

PENGGUNAAN DATA STUDI UNTUK PUBLIKASI – PANDUAN UNTUK PENELITI

Versi 1.0

16 Juli 2018

ABBREVIATIONS AND ACRONYMS:

Abbreviation or Acronym	Full Term
AC	Approval Committee
CP	Concept Plan
DM	Data Management
INA-RESPOND	Indonesia Research Partnership on Infectious Disease
LMWC	Leader of Manuscript Writing Committee
MWC	Manuscript Writing Committee
SOP	Standard Operational Procedure
PI	Principal Investigator
PS	Publication Specialist

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1. Tujuan

Tujuan dari Panduan Penggunaan Data Studi untuk Publikasi ini adalah untuk menggambarkan prosedur permintaan dan persetujuan setiap penggunaan data studi INA-RESPOND untuk publikasi.

2. Cakupan

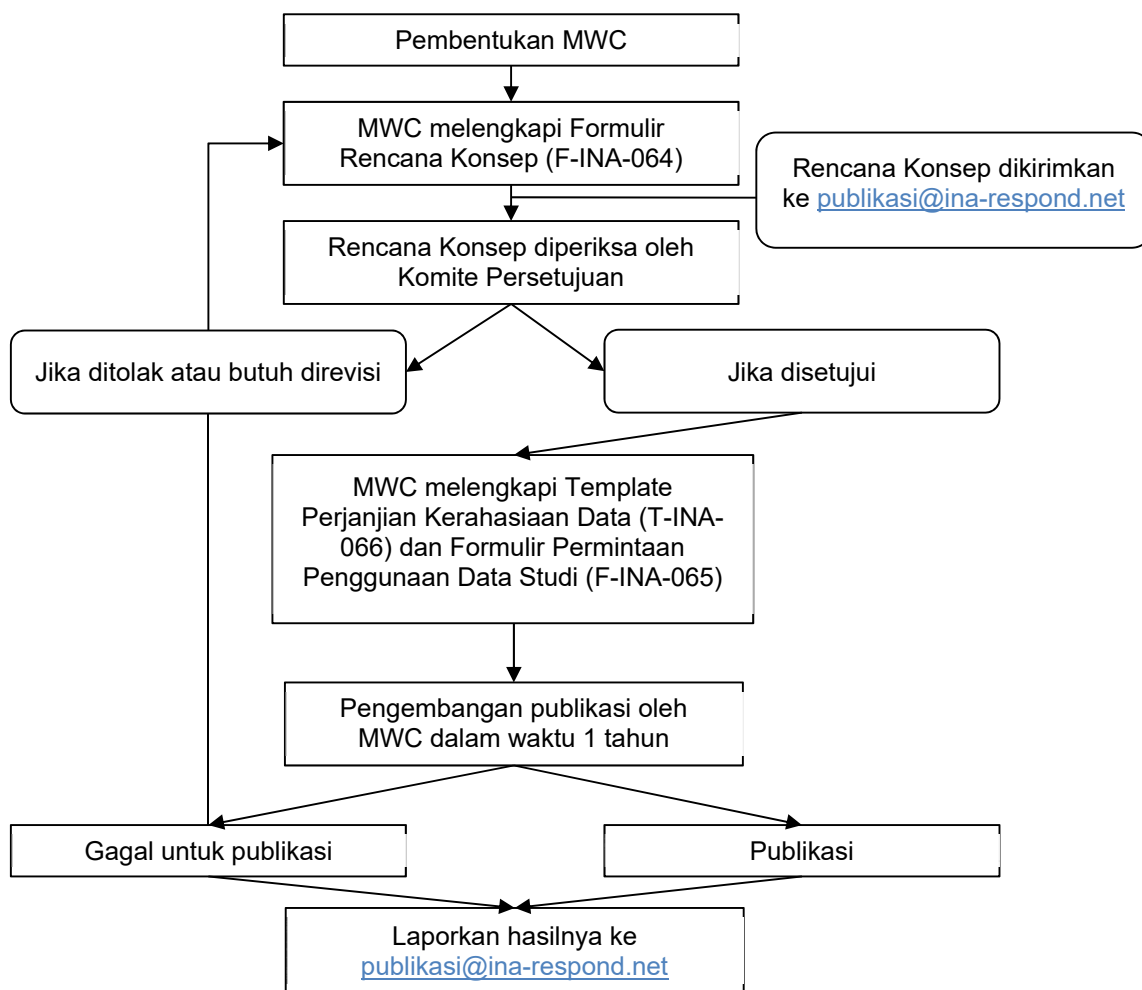
Panduan ini berlaku untuk Peneliti utama dan/atau tim studi dalam jejaring INA-RESPOND dan/atau staf sekretariat INA-RESPOND yang ditunjuk untuk membuat permintaan persetujuan penggunaan data studi INA-RESPOND tertentu untuk publikasi. Publikasi didefinisikan sebagai kegiatan dan hasil penelitian yang disebarluaskan di pertemuan ilmiah (presentasi lisan atau poster) atau dalam tulisan, seperti (tetapi tidak terbatas pada) kebijakan pendek, catatan/laporan rapat, artikel, laporan atau buku yang ditelaah oleh rekan sejawat.

3. Prosedur

- a. Peneliti utama dan/atau tim studi jejaring INA-RESPOND dan/atau staf sekretariat INA-RESPOND yang ditunjuk memulai pembentukan komite penulisan manuskrip (MWC) dan menunjuk satu pemimpin MWC (LMWC). Komite ini dapat terdiri hingga 5 orang anggota termasuk LMWC. Peneliti di luar tim dan jejaring penelitian INA-RESPOND yang tertarik menggunakan dan/atau menganalisis data studi INA-RESPOND disambut baik jika anggota NSC dari tempat penelitian yang terlibat memberikan persetujuannya.
- b. MWC mengembangkan ide penggunaan data studi untuk publikasi dengan melengkapi Formulir Rencana Konsep (CP) dan Keputusan Komite Persetujuan (F-INA-064) INA-RESPOND.
- c. Formulir F-INA-064 dikirimkan ke publikasi@ina-respond.net untuk ditinjau lebih lanjut oleh Komite Persetujuan (AC). MWC akan mendapatkan keputusan akhir dalam 10 hari kerja setelah pengajuan dari Protocol Specialist (PS) Sekretariat INA-RESPOND.
- d. Jika formulir F-INA-064 disetujui oleh AC, MWC harus melengkapi dokumen Perjanjian Kerahasiaan Data (T-INA-066) dan Formulir Permintaan Penggunaan Data Studi (F-INA-065) dan menyerahkan formulir ke publikasi@ina-respond.net untuk ditinjau lebih lanjut oleh tim Manajemen Data (DM). Jika formulir F-INA-064

disetujui dengan revisi kecil atau ditolak, MWC perlu merevisi sesuai dengan komentar AC dan mengulangi langkah-langkah 3.1.3 atau dipersilakan untuk mengajukan permintaan baru untuk penggunaan data studi.

- e. Tim DM akan mengirim data studi yang diminta dalam 10 hari kerja.
- f. Setelah MWC menerima data studi yang diminta, MWC bertanggung jawab untuk analisis data dan pengembangan publikasi satu tahun setelah persetujuan diterima. LMWC harus memastikan draf terakhir dari publikasi disampaikan untuk disetujui oleh penulis dan mereka yang mengakui sebelum mengajukan ke jurnal dll.
- g. MWC harus mematuhi Kebijakan Publikasi INA-RESPOND (P-INA-001) Bagian 3 dan INA-RESPOND Studi Penggunaan Data untuk Publikasi (S-INA-GEN-008) untuk setiap proses publikasi terkait.
- h. MWC harus memperbarui kemajuan publikasi ke AC melalui PS yang ditunjuk, setiap 3 bulan melalui email ke publikasi@ina-respond.net.
- i. Jika MWC gagal menghasilkan publikasi dalam satu tahun persetujuan, AC akan memberitahukan MWC untuk penugasan kembali atau pembatalan.



Gambar 1. Diagram alur prosedur permohonan dan persetujuan penggunaan data studi INA-RESPOND.

4. Referensi

F-INA-064	INA-RESPOND Concept Plan and Approval Committee's Decision Form
F-INA-065	INA-RESPOND Study Data Usage Request Form
L-INA-035	Request and Approval of Concept Plan Log
P-INA-001	INA-RESPOND Publication Policy
S-INA-GEN-008	INA-RESPOND Study Data Usage for Publication
T-INA-066	Data Confidentiality Agreement Template

Lampiran A. Formulir Rencana Konsep (CP) dan Keputusan Komite Persetujuan INA-RESPOND (F-INA-064)

Concept Plan #:
*Completed by Publication Specialist
i.e. Protocol ID - 001 (INA101-001)*

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**INA-RESPOND Concept Plan and
Approval Committee's Decision Form**

INA-RESPOND network welcomes dedicated Investigators and/or Study Team to submit the concept of study publication.

This form must be completed in English. Please review the Guideline for Request and Approval for INA-RESPOND Study Data Usage for Publication carefully and provide the required information concisely, yet with enough detail to allow the Approval Committee to understand your Concept Plan.

Submission Date <i>(dd/mmm/yyyy)</i>	
Concept Plan Title	

1. Manuscript Writing Committee Member #1 Information (Leader of MWC)

Full Name	
Institution Name	
Email Address	
Contact Number	

2. Manuscript Writing Committee Member #2 Information

Full Name	
Institution Name	
Email Address	
Contact Number	

3. Manuscript Writing Committee Member #3 Information

Full Name	
Institution Name	
Email Address	
Contact Number	

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4. Manuscript Writing Committee Member #4 Information

Full Name	
Institution Name	
Email Address	
Contact Number	

5. Manuscript Writing Committee Member #5 Information/Study Statistician Information (if applicable)*

Full Name	
Institution Name	
Email Address	
Contact Number	

** Choose the correct one and cross out the incorrect answer.*

6. Sites Involved:

Add another row in table below if needed

Site ID	Site Name

7. Outline of Concept Plan:

a. Background and Objective

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b. Method

c. Desired Variables

d. Planned Statistical Analysis

e. Others (eg. Estimation cost/budget)

8. Desired Publication

Type of Publication	Event/Journal
<input type="checkbox"/> Presentation	Event Name:
<input type="checkbox"/> Manuscript	Prospective Journals:
<input type="checkbox"/> Others, specify:	

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9. Timeline

This section should include the timeline for estimated completion of the Concept Plan - including (but are not limited to) project duration, approval, first and second draft of publication, and submission. At least the first draft of publication should be completed within one year after approval.

10. Acknowledgement:

Refer to INA-RESPOND Publication Policy section 3.5 and 3.6.

Choose one of the examples below:

- 1. Acknowledgment: a section at the end of the manuscript to acknowledge those who have supported the research through funding, in-kind resources, or expertise, but did not provide enough support to be included as authors. Includes study subjects.*
- 2. NIHHD Acknowledgment*
- 3. NIAID Acknowledgement: the following citation must be included for all papers published that have received any funding from the of NIAID: " This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, under contract Nos. HHSN261200800001E and HHSN261201500003I. The content of this publication does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government."*

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Approval Committee's Decision Form

Declined

Please provide the reason(s) below:

Need Revision

Please provide the input below:

Approved

Please provide the comment below (if needed):

Add another row in table below if needed

No	Approval Committee Name & Position	Signature	Signature date

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Lampiran B. Templat Perjanjian Kerahasiaan Data (T-INA-066)

DATA CONFIDENTIALITY AGREEMENT

Title of Research Study: <<Protocol Title>> - <<Protocol ID>>

As a member of this research team I understand that I have access to dataset of <<Protocol Title – Protocol ID>> study. By signing this statement, I am indicating my understanding of my responsibilities to maintain confidentiality and agree to the following:

- I understand that the dataset is completely confidential.
- I agree not to divulge, publish, or otherwise make known to unauthorized persons or to the public any confidential information obtained in this study, unless specifically authorized to do so by approved protocol or by the INA-RESPOND steering committee members.
- I agree to notify the site principal investigator, site INA-RESPOND steering committee, and Chair of INA-RESPOND steering committee immediately should I become aware of an actual breach of confidentiality or a situation which could potentially result in a breach, whether this be on my part or on the part of another person.

<<Protocol ID ie. AFIRE manuscript writing group>>:

Group _____

Name	Signature	Date

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Lampiran C. Formulir Permintaan Penggunaan Data Studi (F-INA-065)

INA-RESPOND Study Data Usage Request Form

1. REQUESTOR INFORMATION

Name of Leader of MWC:		Email address:	
Phone number:		Concept Plan #:	
Department:		Request Date:	
Institution Address:		Data Provided Date: <i>Completed by Data Management Team</i>	

2. DOCUMENTS STATUS

- Approved Concept Plan
- Site PI(s) approval for data usage
- Confidentiality Agreement

3. DATA STATUS

By signing this document, I am as Data Management Team confirmed that data request as stated in the approve Concept Plan has been distributed to the Leader of MWC via email as mentioned in the section 1.

Data Management Signature	Signature:		
	Print:	Date	

Data Management will archive the original following documents:

- Approved INA-RESPOND Concept Plan and Approval Committee's Decision Form (F-INA-064)
- The Confidentiality Agreement Template (T-INA-066)
- The Site PI(s) Signature Sheet of Data Usage (L-INA-034)
- The INA-RESPOND Study Data Usage Request Form (F-INA-065)

And provide the copy of documents above to the Protocol Specialist