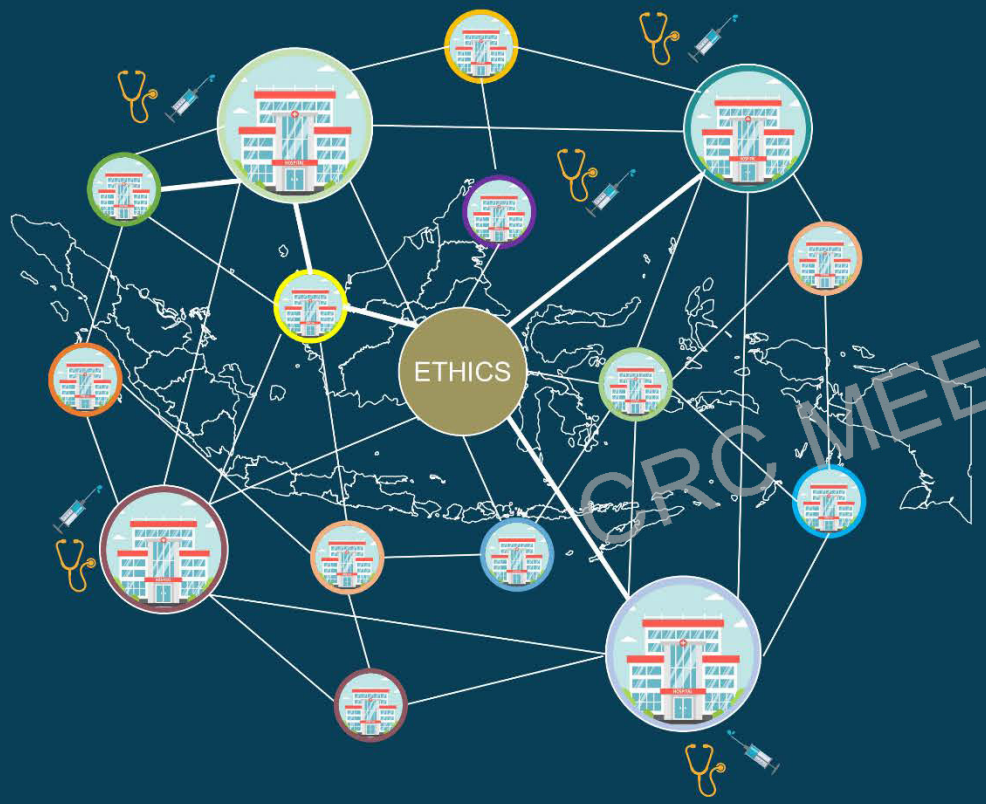
KEMENTERIAN KESEHATAN REPUBLIK INDONESIA

INA-CRC Indonesia Clinical Research Center

Centre for Health Services Policy
Health Policy Agency

THE SITUATION OF MULTICENTER
CLINICAL RESEARCH IN INDONESIA AND THE CENTRALIZATION OF ETHICS APPROVAL

March 29, 2023



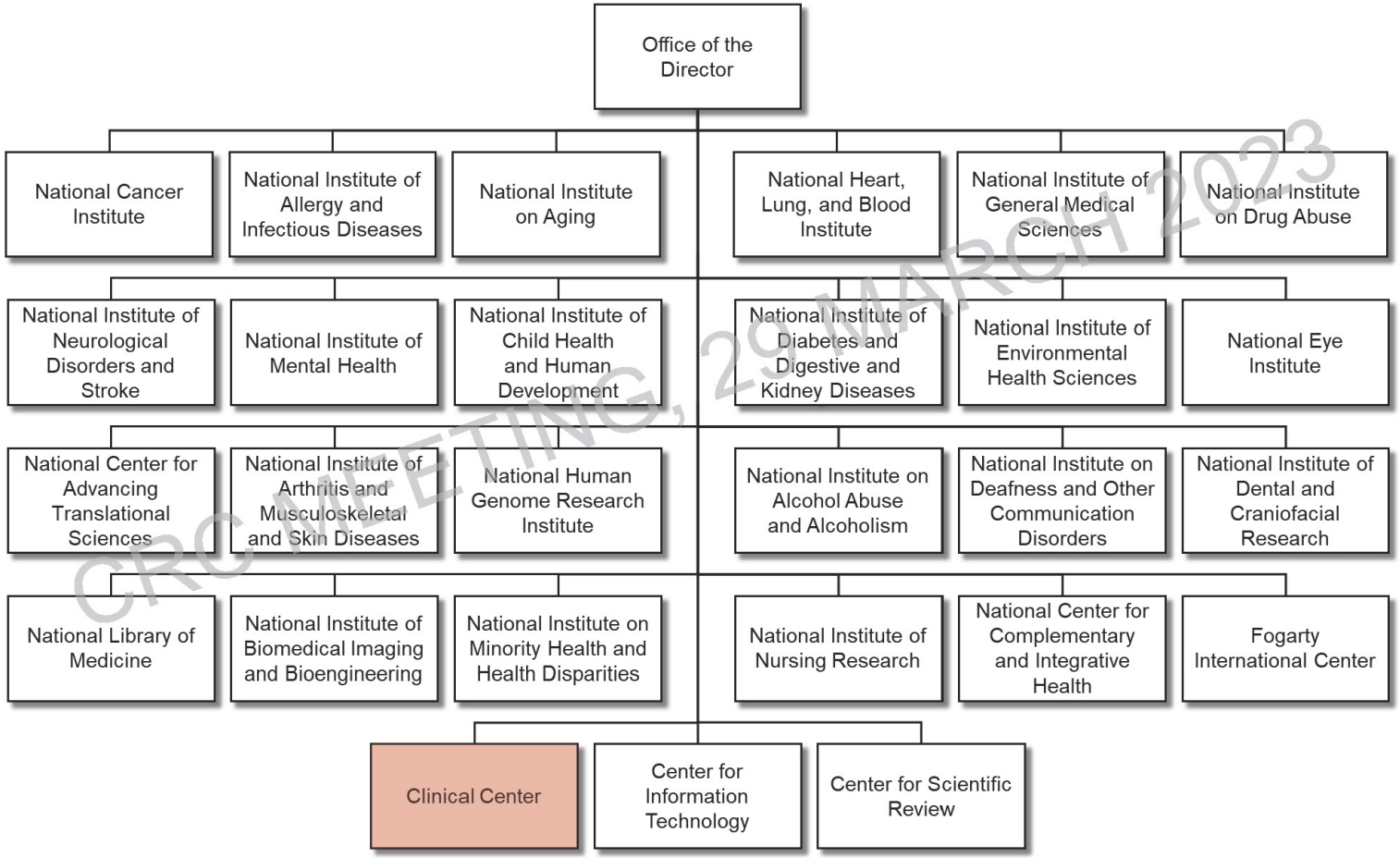
KUNJUNGAN KE US NATIONAL INSTITUTE OF HEALTH (NIH), 20 MARET 2023

DWI ALIFATUL HIMIYAH, SKM, MPH

CENTER FOR GLOBAL HEALTH AND TECHNOLOGY POLICY,

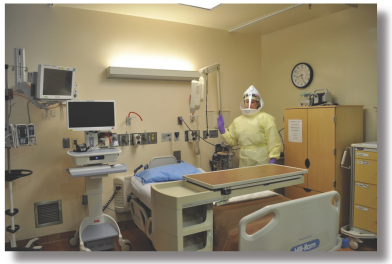
MINISTRY OF HEALTH INDONESIA

National Institutes of Health



NIH Clinical Center

- World's largest research-only hospital
  - 200 inpatient beds, 11 operating rooms
  - Over 1,600 laboratories
  - All clinical specialties, except for typical Emergency Room or A&E Department
- All patients enrolled on a research study
  - Patients do not pay for clinical care or study participation
- Shared by all NIH Institutes and Centers (ICs)
- $617.7 million USD budget in FY 2021
- About 1,600 active clinical protocols
  - First-in-human, Phase I, Phase II
  - Half are natural history studies



NIH Clinical Center Organization

Chief Executive Officer

James Gilman, MD

- Transplant and Cell Therapy Program
- Chief Diversity Officer
- Chief Operating Officer
  - Office of Patient Safety and Clinical Quality
  - Office of Employee Ethics
  - Office of Communications and Media Relations
  - Office of Clinical Research Training and Medical Education
  - Office of the Executive Officer
  - Office of the Chief Medical Officer
  - Office of the Chief Nurse Officer
  - Office of the Chief Financial Officer
  - Patient Representative
- Chief Scientific Officer
  - Translational Biobehavioral and Health Disparities
  - Biomedical Translational Research Information System
  - Office of Protocol Services
  - Clinical Pharmacology Lab
  - Animal Program

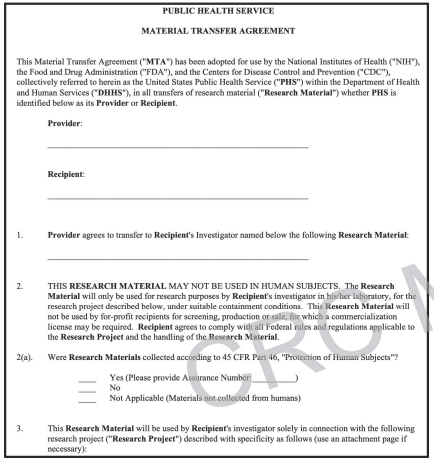
NIH Clinical Center Registry

- ClinicalStudies.info.NIH.gov
  - Database of studies conducted at the NIH Clinical Center
  - Studies are also registered on ClinicalTrials.gov
- Patient recruitment can occur through several mechanisms
  - CC.NIH.gov/recruit
    - Interested individuals can search open clinical studies at NIH and request to volunteer
    - Includes healthy volunteers
  - CC.NIH.gov/referpatients
    - Physicians can refer patients to open studies at NIH to consider volunteering for
  - IRB-approved advertisements soliciting study volunteers

Masukan terkait pembentukan CRC dan CRU di Indonesia (1)

1. *Multicenter study:* uji etik hanya perlu dilakukan satu kali dan kemudian melakukan *reliance agreement* untuk CRU yang membutuhkan. Uji etik dimaksud juga tidak harus dilakukan di salah satu CRU, namun dapat dilakukan oleh organisasi yang dikontrak.

2. NIH memiliki *template material transfer agreement* (MTA) yang harus dipenuhi yang menjadi skrining awal penilaian.



PUBLIC HEALTH SERVICE

MATERIAL TRANSFER AGREEMENT

This Material Transfer Agreement ("**MTA**") has been adopted for use by the National Institutes of Health ("NIH"), the Food and Drug Administration ("FDA"), and the Centers for Disease Control and Prevention ("CDC"), collectively referred to herein as the United States Public Health Service ("**PHS**") within the Department of Health and Human Services ("**DHHS**"), in all transfers of research material ("**Research Material**") whether **PHS** is identified below as its **Provider** or **Recipient**.

Provider:

_____

Recipient:

_____

1. **Provider** agrees to transfer to **Recipient**'s Investigator named below the following **Research Material**:

_____

2. THIS **RESEARCH MATERIAL** MAY NOT BE USED IN HUMAN SUBJECTS. The **Research Material** will only be used for research purposes by **Recipient**'s investigator in his/her laboratory, for the research project described below, under suitable containment conditions. This **Research Material** will not be used by for-profit recipients for screening, production or sale, for which a commercialization license may be required. **Recipient** agrees to comply with all Federal rules and regulations applicable to the **Research Project** and the handling of the **Research Material**.

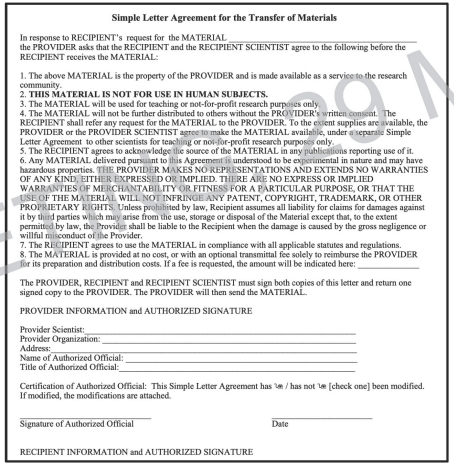
2(a). Were **Research Materials** collected according to 45 CFR Part 46, "Protection of Human Subjects"?

___ Yes (Please provide Assurance Number: _____)
___ No
___ Not Applicable (Materials not collected from humans)

3. This **Research Material** will be used by **Recipient**'s investigator solely in connection with the following research project ("**Research Project**") described with specificity as follows (use an attachment page if necessary):

Sample MTA

Dapat dimodifikasi sesuai kebutuhan untuk memenuhi persyaratan tertentu dari pihak yang menandatangani MTA



Simple Letter Agreement for the Transfer of Materials

In response to RECIPIENT's request for the MATERIAL _____ the PROVIDER asks that the RECIPIENT and the RECIPIENT SCIENTIST agree to the following before the RECIPIENT receives the MATERIAL:

1. The above MATERIAL is the property of the PROVIDER and is made available as a service to the research community.
2. **THIS MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.**
3. The MATERIAL will be used for teaching or not-for-profit research purposes only.
4. The MATERIAL will not be further distributed to others without the PROVIDER's written consent. The RECIPIENT shall refer any request for the MATERIAL to the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agree to make the MATERIAL available, under a separate Simple Letter Agreement to other scientists for teaching or not-for-profit research purposes only.
5. The RECIPIENT agrees to acknowledge the source of the MATERIAL in any publications reporting use of it.
6. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.
7. The RECIPIENT agrees to use the MATERIAL in compliance with all applicable statutes and regulations.
8. The MATERIAL is provided at no cost, or with an optional transmittal fee solely to reimburse the PROVIDER for its preparation and distribution costs. If a fee is requested, the amount will be indicated here: _____

The PROVIDER, RECIPIENT and RECIPIENT SCIENTIST must sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER will then send the MATERIAL.

PROVIDER INFORMATION and AUTHORIZED SIGNATURE

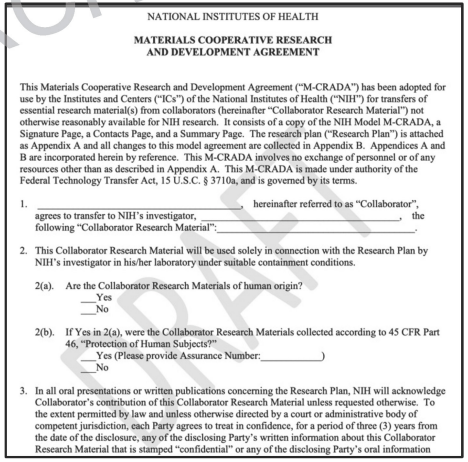
Provider Scientist: _____
Provider Organization: _____
Address: _____
Name of Authorized Official: _____
Title of Authorized Official: _____

Certification of Authorized Official: This Simple Letter Agreement has \=n / has not \=n [check one] been modified. If modified, the modifications are attached.

_____ _____
Signature of Authorized Official Date

RECIPIENT INFORMATION and AUTHORIZED SIGNATURE

Jenis MTA yang **umum** digunakan di NIH (**sederhana**), biasanya untuk pertukaran reagen laboratorium atau spesimen untuk pengujian sederhana



NATIONAL INSTITUTES OF HEALTH

MATERIALS COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT

This Materials Cooperative Research and Development Agreement ("M-CRADA") has been adopted for use by the Institutes and Centers ("ICs") of the National Institutes of Health ("NIH") for transfers of essential research material(s) from collaborators (hereinafter "Collaborator Research Material") not otherwise reasonably available for NIH research. It consists of a copy of the NIH Model M-CRADA, a Signature Page, a Contacts Page, and a Summary Page. The research plan ("Research Plan") is attached as Appendix A and all changes to this model agreement are collected in Appendix B. Appendices A and B are incorporated herein by reference. This M-CRADA involves no exchange of personnel or of any resources other than as described in Appendix A. This M-CRADA is made under authority of the Federal Technology Transfer Act, 15 U.S.C. § 3710a, and is governed by its terms.

1. _____, hereinafter referred to as "Collaborator", agrees to transfer to NIH's investigator, _____, the following "Collaborator Research Material": _____.

2. This Collaborator Research Material will be used solely in connection with the Research Plan by NIH's investigator in his/her laboratory under suitable containment conditions.

2(a). Are the Collaborator Research Materials of human origin?
___Yes
___No

2(b). If Yes in 2(a), were the Collaborator Research Materials collected according to 45 CFR Part 46, "Protection of Human Subjects?"
___Yes (Please provide Assurance Number: _____)
___No

3. In all oral presentations or written publications concerning the Research Plan, NIH will acknowledge Collaborator's contribution of this Collaborator Research Material unless requested otherwise. To the extent permitted by law and unless otherwise directed by a court or administrative body of competent jurisdiction, each Party agrees to treat in confidence, for a period of three (3) years from the date of the disclosure, any of the disclosing Party's written information about this Collaborator Research Material that is stamped "confidential" or any of the disclosing Party's oral information

M-CRADA

Jenis MTA yang digunakan saat bekerja dengan mitra industri untuk mengembangkan atau bertukar materi. Memungkinkan industri untuk kontribusi dana dan materi.

Masukan terkait pembentukan CRC dan CRU di Indonesia (2)

3. CRC kiranya juga berperan dalam melakukan prioritisasi penelitian, harmonisasi *tools* yang digunakan, serta menjadi *spokesperson* dan *matching* mitra industri yang terkait.

4. Tantangan utama yang perlu diantisipasi adalah pada manajemen data dan teknologi informasi.

5. Terkait kerja sama CRU dengan NIH, dapat dimulai dengan *center* di NIH yang memiliki minat tinggi terlebih dahulu, seperti *National Cancer Institute*. Selain itu, kerja sama tidak perlu dilakukan melalui MoU antara NIH dengan masing-masing CRU, namun dapat dilakukan antara CRC dengan NIH, dan kemudian MoU antara CRC dengan CRU.

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