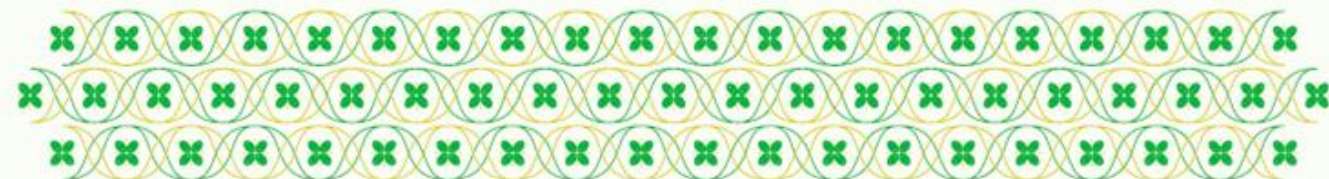




Metodologi Penelitian: Etika Penelitian

Cesa Septiana Pratiwi, M.Mid., Ph.D





Content

- **Research ethics and its history**
- **Why ethics is importance when conducting research**
- **Research ethics aspects**
- **SIM-EPK**
- **Developing Research Protocol**
- **Consent Form**
- **Several ethical issues**

DEFINITION and IMPORTANCE



a set of principles that distinguish between acceptable and unacceptable behavior or way of conducting a task

- 1 ethical codes not only help maintain scientific integrity but also safeguard the primary aim of conducting the research i.e. to promote knowledge and truth 
- 2 promote trust, respect, and objectivity in a collaborative work environment by avoiding conflicts related to authorship, copyrights, and others 
- 3 help maintain the safety and interest of human subjects and ensure appropriate care of animal subjects in a clinical or laboratory setting 
- 4 make researchers accountable for the quality and outcome of the research that may directly or indirectly affect public health and interests 

(What is Ethics in Research & Why is It Important?:

<https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm>)

1932–1972

The **Tuskegee Syphilis Study** sponsored by U.S. Dept. of Health observed the effect of untreated Syphilis in 400 African men. The patients were uninformed about the experiment and researchers withheld the penicillin treatment.

1939–45

German scientists conducted research on concentration camp prisoners.

1944–1980s

The U.S. government sponsored research on effects of radiation on uninformed subjects including cancer patients, pregnant women, and military personnel.

1947

The **Nuremberg Code** for research on human subjects was introduced.

1953

James Watson and Francis Crick discovered the structure of DNA after secretly obtaining diffraction data from Rosalind Franklin without her permission.

1964

The World Medical Association developed **Declaration of Helsinki** as a statement of ethical principles for medical research involving human subjects.

1960s /1970s

Animal protection laws adopted following animal rights movement.

1966

Henry Beecher exposed 22 unethical studies in an article in *N. Engl. J. Med.* that included the Tuskegee syphilis study and the Willowbrook hepatitis study. The first Research Ethics Committee (REC) appeared in the UK.



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1979

The **Belmont Report** was released that became a milestone in human research ethics regulation in the U.S.

1989

NIH mandates **responsible conduct of research** education be imparted to graduate students receiving training grants.

2001

European Union's **Directive 2001/20/EC** came into existence.
Journals such as *Nature* and *JAMA* asked authors to define their responsibilities when publishing research.

2010

NSF introduced responsible conduct of research (RCR) training for students, investigators, and trainees.
The Lancet retracted a fraudulent paper by Andrew Wakefield, linking autism to the measles vaccine.

2013

NIH and NSF revised conflict of interest guidelines for funded research.

2014

Nature retracted two high-profile papers on pluripotent stem cells by Haruko Obokata on the grounds of fabricated and falsified data.
Many journals including *Science* and *Nature*, and funding agencies such as NIH took steps to advance reproducibility in Science.

2016

NIH placed a temporary ban on experiments involving human-animal chimeras.

2017

Seventeen federal agencies published the **Final Rule** that eliminated the controversial rules of requiring prior consent for all research involving human biological samples.



Aspek etik yang penting untuk diperhatikan peneliti



1. Integritas : Memenuhi apa yang dijanjikan dan menjadi kewajiban peneliti berdasarkan kesepakatan. Menunjukkan ketulusan dan konsisten dalam pikiran serta perbuatan
2. Kejujuran: Mengkomunikasikan dan melaporkan data, hasil, metode, prosedur dan publikasi penelitian secara jujur. Secara tegas menghindari pemalsuan, manipulasi dan misinterpretasi luaran penelitian
3. Obyektivitas: Menghindari bias pada penelitian, saat Analisa data, intrpretasi data, peer review, pengambilan keputusan dan penulisan hibah. Mencantumkan kepentingan baik personal maupun finansial (jika ada)
4. Kompetensi: mengusakan peningkatan kemampuan diri dan melakukan Langkah efektif untuk mengembangkan kompetensi di bidang yang diteliti
5. Kehati-hatian: Mempertahan reputasi yang baik terkait aktivitas riset termasuk pengumpulan data dan pencatatan/ pendokumentasian. Memeriksa secara hati-hati dan teliti dengan bantuan sejawat untuk menghindari kesalahan
6. Keterbukaan: Terbuka dalam menyajikan data, hasil, instrument, sumber dan ide penelitian
7. Keabsahan: Patuh dalam proses yng membutuhkan perijinan pemerintah/ institusi terkait



1. Kerahasiaan: menjaga kerahasiaan informasi yang penting seperti data pasien, informasi terkait aplikasi hibah dan artikel yang (akan) diterbitkan
2. *Non-discrimination*: Menghindari sikap diskriminatif terhadap kolega, siswa atau partisipan berdasarkan gender, jenis kelamin, SARA;
3. *Respect for Intellectual Property*: Tidak menggunakan atau mempublikasikan material yang tidak dipublikasikan tanpa permisi. Menghindari plagiarisme dan mengakui serta memberikan kredit pada penulis/ pencipta aslinya. Mengikuti aturan yang terkait dengan paten, hak cipta, hak milik dan lain sebagainya
4. *Responsible Publication*: Menghindari publikasi ganda. Mengikuti etika publikasi untuk meningkatkan keilmuan dan bukan sekedar jenjang karir.
5. Tanggung jawab sosial: mengadvokasi dan meningkatkan perhatian public dan kesehatan melalui riset yang dilakukan
6. Perlakuan terhadap hewan: menunjukkan rasa menghargai dan peduli terhadap hewan yang terlibat dalam penelitian dengan menghindari penggunaan desain dan eksperimen yang buruk
7. Perlindungan terhadap subyek manusia: menjaga kehormatan, kerahasiaan, kesejahteraan dan martabat manusia yang menjadi subyek dalam studi klinis. Meminimalkan risiko/ bahaya terhadap populasi studi

SIM EPK UNISA



<https://komisietik.unisayogya.ac.id/>

The screenshot shows a web browser displaying the website for the Ethics Commission of Universitas 'Aisyiyah Yogyakarta. The browser's address bar shows the URL <https://komisietik.unisayogya.ac.id/>. The website has a blue header with navigation links: "Web UNISA", "Berita Update", and "Pengumuman". Below this is a green navigation bar with the "unisa KOMISI ETIK" logo and links for "Home", "Tentang Komisi Etik", "Biaya Pendaftaran", "Unduh Dokumen", and "Kontak". The main content area features a large image of a building with the text "KOMISI ETIK Universitas 'Aisyiyah Yogyakarta" overlaid. A yellow L-shaped graphic highlights the text. At the bottom right, there is a green button labeled "INFORMASI DAN LAYANAN". On the right side of the page, there are two vertical blue buttons: "Login SIM EPK" and "Pendaftaran Peneliti", both with subtext "Menggunakan aplikasi lokal Unisa Yogya".



Dokumen Penting

+ Curriculum Vitae

UNDUH

+ Informed Consent

UNDUH

+ Protokol

UNDUH

+ Surat Pernyataan

UNDUH

+ Contoh Isian Form

UNDUH

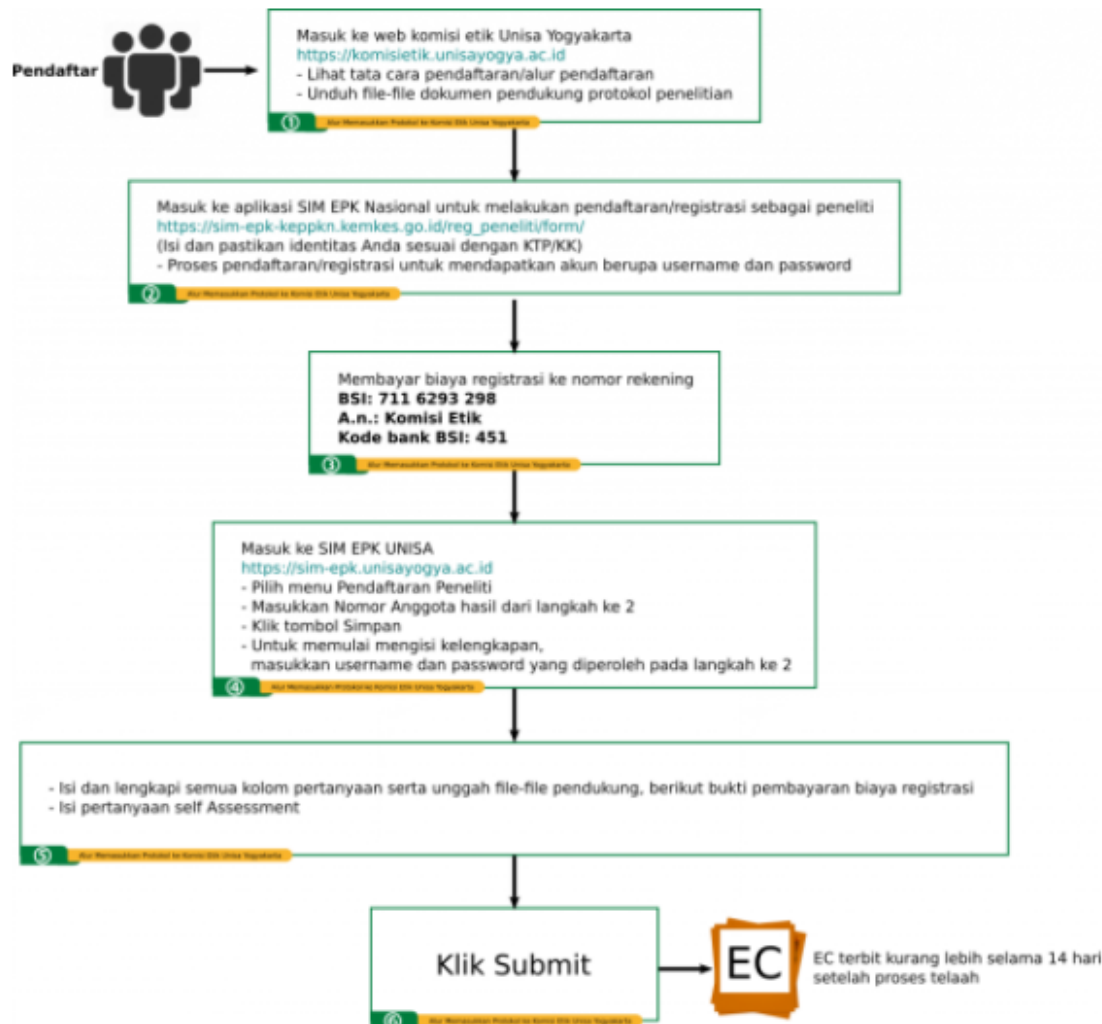
Berita



Login SIM EPK
Menggunakan aplikasi lokal Unisa Yogya

Pendaftaran Peneliti
Menggunakan aplikasi lokal Unisa Yogya

ALUR PENDAFTARAN



Keterangan No. 1

Keterangan No. 2

Keterangan No. 3
Foto atau Scan bukti pembayaran Anda.
Bukti pembayaran akan disertakan saat proses isi kelengkapan dokumen

Keterangan No. 4

Keterangan No. 5

Keterangan No. 6



1. Lakukan pendaftaran peneliti di SIM EPK Kemenkes

https://sim-epk-keppkn.kemkes.go.id/reg_peneliti/form/ (bisa juga masuk ke tautan eksternal di web komisietik unisa (bagian bawah))

Nomer, Username dan password akan dikirimkan ke email

The screenshot shows the SIM-EPK registration page. At the top, there is a navigation bar with the following links: Home, Lembaga/Institusi, KEPK, Sebaran KEPK, Pendaftaran Peneliti, Demo SIM-EPK, and Login. The main heading is "Pendaftaran Peneliti". Below this, there is a sub-heading "Pendaftaran Peneliti" with a close button. A green success message box displays the following information:

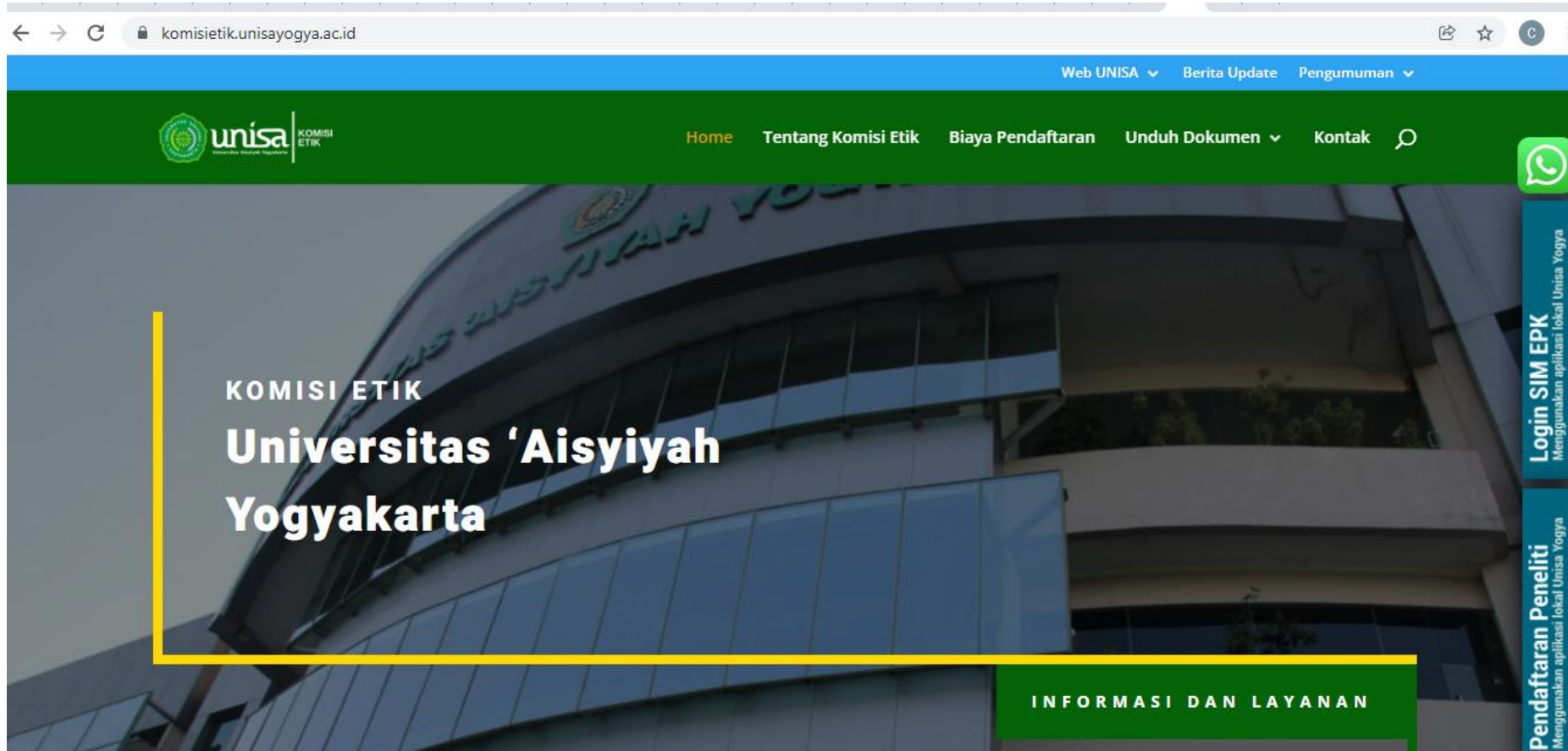
Pendaftaran Peneliti Berhasil
Berikut nomor dan data akun Anda:

Nomor	4103440123
Username	4103440123
Password	4103440123

A "Cetak" (Print) button is located at the bottom left of the message box.



Kembali ke menu utama sim epk unisa: <https://komisietik.unisayogya.ac.id/>





Masukkan nomer peneliti dan simpan, lalu login!

The screenshot shows a web browser window with the URL `sim-epk.unisayogya.ac.id/dashboard/`. The page title is "SIM-EPK :: KEPK UNISA YOGYAKARTA". The user is logged in as "Cesa Septiana ...". The dashboard features a sidebar menu with the following items: Dashboard, Pengajuan, Protokol, Self Assesment, Hasil Telaah, Perbaikan Protokol, Monev Penelitian, Desiminasi Hasil, Pemberitahuan Fullboard, and Progress Protokol. The main content area displays "Dashboard" and two data cards: "Pemberitahuan Fullboard" and "Perbaikan Protokol", both showing a count of 0. The footer contains the text "SIM-EPK © 2018".

Jangan lupa untuk mendownload dan mempelajari semua petunjuk manual yang dapat diunduh di sim-epk.unisayogya.ac.id/home



The screenshot shows the SIM-EPK website interface. At the top, there is a navigation bar with the following items: SIM-EPK, Home, KEPK, Akun Bank & Tarif/Biaya Telaah, Protokol, Pendaftaran Peneliti, and Log in. Below the navigation bar, the page title is "Home". The main content area features a large heading: "Selamat Datang di Aplikasi SIM-EPK KEPPKN lokal Universitas 'Aisyiyah Yogyakarta". Below this heading, there is a sub-heading "Kemudahan Penggunaan" and a list of user groups: Peneliti (pengusul protokol etik penelitian kesehatan), KEPK (manajemen team Penelaah KEPK), Penelaah (penelaah protokol etik yang diusulkan oleh peneliti berdasarkan 7 standar CIOMS), and KEPPKN melakukan monitoring terhadap proses telaah etik KEPK. A red arrow points to the text "Petunjuk Manual unduh di bawah ini:", which is followed by three links: "Manual 48 Protokol", "Check List 7 Standar dan Indikator", and "Formulir Informed Consent WHO". At the bottom of the page, there is a footer that reads "SIM-EPK © 2021".

← → ↻ sim-epk.unisayogya.ac.id/home/

[SIM-EPK](#) [Home](#) [KEPK](#) [Akun Bank & Tarif/Biaya Telaah](#) [Protokol](#) [Pendaftaran Peneliti](#) [Log in](#)

Home

Selamat Datang di Aplikasi SIM-EPK KEPPKN lokal Universitas 'Aisyiyah Yogyakarta

Aplikasi di rancang untuk kemudahan penggunaan dalam pengajuan etik penelitian kesehatan oleh Peneliti ke KEPK secara online sistem, dan proses telaah etik secara online sistem.

Kemudahan Penggunaan

User pada aplikasi ini dikelompokkan antara lain:

- ✓ Peneliti (pengusul protokol etik penelitian kesehatan)
- ✓ KEPK (manajemen team Penelaah KEPK)
- ✓ Penelaah (penelaah protokol etik yang diusulkan oleh peneliti berdasarkan 7 standar CIOMS)
- ✓ KEPPKN melakukan monitoring terhadap proses telaah etik KEPK.

Untuk impor Data KEPK dari file JSON yang diunduh dari Aplikasi SIM-EPK Pusat, silakan masuk ke menu KEPK

Petunjuk Manual unduh di bawah ini:

- [Manual 48 Protokol](#)
- [Check List 7 Standar dan Indikator](#)
- [Formulir Informed Consent WHO](#)

SIM-EPK © 2021

Developing Research Protocol



Memuat informasi mengenai rencana keseluruhan pelaksanaan penelitian.

Wajib diisi dan dilampirkan pada saat pengajuan ijin etik penelitian

[Contoh Protokol](#) dapat didownload pada menu Unduh di website komisi etik Unisa Yogya

The screenshot shows a web browser at the URL komisietik.unisayogya.ac.id. The page features a green header with the UNISA logo and navigation links: Home, Tentang Komisi Etik, Biaya Pendaftaran, Unduh Dokumen, and Kontak. Below the header, the main content area is titled "Dokumen Penting" (Important Documents). It contains four document cards, each with a plus sign icon and a download button labeled "UNDUH":

- Curriculum Vitae
- Informed Consent
- Protokol
- Surat Pernyataan


A red arrow points to the "Unduh Dokumen" menu item in the header. On the right side of the page, there is a vertical sidebar with a WhatsApp icon and a "Login SIM EPK" button.



LEMBAR INFORMASI PARTISIPAN



Berisi: contoh

- Apa tujuan dari penelitian ini?
 - Siapa yang melakukan penelitian?
 - Mengapa saya diminta untuk berpartisipasi?
 - Apa keterlibatan saya jika saya ambil bagian dalam penelitian ini?
 - Apakah saya wajib ambil bagian?
 - Bisakah saya mundur dari penelitian ini kapan saja?
 - Apakah saya akan dibayar jika ikut serta?
 - Apa keuntungan dan kerugian yang akan didapat jika ikut serta?
 - Apakah informasi yang saya berikan akan dirahasiakan?
 - Apa yang akan terjadi pada hasil penelitian?
 - Siapa yang telah meninjau studi ini?
 - Bagaimana jika saya memiliki kepentingan tentang penelitian ini?
 - Apa yang harus saya lakukan sekarang?
 - *Contact person* peneliti
- 

Consent Form/ Formulir Persetujuan



Berisi judul, nama lengkap dan poin-poin persetujuan, nama dan ttd responden, saksi dan wali (jika ada)

Wajib diisi dan dilampirkan pada saat pengajuan ijin etik penelitian

[Contoh](#) Consent Form dapat didownload pada menu Unduh di website komisi etik Unisa Yogya

The screenshot shows a web browser at the URL komisietik.unisayogya.ac.id. The website has a blue header with navigation links: Web UNISA, Berita Update, and Pengumuman. Below the header is a green navigation bar with links: Home, Tentang Komisi Etik, Biaya Pendaftaran, Unduh Dokumen, and Kontak. The main content area is titled "Dokumen Penting" and features four document cards, each with a plus icon and a green "UNDUH" button:

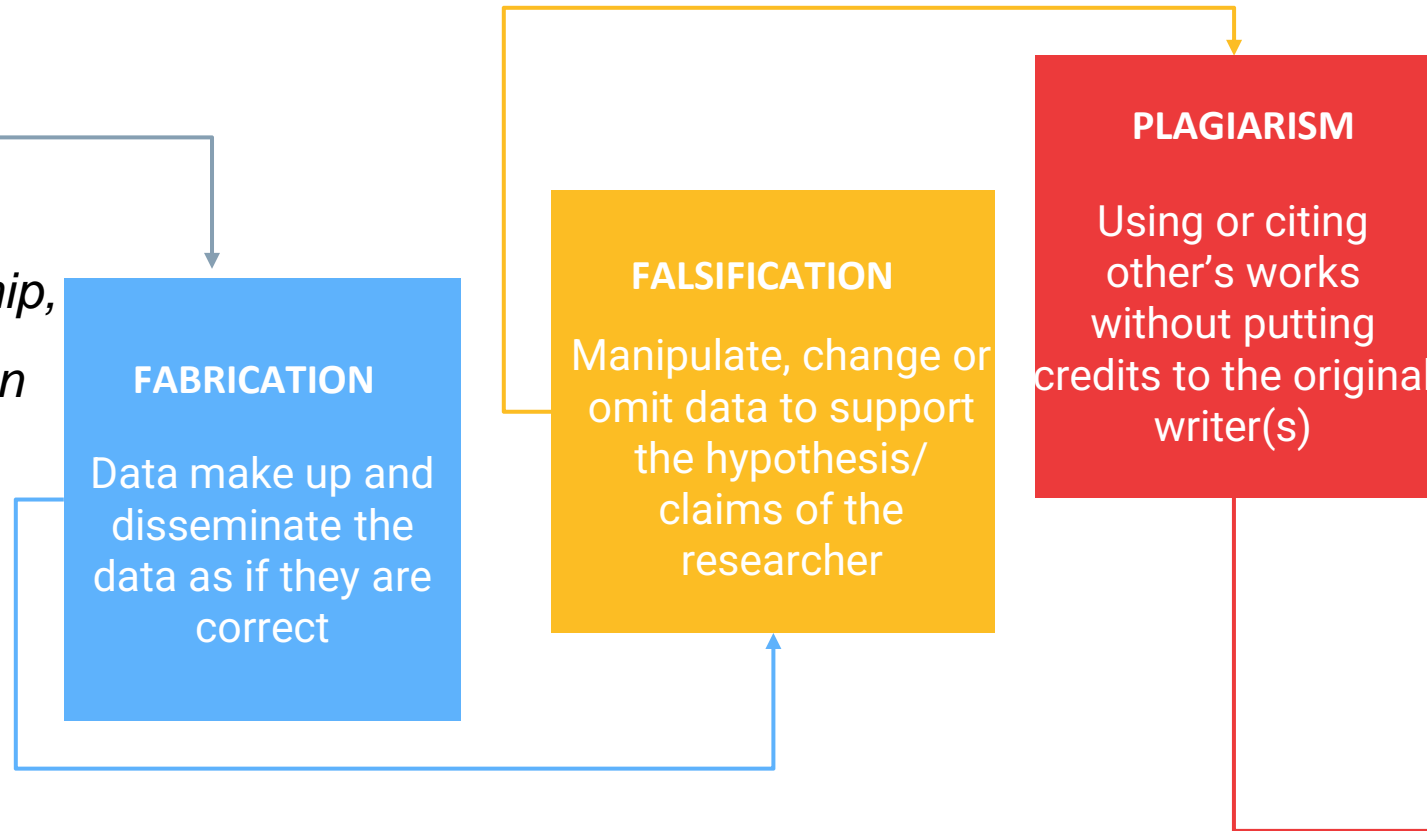
- Curriculum Vitae
- Informed Consent
- Protokol
- Surat Pernyataan

A dropdown menu is open over the "Surat Pernyataan" card, listing: Curriculum Vitae, Informed Consent, Protokol, and Surat Pernyataan. Below the "Dokumen Penting" section is a "Berita" section. On the right side, there is a vertical sidebar with a WhatsApp icon, a "Login SIM EPK" button, and a "Meliti Unisa Yogya" button.

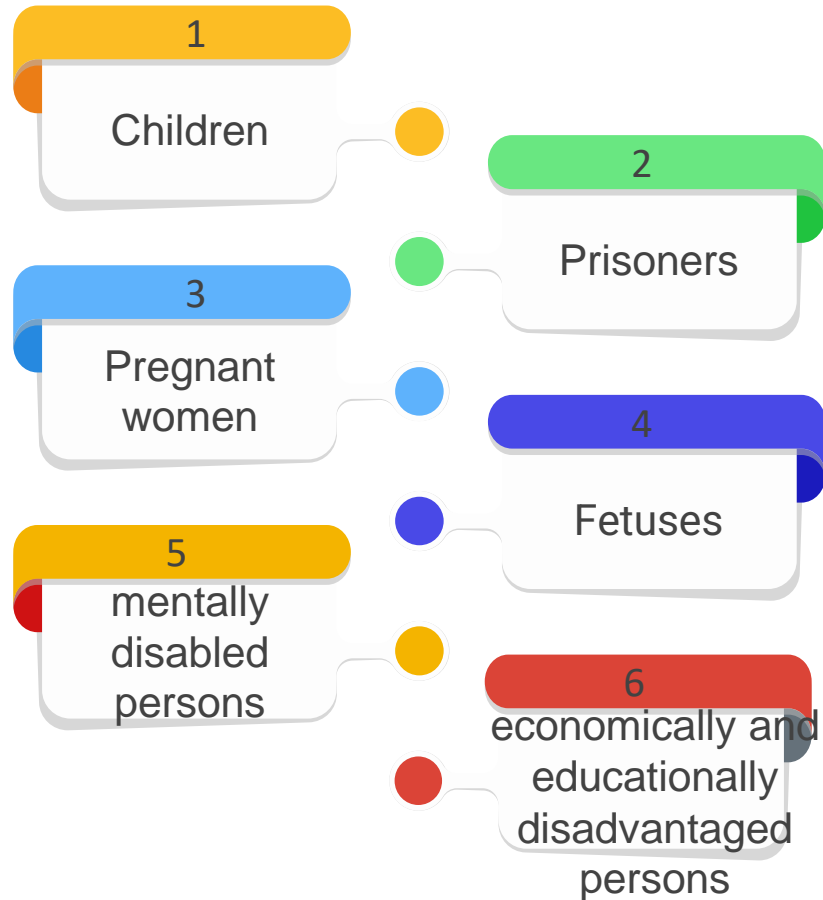
Isu penting:

Ethics violation/ pelanggaran etik:

- *fabrication or falsification of data,*
- *plagiarism,*
- *undisclosed conflict of interest*
- *inappropriate claims of authorship,*
- *duplicate publication/ submission*



PENELITIAN DENGAN RESPONDEN RENTAN (VULNERABLE PARTICIPANTS)

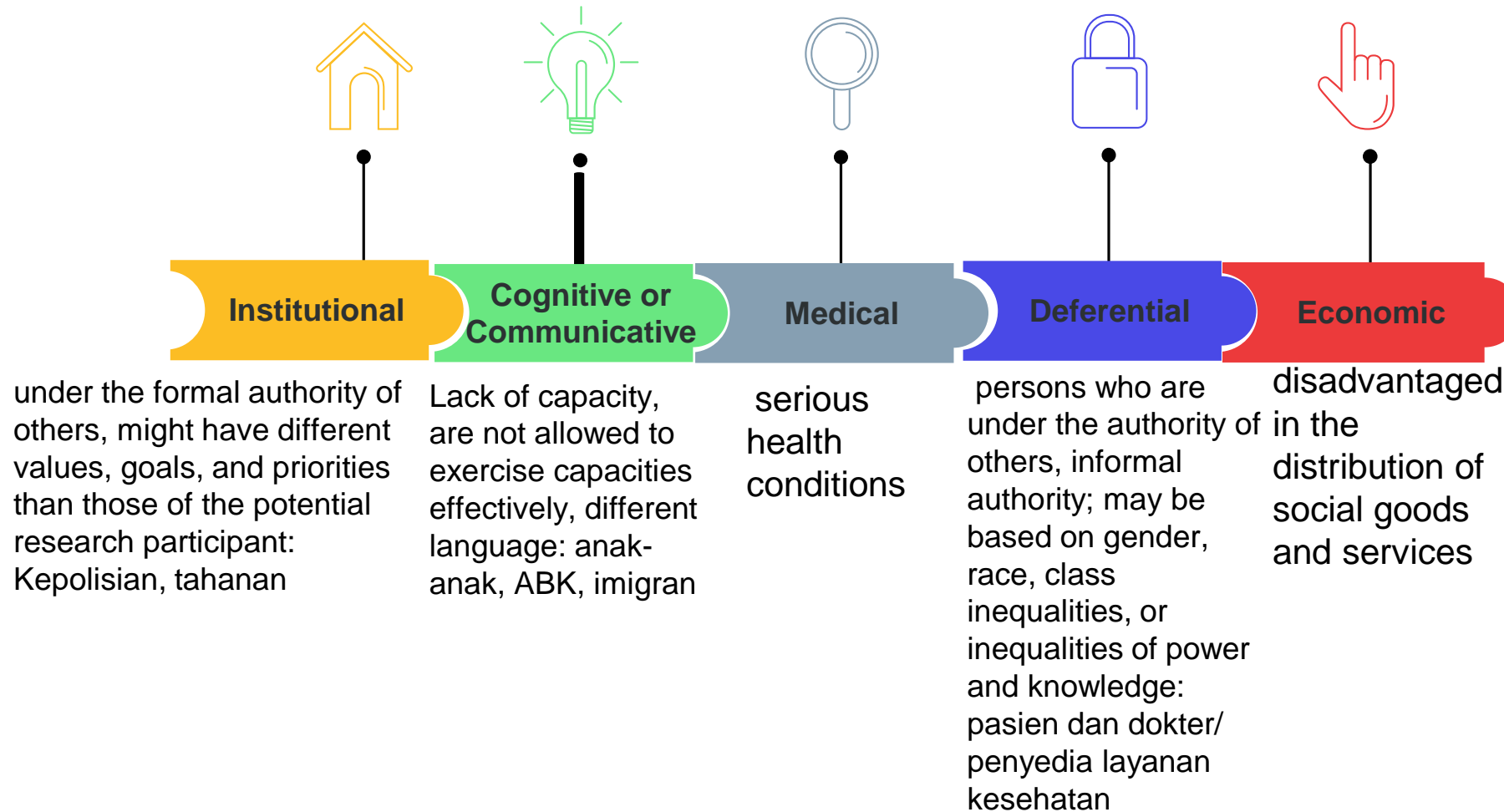


CATEGORICAL VULNERABILITY

groups in society whose members share features that might make them vulnerable

CONTEXTUAL VULNERABILITY

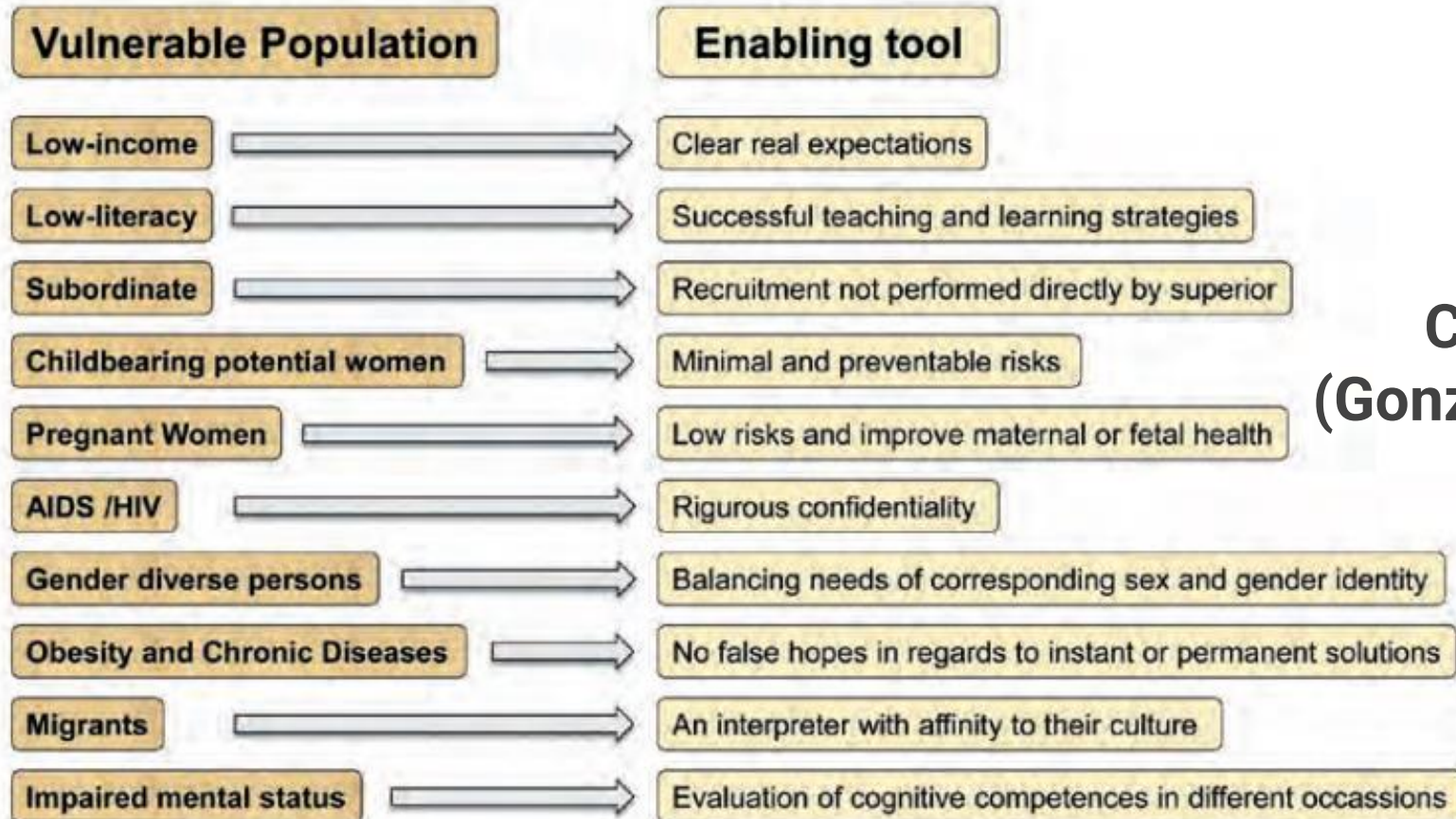
(Gordon, 2020)



Upaya meminimalkan risiko!



Figure 1. Vulnerable groups in research. Some individuals are more vulnerable than others; this is highly dependent on particular situation or context of the subject. Enabling tools can protect the subject and avoid his or her exclusion for the sole reason of being considered vulnerable.



CAREFUL MEASURES
(Gonzales Duarte et.al., 2019)



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Thanks



Do you have any questions?
cesaseptianapratiwi@unisayogya.ac.id