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Common Issues Faced by Researchers during the Protocol Development of Research Protocol Related to Health Innovation

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Current Position

Secretary of Medical & Health Research Ethics Committee Faculty of Medicine Public Health and Nursing, Universitas Gadjah Mada – Sardjito General Hospital, Yogyakarta, Indonesia

Highest Education Attainment

Doctoral degree in Pharmacology, Universitas Gadjah Mada, Yogyakarta, Indonesia

Expertise: Experimental Pharmacology, Drug Development,Toxicology

Curriculum Vitae

1. Head of Department of Pharmacology and Therapy, Faculty of Medicine Public Health and Nursing, UGM (2021-now)
2. Member of Indonesian Pharmacology Association (1996-now)
3. Member of IUPHAR (Iinternational Union of Basic and Clinical Pharmacology) (2023 – now)
4. Member of FERCAP (2012 –now)
5. Member of Material Transfer Agreement Committee, Ministry of Health, Indonesia (2024 –now)

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The research in health innovation drives advancements that improve patient care, treatment outcomes, and overall public health.

The process of ethical review is a critical component of research integrity, ensuring that studies adhere to established ethical standards and protect the rights and welfare of participants.

However, researchers often encounter significant obstacles when developing study protocols

particularly **during ethical review processes conducted by ethics committees**, which can delay the approval and implementation of their studies

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Research Objectives

To identify common issues faced by researchers during the protocol development of research protocol related to health innovation.

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Methods

Data were collected
from the review of all clinical research protocols
related to health innovation

from 2018 to 2023

in Medical and Health Research Ethics Committee of Faculty of Medicine Public Health and Nursing Universitas Gadjah Mada - Sardjito General Hospital, Yogyakarta, Indonesia.

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CATEGORY/YEAR	2018	2019	2020	2021	2022	2023
VACCINE	1	1	1	5	2	0
SOFTWARE/APLICATION	2	0	0	0	2	0
MEDICAL DEVICE	2	5	4	2	0	3
TRADITIONAL MEDICINE	2	6	4	4	1	8
NON-PHARMACOLOGICAL INTERVENSION	6	6	15	8	18	10
FOOD SUPPLEMENT	14	20	9	20	11	18
DRUG	14	16	22	10	9	23
MEDICAL PROCEDURES	5	1	10	6	2	4
	46	55	65	55	45	66

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Reviewers Findings and Comments to The Protocols

a. Lack of clarity in study design
b. Insufficient details regarding informed consent procedures
c. Inadequate risk-benefit analysis
d. Poor justification of sample size
e. Lack of appropriate plans for adverse events
f. Insufficient consideration of vulnerable populations

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Reviewers findings and comments to the protocols were classified to some problem in:

1. Appropriateness of Methodology
2. Declaration of conflict of interest
3. Good Clinical Practice (GCP) training for researcher
4. Appropriateness of Informed Consent
5. Completeness of Investigational Product information

	Methodology	Invetigational Product	Informed Consent	Conflict of Interest	Good Clicinal Practice
Vaccine	9	1	7	4	3
Software/ Aplication	3	0	3	0	0
Medical Device	14	1	10	3	3
Traditional Medicine	18	4	14	0	3
Non-pharmacological intervension	42	6	41	7	11
Food Supplement	59	30	67	14	10
Drug	49	15	65	31	17
Medical Procedures	13	0	17	4	3
	207	57	224	63	50

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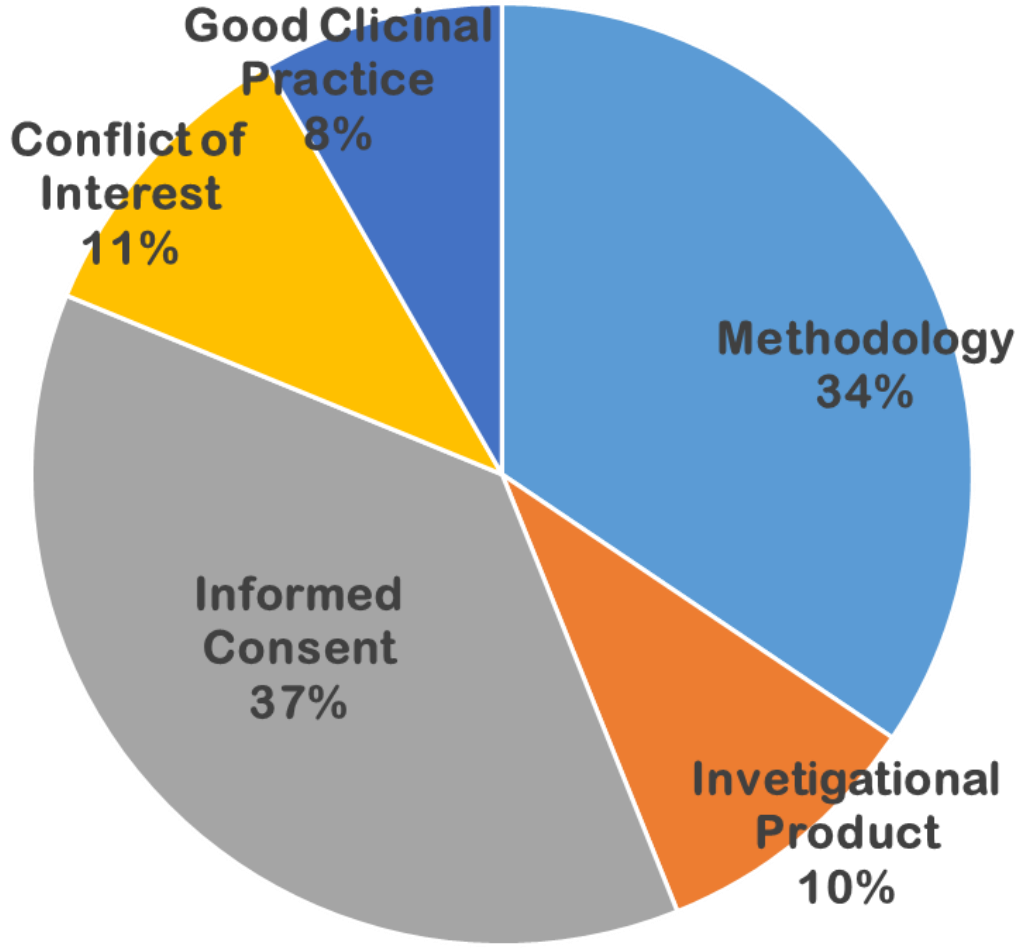

The sequence of training topic needs for researchers:

1. **Methodology**
2. **Informed consent**
3. **Conflict of Interest**
4. **Investigational Product**
5. **Good Clinical Practice**