>:

- Apakah modifikasi justru menimbulkan risiko baru kepada subjek penelitian?
- Apakah memungkinkan mengurangi risiko dengan mengubah (*amending*) prosedur/proses penelitian?
- Bagaimana kelanjutan suplai dan penyimpanan produk uji?
- Lokasi/tempat penelitian memenuhi syarat untuk penilaian langsung, atau lokasi alternatif, atau virtual?
- Apakah SDM peneliti/yang mewakili memadai: kualitas dan kuantitas?
- dll.

Tangani bahaya langsung pada subjek penelitian
Modifikasi Protokol

- Perubahan protokol penelitian atau prosedur yang responsif terhadap pandemi
  - *Hospital/clinic visit?* --- gunakan *telehealth appointments* atau home visits ,
  - Desain: *online* vs *face to face* – P*a*stikan keamanan koleksi data online (Universitas)
  - Kirim obat uji ketimbang memberikannya langsung di RS/klinik. Jasa Vendor?
  - Hilangkan/kurangi prosedur tertentu yang memungkinkan,
  - Pengambilan darah atau uji lain (imaging) pada fasilitas yang lebih aman. Terstandard !
  - *Remote monitoring* untuk memastikan keamanan subjek, jika memungkinkan
- Prosedur skrining Covid-19 pada **subjek penelitian** tidak perlu dilaporkan ke KE sbg amandemen protokol (masker bukan hanya untuk personel peneliti !)
- Komunikasikan dan ajukan persetujuan untuk setiap perubahan/modifikasi kepada subjek penelitian (revisi informed Consent)

FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency

- Kebutuhan membuat proses baru atau membuat modifikasi proses yang ada akan bervariasi dengan protokol dan situasi lokal.
- Layakkah menunda beberapa penilaian untuk uji coba yang sedang berlangsung, atau,
- jika studi tidak dapat dilakukan dengan benar di bawah protokol yang ada, apakah akan menghentikan perekrutan yang sedang berlangsung, atau bahkan menarik peserta uji coba.?

Komunikasikan dengan Komite Etik Penelitian modifikasi protokol yang direncanakan

- Ajukan Modifikasi protokol dan revisi *informed consent*
- Laporkan Deviasi protokol yang terjadi
- Dokumentasi setiap Deviasi protokol -- Case Report Form
- Review oleh Komite Etik --- Disetujui atau tidak

Fundamental Ethics Principles: (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1974.)

- ***Respect for persons***
- ***Beneficence , non Maleficence***
- ***Justice***

Penelitian Kesehatan Mental sebagai respons pandemik Covid-19

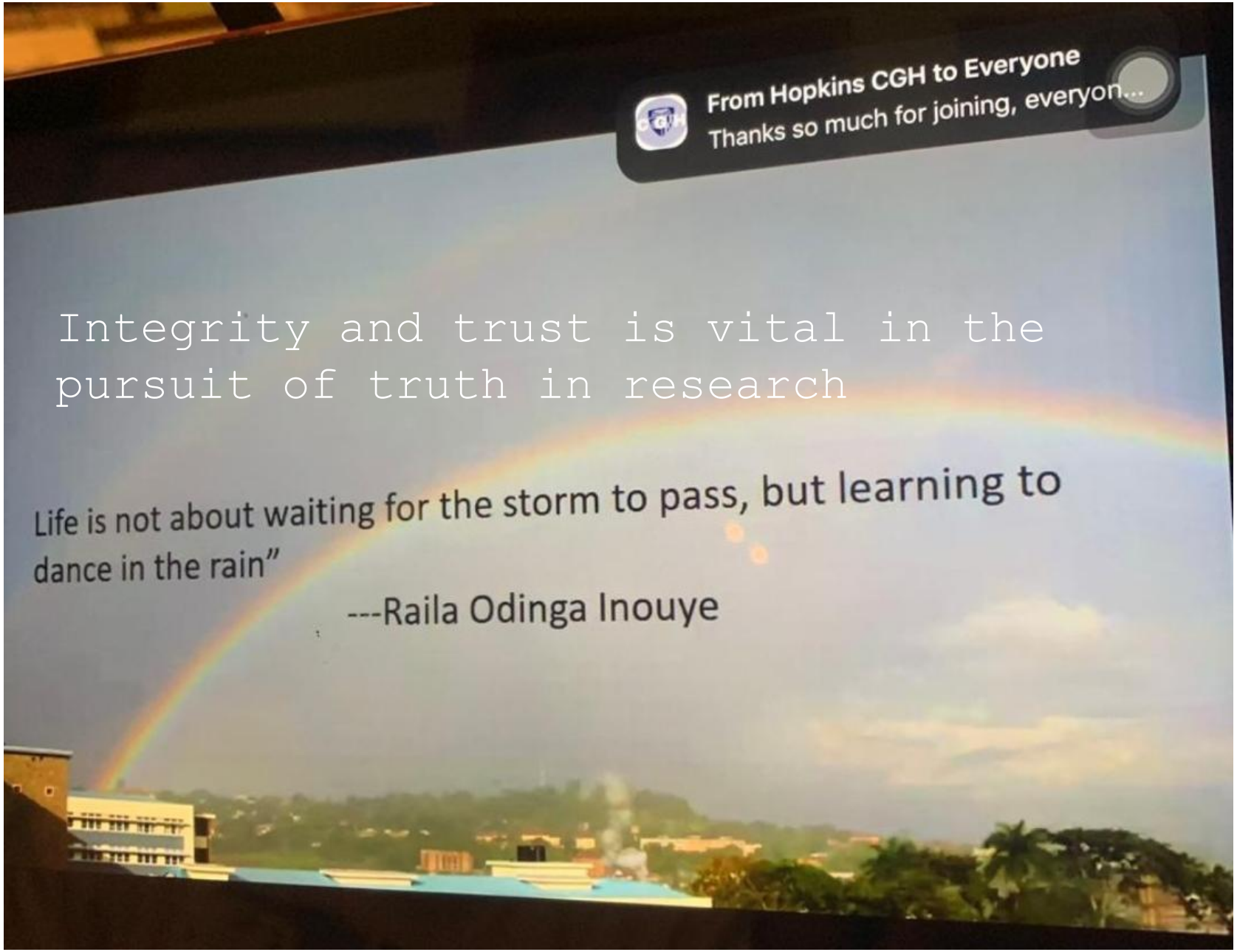
- In these times of rapid change, with high levels of uncertainty, anxiety, social isolation, and financial pressure, mental health worldwide is likely to be at risk.
- Survai, kuesioner , apps, *remote interview*
- Anonimitas, kerahasiaan data subjek penelitian
- Informed Consent: tatap muka, online/websurvey

Warren M.How Psychology Researchers Are Responding To The COVID-19 Pandemic

Townsend E. THE LANCET. PSYCHIATRY. VOLUMKey ethical questions for research during the COVID-19 pandemicE 7, ISSUE 5, P381-383, MAY 01, 2020

Take Home Message

- Tantangan dalam pelaksanaan *Ongoing Research* di masa Pandemik
- Suspend or Continue?
  - Keamanan, Kesejahteraan dan Hak subjek penelitian hal yang utama
  - Prinsip GCP (Good Clinical Practice)
  - Integritas data penelitian terjaga
- Lakukan Modifikasi Protokol yang memungkinkan --- amandemen – ajukan untuk persetujuan Komite Etik Penelitian Kesehatan
- Laporkan deviasi protokol yang terjadi ke Komite Etik Penelitian Kesehatan
- Subjek penelitian perlu diinformasikan dan dimintakan persetujuannya atas modifikasi yang direncanakan.



TERIMA KASIH