

Clinical trial databases are a crucial investment in clinical research

Part 3 – Database Development Considerations and REDCap Demo



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12 Oct 2018

What is Clinical Data Management System (CDMS)

- A **clinical data management system** or CDMS is a tool used in **clinical** research to manage the **data** of a **clinical** trial.
- The clinical data management system (CDMS) used to conduct a clinical study "...should be designed to...prevent errors in data creation, modification, maintenance, archiving, retrieval or transmission...". (21 CFR Part 11)
- GCP requirement: "Ensure that the systems are designed to permit data changes in such a way that the data changes are documented and that there is no deletion of entered data (i.e., maintain an audit trail)".
- Commercial vs Open-Source software

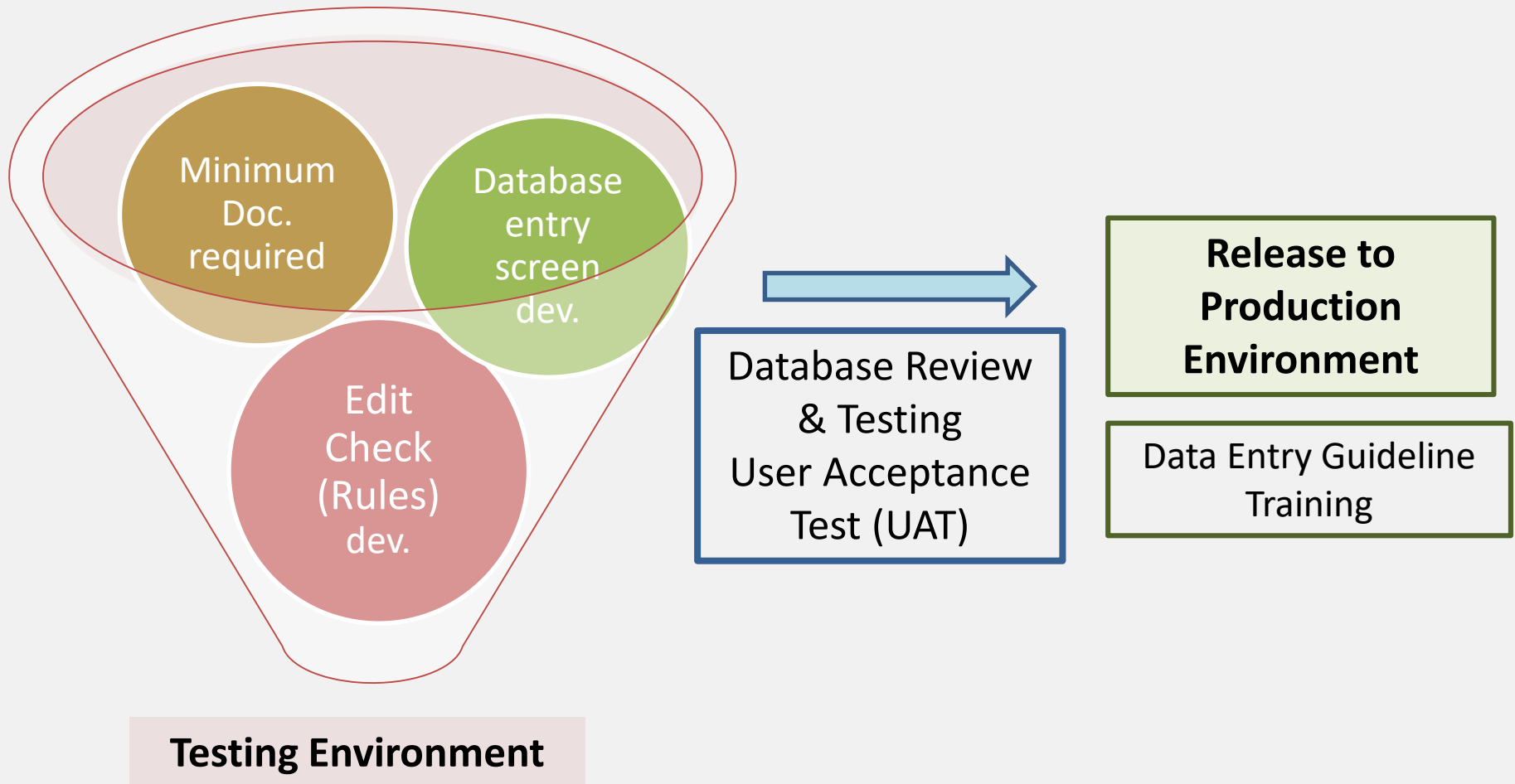
Commercial vs Open-Source software

	Commercial	Open-Source
Developer	For-profit company or developer group	A single or group of developers, often as a voluntary effort.
Charges:	User licenses with or without annual support contracts	Free of charge *requires personnel training
Source Code:	Not published	Published online and can be downloaded for free
Examples:	Oracle® Clinical (Oracle, USA) Clinsys® (Jubilant Organosys, USA) InForm™ (Phase forward, USA) Medidata Rave® (Medidata Solutions) OpenClinica® Enterprise (Akaza Research, USA)	OpenClinica® Community (Akaza Research, USA) Redcap (Vanderbilt University, USA) TrialDB (Yale University, USA)

Clinical Data Management System (CDMS)

- Success of a clinical trial depends on quality and integrity of its database
- Key goal for the database setup:
 - ✓ high quality database
 - ✓ REAL TIME Automatic Edit Checks
 - ✓ meet both clinical and regulatory requirements
 - ✓ store data accurately
 - ✓ worldwide connectivity - Real Time Data Accumulation
 - ✓ ability to control both hierarchical data access and data transparency
 - ✓ reports easily accomplished

Database Development Flowchart



Minimum Documents Required

- Final, approved and most current research study protocol
- Current annotated Case Report Form (aCRF)
- Completed and field Project Database Configuration Specifications
- Edit Specification Documents (ESD)

INA RESPOND PAGE 2.0_IE Protocol: INA102

Subject Identification Number	Initials	VISIT N 3.0	Visit
102 SUBJID N 10.0	SUBJINIT IC3		BASELINE & ENROLLMENT

KRITERIA INKLUSI INCLUSION CRITERIA			
Semua kriteria inklusi harus dijawab YA (kecuali untuk 3a,b,c,d,e,f,g,h) agar subyek memenuhi serta dalam penelitian ini. <i>All inclusion criteria (except for 3a,b,c,d,e,f,g,h) must be answered YES in order for the sub eligible for the study.</i>			
1. Pasien suspek TB paru : <i>Patients suspected of having pulmonary TB :</i>	IEICOR1 N1.0	<input type="checkbox"/> Ya/Yes	
2. Batuk ≥ 2 minggu : <i>Cough ≥ 2 weeks :</i>	IEICOR2 N1.0	<input type="checkbox"/> Ya/Yes	
3. Memiliki minimal 1 gejala TB klinis lainnya : <i>At least one other TB clinical symptom</i>	IEICOR3 N1.0	<input type="checkbox"/> Ya/Yes	
<input type="checkbox"/> Ya/Yes <input type="checkbox"/> Tidak /No <input type="checkbox"/> Ya/Yes <input type="checkbox"/> Tidak /No <input type="checkbox"/> Ya/Yes <input type="checkbox"/> Tidak /No <input type="checkbox"/> Ya/Yes <input type="checkbox"/> Tidak /No	a. Demam/Fever IEICOR3a N1.0 IEICOR3b N1.0 b. Penurunan berat badan tanpa sebab yang jelas/ <i>Unexplain</i> c. Berkurangnya nafsu makan/ <i>Loss of appetite</i> IEICOR3c N1.0 d. Batuk darah/ <i>Hemoptysis</i> IEICOR3d N1.0		

INA RESPOND Edit Specifications Document

Check ID	Event	Page	Target Variable	Check Expression	Executs	Action type	Error message	Check Type
PAGE1_0_1	Baseline & Enrolment	1	FORMND	FORMND is null and SUBJINIT is null and IEICOR1-IEICOR3, IEICOR3a-IEICOR3h, IEICOR1 is null - IEICOR4 is null and SPINNT is null and SPICDT is null and VISDT is null and ICOT is null	TRUE	Discrepancy Note Action	All data for the Inclusion and Exclusion CRF is missing. Please provide missing data or confirm that this CRF was not done. Seluruh data Inklusi dan Eksklusi pada CRF tidak ada. Lengkapi data tersebut atau berikan konfirmasi bahwa CRF ini belum selesai.	Manual
PAGE1_0_2	Baseline & Enrolment	1	I_INA20_IEICOR1	I_INA20_FORMND eq "" and (I_INA20_IEICOR1 eq "" or I_INA20_IEICOR2 eq "" or I_INA20_IEICOR3a eq "" or I_INA20_IEICOR3b eq "" or I_INA20_IEICOR3c eq "" or I_INA20_IEICOR3d eq "" or I_INA20_IEICOR3e eq "" or I_INA20_IEICOR3f eq "" or I_INA20_IEICOR3g eq "" or I_INA20_IEICOR3h eq "")	TRUE	Discrepancy Note Action	All data for the Inclusion CRF is missing. Please provide missing data or confirm that this CRF was not done.	PROGRAM CHECK
PAGE1_0_3	Baseline & Enrolment	1	I_INA20_IEICOR1	I_INA20_FORMND eq "" and (I_INA20_IEICOR1 eq "" or I_INA20_IEICOR2 eq "" or I_INA20_IEICOR3a eq "" or I_INA20_IEICOR3b eq "" or I_INA20_IEICOR3c eq "" or I_INA20_IEICOR3d eq "" or I_INA20_IEICOR3e eq "" or I_INA20_IEICOR3f eq "" or I_INA20_IEICOR3g eq "" or I_INA20_IEICOR3h eq "")	TRUE	Discrepancy Note Action	At least one Exclusion Criteria is blank. Please provide missing information. Kriteria Eksklusi ada yang tidak diisi. Lengkapi data tersebut.	PROGRAM CHECK
PAGE1_0_4	Baseline & Enrolment	1	I_INA20_SUBJINIT	I_INA20_SUBJINIT eq "" or I_INA20_SPINNT eq "" or I_INA20_SPICDT eq ""	TRUE	Discrepancy Note Action	Subject Initial or PI Initial or PI date is blank. Please clarify. Inisial Subyek atau Inisial PI atau Tgl PI ttd ada yang belum diisi.	PROGRAM CHECK
PAGE1_0_5	Baseline & Enrolment	1	I_INA20_IEICOR2	I_INA20_IEICOR2 eq "" and	TRUE	Discrepancy Note Action	Inclusion criteria #2 is "Yes" but all 2a-2g are	PROGRAM

Database Entry Screen Development

- Entry Screen is developed in the Testing environment in accordance with the specifications outlined in the aCRF.

Edit Check (Rules) Development

- Edit checks → automatic warnings or notices that are generated by a database, CDMS, or other data entry application, and are triggered by data that are missing, out of range, unexpected, redundant, incompatible or otherwise discrepant with other data or study parameters.
- Edit checks → invaluable tools for increasing data quality and providing greater efficiency during data review and cleaning activities.
- Purpose: draw attention to data that are inconsistent or potentially erroneous.
- Edit Check is developed in the Testing environment
- Programming of the Check occurs according with the specifications outlined in the ESD.

Database Review & Testing

- The data entry features of the database are tested for appropriate field types, logic, ease of use, and functionality.
- User Acceptance Testing (UAT) is conducting as part of the database validation.

Recommended SOPs & other Supporting Documents

- Study Database Setup and Validation
- Programmed Edit Checks
- Study Database Change Control

REDCap Overview

- **REDCap (Research Electronic Data Capture)** is a browser-based, data-driven software solution for designing and building clinical and research databases.
- The REDCap application allows users to build and manage online surveys and databases quickly and securely.
- Data entry operators enter data in a web browser, either locally or from remote locations. The data is stored in a secure database.
- The REDCap Consortium supports this secure web application.

REDCap Overview

REDCap
Logged in as mduvenhage | Log out

My Projects
Project Home or Project Setup
REDCap Messenger
Project status: **Production**

Data Collection

- Record Status Dashboard
- Add / Edit Records

Applications

- Calendar
- Data Exports, Reports, and Stats
- Data Import Tool
- Data Comparison Tool
- Logging
- Field Comment Log
- File Repository
- User Rights and DAGs
- Data Quality
- API and API Playground
- REDCap Mobile App

Help & Information

- Help & FAQ
- Video Tutorials
- Suggest a New Feature
- Contact REDCap administrator

INA-RESPOND Demo

Project Home | **Project Setup** | Other Functionality | Project Revision History

Quick Tasks

- Codebook
- Export data
- Create a report
- Check data quality
- User Rights
- Online Designer and Data Dictionary Upload
- Copy this project
- Data Access Groups

Project Setup area

The Codebook is a human-readable, read-only version of the project's data dictionary. It is a quick reference for viewing field attributes.

Export your data from REDCap to open or view in Excel or various other formats.

Build custom reports for quick views of your data, and export reports to Excel/CSV.

Build or execute data quality rules to find discrepancies and errors in your project data.

Grant new users access to this project or modify user privileges for current users.

Create new fields/questions on your data collection instruments or modify existing ones using the Online Designer or by uploading a Data Dictionary. Quick link: [Download the current Data Dictionary](#) OR [Download Data Dictionary with drafted changes](#)

Create an exact duplicate of this project, which copies over all data collection instruments, any surveys that exist, as well as the option to copy all users and reports to the new project.

Create groups of users to limit user access to certain records/responses, in which only users within a given Data Access Group can access records created by users within that group.

User Rights

The User Rights page provides information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (any).

Current Users (4)

User	Expires
dpramanto (Dwi Pramanto)	never
klaras (Kanti Laras)	never
mduvenhage (michael duvenhage)	never
serari (Silvera Erari)	never

Project Statistics

Records in project	5
Most recent activity	11-10-2018 12:13
Space usage for docs	0,00 MB

Upcoming Calendar Events (next 7 days)

Time	Date	Description
		No upcoming events

Building REDCap projects


1. Create project
2. Build data collection instrument
 - Online designer
 - Develop event schedule
 - Data dictionary
3. Preview your data form or survey
4. Enter practice data
5. Test applications : data export, data comparison, graphic data view and report builder
6. Modify project
7. Move to production mode to capture real data

REDCap Project Setup Menu

INA-RESPOND Demo

[Project Home](#) [Project Setup](#) [Other Functionality](#) [Project Revision History](#)

Project status: ☒ Production Completed steps 8 of 8


Complete!
[Not complete?](#)


Main project settings

Some options below are disabled because they may not be modified once the project is in production status.

[Enable](#) [Use surveys in this project?](#) [VIDEO: How to create and manage a survey](#)

[Disable](#) [Use longitudinal data collection with defined events?](#)

[Modify project title, purpose, etc.](#)


Complete!
[Not complete?](#)


Design your data collection instruments

Add or edit fields on your data collection instruments. This may be done by either using the Online Designer (online method) or by uploading a Data Dictionary (offline method). Quick links: [Download PDF of all instruments](#) OR [Download the current Data Dictionary](#) OR [Download Data Dictionary with drafted changes](#)

[Go to](#) [Online Designer](#) or [Data Dictionary](#) [Explore the](#) [REDCap Shared Library](#)

Have you checked the [Check For Identifiers](#) page to ensure all identifier fields have been tagged?

Learn how to use [Smart Variables](#) [Piping](#) [Action Tags](#)


Complete!
[Not complete?](#)

Define your events and designate instruments for them

Create events for re-using data collection instruments and/or set up scheduling.

[Go to](#) [Define My Events](#) or [Designate Instruments for My Events](#)

REDCap Project Setup Menu



Complete!

[Not complete?](#)

Enable optional modules and customizations

Some options below are disabled because they may not be modified once the project is in production status.

Enable

Repeatability instruments and events ?

Enable

Auto-numbering for records ?

Enable

Scheduling module (longitudinal only) ?

Enable

Randomization module ?

Enable

Designate an email field for sending survey invitations ?

Additional customizations



Complete!

[Not complete?](#)

Set up project bookmarks (optional)

You may create custom bookmarks to webpages that exist inside or outside of REDCap. These bookmarks will be seen as links on the left-hand project menu and can be accessed at any time by users who are given privileges to do so. Every project bookmark has custom settings that allow one to control its appearance and behavior.

Go to [Add or edit bookmarks](#)



Complete!

[Not complete?](#)

User Rights and Permissions

You may grant other users access to this project or edit the user privileges of current users on this project by navigating to the User Rights page. Additionally, if you wish to limit user access to certain records/responses for this project, you may want to use Data Access Groups, in which only users within a given Data Access Group can access records created by users within that group.

Go to [User Rights](#) or [Data Access Groups](#)

REDCap Project Setup Menu



Complete!

[Not complete?](#)

Test your project thoroughly

It is important to test the essential components of your project before moving it into production. Try creating a few test records and entering some data for each to ensure that your data collection instruments look and behave how you expect, especially branching logic and calculations. Then review your test data by creating reports and exporting your data to view in Excel or a statistical analysis package. If you have surveys, complete the surveys as if you were a participant by using the Public Survey Link or Participant List by sending a survey invitation to yourself. If other project modules will be used regularly, test them out a bit too. The best way to test your project is to use it as if you were entering real production data, and it is always helpful to have colleagues (especially team members) take a look at your project to get a fresh set of eyes looking at it.



Complete!

Move your project to production status

Move the project to production status so that real data may be collected. Once in production, you will not be able to edit the project fields in real time anymore. However, you can make edits in Draft Mode, which will be auto-approved or else might need to be approved by a REDCap administrator before taking effect.

REDCap Development Mode

- Development mode means still developing/testing the database
- Test all aspects of your project. Changes /updates will happen immediately to screens and database structures
- Moved into production mode after testing
- In production mode, all test data entered in development mode will be deleted
- Production mode: adding new forms/fields is typically safe
- Production mode: problems typically occur when changing variable names, coding, and field types. Data loss might be inevitable
- Changes in the production mode needs to be approved by your local REDCap administrator

REDCap Online designer

INA-RESPOND Demo

[Project Home](#) [Project Setup](#) [Online Designer](#) [Data Dictionary](#)

Since this project is currently in **PRODUCTION**, changes will not be made in real time. [Tell me more](#)

[Submit Changes for Review](#) Fields to be added: **0** / Total resulting field count: **76**
Fields to be deleted: **0** / Existing field count: **76**

[Remove all drafted changes](#) [View detailed summary of all drafted changes](#)

[Create snapshot of instruments](#) [VIDEO: How to use this page](#)
Last snapshot: never ?

The Online Designer will allow you to make project modifications to fields and data collection instruments very easily using only your web browser. Below you have the options to modify an existing instrument, delete an instrument, create a new instrument, download an instrument as a PDF document, or reorder your instruments.

Data Collection Instruments

Add new instrument:

[Create](#) a new instrument from scratch

[Import](#) a new instrument from the official [REDCap Shared Library](#)

[Upload](#) instrument ZIP file from another project/user or [external libraries](#)

Instrument name	Fields	View PDF	Instrument actions
Demografi / Demographics	14		Choose action
Kriteria Inklusi & Ekskusi / Inclusion & Exclusion Criteria	9		Choose action
Sistem Informasi Geografis / Location Information	3		Choose action
Faktor Risiko / Risk Factors	15		Choose action
Koleksi Sampel / Sample Collection	13		Choose action
Mass Drug Administration	3		Choose action
Status Akhir Penelitian / Study Disposition	12		Choose action

Collection
Instruments

REDCap Online designer

Current instrument: **Demografi / Demographics** Preview instrument

Variable: record_id
Subject Identification Number

NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.

Add Field Add Matrix of Fields

DEMOGRAFI / DEMOGRAPHICS

Add Field Add Matrix of Fields

Variable: subjinit
Subject Initials
* must provide value

Add Field Add Matrix of Fields

Variable: dob
1. Tanggal lahir / Date of Birth
dd/mm/yyyy Today D-M-Y

Add Field Add Matrix of Fields

Variable: age *Branching logic: [dob] = ""*
1.1 Jika tanggal tidak tertulis lengkap (Umur) / If full date is not recorded (Age)
tahun / years

Add Field Add Matrix of Fields

Variable: sex
2. Jenis kelamin saat lahir / Sex at birth
* must provide value
☐ Laki-laki / Male
☐ Perempuan / Female

Add Field Add Matrix of Fields reset

Field Type
(Text)

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: Text Box (Short Text, Number, Date/Time, ...)

Field Label
Subject Initials

Variable Name (utilized in logic, calcs, and exports)
subjinit ☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use ☒ Smart Variables ☒ Piping

Validation? (optional) None

Enable searching within a biomedical ontology? ☐
-- choose ontology to search --

Required? ☐ No ☒ Yes
* Prompt if field is blank

Identifier? ☒ No ☐ Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV)

Align the position of the field on the page

Field Note (optional)

Small reminder text displayed underneath field

Save Cancel

Field Label

Field Name

REDCap Online designer

Current instrument: **Demografi / Demographics** Preview instrument

Variable: record_id
Subject Identification Number

NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.

Add Field Add Matrix of Fields

DEMOGRAFI / DEMOGRAPHICS

Add Field Add Matrix of Fields

Variable: subjinit
Subject Initials
* must provide value

Add Field Add Matrix of Fields

Variable: dob
1. Tanggal lahir / Date of Birth
dd/mm/yyyy Today D-M-Y

Add Field Add Matrix of Fields

Variable: age **Branching logic:** [dob] = ""
1.1 Jika tanggal tidak tertulis lengkap (Umur) / If full date is not recorded (Age)
tahun / years

Add Field Add Matrix of Fields

Variable: sex
2. Jenis kelamin saat lahir / Sex at birth
* must provide value
☐ Laki-laki / Male
☐ Perempuan / Female

Add Field Add Matrix of Fields

Field Type
(Radio buttons)

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min\)](#).

Field Type: **Multiple Choice - Radio Buttons (Single Answ**

Field Label
2. Jenis kelamin saat lahir / Sex at birth

Variable Name (utilized in logic, calcs, and exports)
sex ☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use: [Smart Variables](#) [Piping](#)

Require? ☐ No ☒ Yes
* Prompt if field is blank

Identifier? ☐ No ☒ Yes
Identifying information (e.g., name, SSN, address)?

Right / Vertical (RV) ☐

Action Tags / Field Annotation (optional)
Learn about [@ Action Tags](#) or [using Field Annotation](#)

Save Cancel

Coded
values

Field Label

Field Name

REDCap Online designer (Branch logic)

Variable: occup

5. Kategori Pekerjaan / Occupation category

* must provide value

Add Field Add Matrix of Fields

Variable: occup_oth Branching logic: [occup] = '12'

5.1 Lainnya, sebutkan / Other, specify

Adding Branch
logic code

Edit Field

You may add a new project field to this data collection instrument by completing the fields below and clicking the Save button at the bottom. When you add a new field, it will be added to the form on this page. For an overview of the different field types available, you may view the [Field Types video \(4 min.\)](#).

Field Type: Multiple Choice - Drop-down List (Single Answer)

Field Label
5. Kategori Pekerjaan / Occupation category

Variable Name (utilized in logic, calcs, and exports)
occup ☐ Enable auto naming of variable based upon its Field Label?

ONLY letters, numbers, and underscores

How to use [Smart Variables](#) [Piping](#)

Required?* ☐ No ☒ Yes
* Prompt if field is blank

Identifier? ☒ No ☐ Yes
Does the field contain identifying information (e.g., name, SSN, address)?

Custom Alignment Right / Vertical (RV)

Align the position of the field on the page

Field Note (optional)

Small reminder text displayed underneath field

Choices (one choice per line) [Copy existing choices](#)

10, Pendidikan atau Akademia / Education or Akademia
11, Militer atau Kepolisian / Military or Police
12, Lainnya / Other

☒ Enable auto-complete for this drop-down [How do I manually code the choices?](#)

Action Tags / Field Annotation (optional)

Learn about [@ Action Tags](#) or [using Field Annotation](#)

Save Cancel

Define item
properties & code
values

Add/Edit Branching Logic

Branching Logic may be employed when fields/questions need to be hidden under certain conditions. If branching logic is defined, the field will only be visible if the conditions provided are true (i.e. show the field only if...). You may specify those conditions in the text box below for the Advanced Branching Logic Syntax or by choosing the Drag-N-Drop Logic Builder method, which allows you to build your logic in a much easier fashion by simply dragging over the options you want. You may switch back and forth between each method if you wish, but please be aware that since the advanced logic allows for greater complexity, it may not be able to be switched over to the Drag-N-Drop method if it becomes too complex.

Choose method below for the following field: **occup_oth** - 5.1 Lainnya, sebutkan / Other, specify

☒ Advanced Branching Logic Syntax [How to use](#) [Branching Logic](#) [Smart Variables](#)

Show the field ONLY if...









[occup] = '12'

Test logic with a record: -- select record --

Clear logic

[occup] = '12'

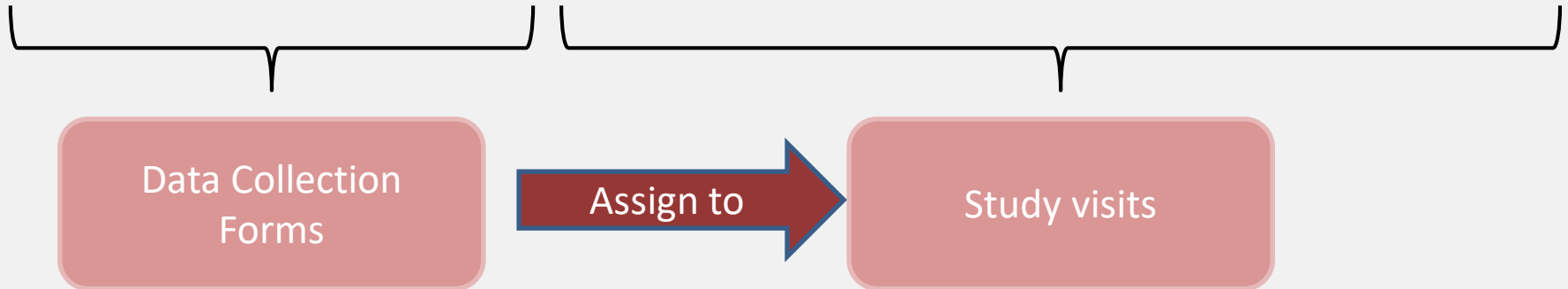
REDCap – Events (Study visits)

		Event #	Event Name	Custom Event Label  (optional)	Unique event name  (auto-generated)
		1	Screening / Enrollment		screening_enrollm_arm_1
		2	MDA Round 1 - Day 1		mda_round_1_day_1_arm_1
		3	Week 8 Follow-up		week_8_followup_arm_1
		4	MDA Round 2 - Day 1		mda_round_2_day_1_arm_1
		5	End of Study		end_of_study_arm_1
Add new event			<input type="text"/> Descriptive name for this event	<input type="text"/> Custom Event Label (optional) Example: [visit_date], [weight] kg	

Define Event
numbers and names

REDCap – Events (Study visits)

Data Collection Instrument	Screening / Enrollment (1)	MDA Round 1 - Day 1 (2)	Week 8 Follow-up (3)	MDA Round 2 - Day 1 (4)	End of Study (5)
Demografi / Demographics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Kriteria Inklusi & Ekslusi / Inclusion & Exclusion Criteria	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sistem Informasi Geografis / Location Information	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Faktor Risiko / Risk Factors	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Koleksi Sampel / Sample Collection	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Mass Drug Administration	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Status Akhir Penelitian / Study Disposition	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>



REDCap – Data Quality (queries)

Data Quality

This module will allow you to execute data quality rules upon your project data to check for discrepancies in your data. Listed below are some pre-defined data rules that you may utilize and run. You may also create your own rules or edit, delete, or reorder the rules you have already created. To find discrepancies for a given rule, simply click the Execute button next to it, or click the Execute All Rules button to fire all the rules at once. It will provide you with a total number of discrepancies found for each rule and will allow you to view the details of those discrepancies by clicking the View link next to each. [Read more detailed instructions.](#)

Data Quality Rules

Execute rules: All All except A&B Clear

Apply to: -- All records --

Rule #	Rule Name	Rule Logic (Show discrepancy only if...)	Real-time execution ?	Total Discrepancies	Delete rule?
A	Missing values*	-		Execute	
B	Missing values* (required fields only)	-		Execute	
C	Field validation errors (incorrect data type)	-		Execute	
D	Field validation errors (out of range)	-		Execute	
E	Outliers for numerical fields (numbers, integers, sliders, calc fields)**	-		Execute	
F	Hidden fields that contain values***	-		Execute	
G	Multiple choice fields with invalid values	-		Execute	
H	Incorrect values for calculated fields	-		Execute	
	<div>Check Age</div> <div>Add</div> <div>Enter descriptive name for new rule (e.g., Participants below age 18)</div>	<div>[age] < 18</div> <div>Valid</div> <div>Enter logic for new rule (e.g., [age] < 18)</div> <div>How do I use special functions?</div>	<div><input checked="" type="checkbox"/></div> <div>Execute in real time on data entry forms ?</div>		

Standard Rules

Custom Rules

REDCap – Online Data Entry

Edit existing data

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 5

Choose an existing Subject Identification Number

✓ -- select record --
1001
1002
1003
1004
1005

Enter a new or existing Subject Identification Number

Add new participants

Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 5

Choose an existing Subject Identification Number

-- select record --

Enter a new or existing Subject Identification Number

1006





REDCap – Online Data Entry

Record Home Page












Record "1006" is a new Subject Identification Number. To create the record and begin entering data for it, click any gray status icon below.

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event. If you wish, you may modify the events below by navigating to the [Define My Events](#) page.

Legend for status icons:

-  Incomplete
-  Incomplete (no data saved) ?
-  Unverified
-  Complete

NEW Subject Identification Number 1006

Data Collection Instrument	Screening / Enrollment	MDA Round 1 - Day 1	Week 8 Follow-up	MDA Round 2 - Day 1	End of Study
Demografi / Demographics					
Kriteria Inklusi & Eksklusi / Inclusion & Exclusion Criteria					
Sistem Informasi Geografis / Location Information					
Faktor Risiko / Risk Factors					
Koleksi Sampel / Sample Collection					
Mass Drug Administration					
Status Akhir Penelitian / Study Disposition					

Use Event schedule to navigate

Demographics at Screening

REDCap – Online Data Entry

Data
collection
questions

Demografi / Demographics

Adding new Subject Identification Number 1006

Event Name: **Screening / Enrollment**

Subject Identification Number 1006

DEMOGRAFI / DEMOGRAPHICS

Subject Initials * must provide value ABC

1. Tanggal lahir / Date of Birth * must provide value 11-10-1976 Today D-M-Y
dd/mm/yyyy

2. Jenis kelamin saat lahir / Sex at birth * must provide value
☒ Laki-laki / Male
☐ Perempuan / Female reset

3. Identitas gender saat ini / Current gender identity: * must provide value
☒ Laki-laki / Male
☐ Perempuan / Female
☐ Waria / Transgender
☐ Tidak tahu atau tidak mau memberitahu / Unknow of unwilling to disclose reset

4. Jengang pendidikan tertinggi / Highest education attainment * must provide value SMA atau sederajat / Senior high school

5. Kategori Pekerjaan / Occupation category * must provide value Lainnya / Other

5.1 Lainnya, sebutkan / Other, specify Data Manager

TANGGAL PERSETUJUAN SETELAH PENJELASAN & KODE SITE INFORMED CONSENT DATE & SITE CODE

1. Tanggal persetujuan setelah penjelasan / Informed consent date * must provide value 11-10-2018 Today D-M-Y
dd/mm/yyyy

2. Lokasi (Rumah) / Site (Home) * must provide value 2
1-99

3. Lokasi (Tempat Kerja) / Site (Place of work) 3
1-99

Form Status

Complete? Complete

Save & Exit Form Save & ...

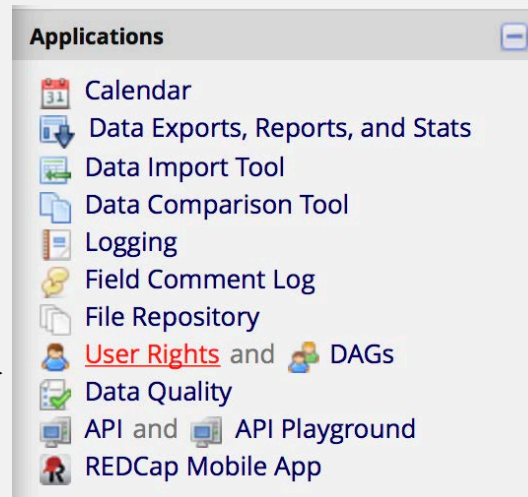
Responses

Form save
controls

REDCap – User Management

- REDCap super user add the people to REDCap user accounts (name, email address)
- Once created, the user will receive an email with log in information to REDCap.
- Data Manager add the REDCap user to the project that he/she needs to work on.

User Rights
function



REDCap – User Management

Creating new role "Test Role"

You may set the rights for the user below by checking the boxes next to the application tools to which you wish to grant them access. You may also grant them or deny them access to individual data collection instruments, if so desired. To save your selections, click the "Create role" button at the bottom of the page.

Creating new role "Test Role"

Basic Rights

Highest level privileges:

- Project Design and Setup ☐
- User Rights ☐
- Data Access Groups ☐

Privileges for data exports (including PDFs and API exports), reports, and stats:

- Data Exports ☐ No Access ☐ De-identified* ☒ Remove all tagged Identifier fields ☐ Full Data Set ☐
- Add / Edit Reports ☒ Also allows user to view ALL reports (but not necessarily all data in the reports)
- Stats & Charts ☒

Other privileges:

- Calendar ☒
- Data Import Tool ☐
- Data Comparison Tool ☐
- Logging ☐
- File Repository ☒
- Data Quality ☐ Create & edit rules ☐ Execute rules ☐
- API ☐ API Export ☐ API Import/Update ☐

Settings pertaining to the REDCap Mobile App:

- REDCap Mobile App ☐ Allows user to collect data offline in the mobile app
- Allow user to download data for all records to the app? ☐

Settings pertaining to project records: [Explain these settings](#)

- Create Records ☒
- Rename Records ☐
- Delete Records ☐

Data Entry Rights

NOTE: The data entry rights *only* pertain to a user's ability to view or edit data on a web page in REDCap (e.g., data entry forms, reports). It has no effect on data imports or data exports.

	No Access	Read Only	View & Edit
Demografi / Demographics	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Kriteria Inklusi & Ekskusi / Inclusion & Exclusion Criteria	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Sistem Informasi Geografis / Location Information	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Faktor Risiko / Risk Factors	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Koleksi Sampel / Sample Collection	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Mass Drug Administration	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Status Akhir Penelitian / Study Disposition	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Create role Cancel

Basic Rights
(for Role)

Role Name

Form specific
Rights

Edit setup using REDCap Online Designer

Edit in Development mode

- Add/edit/delete/copy
- Enable validation
- Move orders of data field
- Preview data instrument
- Change different data types
- Add section header
- Add matrix of fields
- Add branching logic (hidden questions)
- Create new data collection instrument
- Rename or delete data collection instrument

Current instrument: **Demografi / Demographics** Preview instrument

Variable: record_id
Subject Identification Number
NOTE: The field above is the record ID field and thus cannot be deleted or moved. It can only be edited.
Add Field Add Matrix of Fields

DEMOGRAFI / DEMOGRAPHICS
Add Field Add Matrix of Fields

Variable: subjinit
Subject Initials
* must provide value
Add Field Add Matrix of Fields

Variable: dob
1. Tanggal lahir / Date of Birth
dd/mm/yyyy Today ONLY
Add Field Add Matrix of Fields

Variable: age Branching logic: (dob) = ""
1.1 Jika tanggal tidak tertulis lengkap (Umur) / If full date is not recorded (Age)
tahun / years
Add Field Add Matrix of Fields

Variable: sex
2. Jenis kelamin saat lahir / Sex at birth
* must provide value
☐ Laki-laki / Male
☐ Perempuan / Female
Add Field Add Matrix of Fields reset

REDCap - Data Exports

- Export data in various formats
- Microsoft excel CSV (comma-separated) format
 - Labels data : the data either with the full headers and answer labels
 - Raw data : just with the answer codes
 - Other analysis and statistical software

REDCap - Data Exports

Name of Report:	<input type="text" value="Demographics"/>
Description (optional): <small>Displayed on page below report name</small>	<div><div></div><div>HTML may be used in order to add links or to add style to text.</div><div>Expand</div></div>

STEP 1

User Access: Choose who sees this report on their left-hand project menu ?

☒ **All users** - OR - ☐ **Custom user access** (Choose specific users, roles, or data access groups who will have access)

STEP 2

Fields to include in report

Quick Add

Add all fields from selected instrument

✓ -- choose instrument --

Demografi / Demographics
Kriteria Inklusi & Eksklusi / Inclusion & Exclusion Criteria...
Sistem Informasi Geografis / Location Information
Faktor Risiko / Risk Factors
Koleksi Sampel / Sample Collection
Mass Drug Administration
Status Akhir Penelitian / Study Disposition

Field 1	record_id "Subject Identification Number"		Instrument: Demografi / Demographics	
Field 2	subjinit "Subject Initials"		Instrument: Demografi / Demographics	
Field 3	dob "1. Tanggal lahir / Date of Birth"		Instrument: Demografi / Demographics	
Field 4	age "1.1 Jika tanggal tidak tertulis lengkap"		Instrument: Demografi / Demographics	
Field 5	sex "2. Jenis kelamin saat lahir / Sex at bir		Instrument: Demografi / Demographics	
Field 6	gender "3. Identitas gender saat ini / Curr		Instrument: Demografi / Demographics	
Field 7	transgender "3.1 Jika Waria, sebutkan / If		Instrument: Demografi / Demographics	
Field 8	education "4. Jengang pendidikan tertingi		Instrument: Demografi / Demographics	
Field 9	occup "5. Kategori Pekerjaan / Occupation		Instrument: Demografi / Demographics	
Field 10	occup_oth "5.1 Lainnya, sebutkan / Other		Instrument: Demografi / Demographics	
Field 11	ic_date "1. Tanggal persetujuan setelah p		Instrument: Demografi / Demographics	
Field 12	site_home "2. Lokasi (Rumah) / Site (Hom		Instrument: Demografi / Demographics	
Field 13	site_work "3. Lokasi (Tempat Kerja) / Site		Instrument: Demografi / Demographics	
Field 14	site_code_na "3.1 Lokasi (Tempat Kerja) -		Instrument: Demografi / Demographics	
Field 15	demografi_demographics_complete "Con		Instrument: Demografi / Demographics	
Field 16	Type variable name or field label			

Select Form

Available fields
(may include
or exclude)

REDCap – Data Exports

Subject Identification Number record_id	Event Name redcap_event_name	Subject Initials subjinit	1. Tanggal lahir / Date of Birth dob	1.1 Jika tanggal tidak tertulis lengkap (Umur) / If full date is not recorded (Age) age	2. Jenis kelamin saat lahir / Sex at birth sex	3. Identitas gender saat ini / Current gender identity: gender	3.1 Jika Waria, sebutkan / If Transgender, specify transgender	4. Jengang pendidikan tertinggi / Highest education attainment education	5. Kategori Pekerjaan / Occupation category occup	5.1 Lainnya, sebutkan / Other, specify occup_oth	1. Tanggal persetujuan setelah penjelasan / Informed consent date ic_date	2. Lokasi (Rumah) / Site (Home) site_home	3. Lokasi (Tempat Kerja) / Site (Place of work) site_work	3.1 Lokasi (Tempat Kerja) - Tidak berlaku / Site (Place of work) - Not applicable? site_code_na	Complete? demografi_demographics_complete
1001	Screening / Enrollment	MJD	23-06-1978		Laki-laki / Male (1)	Laki-laki / Male (1)		Diploma (D1/D2/D3) / Diploma 1-3 years (5)	Pendidikan atau Akademia / Education or Academia (10)		15-02-2018	22	10		Complete (2)
1002	Screening / Enrollment	KGD	12-01-1978		Laki-laki / Male (1)	Laki-laki / Male (1)			Lainnya / Other (12)	Clinical Research	15-02-2018	20	11		Complete (2)
1003	Screening / Enrollment	ABC	23-07-1983		Laki-laki / Male (1)	Laki-laki / Male (1)		S1 atau D4 / Bachelor or Diploma 4 years (6)	Pertanian / Agriculture (1)		15-02-2018	03	05		Complete (2)
1004	Screening / Enrollment	TRS	12-07-1980		Laki-laki / Male (1)	Laki-laki / Male (1)		S2 atau S3 / Master or Doctor (7)	Pertanian / Agriculture (1)		15-02-2018	2	9		Complete (2)
1005	Screening / Enrollment	QRT	01-02-1990		Perempuan / Female (2)	Perempuan / Female (2)		Diploma (D1/D2/D3) / Diploma 1-3 years (5)	Sains + Teknologi / Science + technology (8)		15-02-2018	20	10		Incomplete (0)

REDCap – Tablet Data Entry



REDCap
Mobile App

INA-RESPOND: Schistosomiasis
Screening / Enrollment
Sistem Informasi Geografis Location Information

Show instrument controls

Subject Identification Number 5

Pekerja lapangan menemani subjek ke lokasi kerjanya / Field worker to accompany subject to place of work

1. Apakah pekerja lapangan menemani subjek ke lokasi kerjanya? / Did the field worker accompany the subject to his/her place of work?

☒ Ya/ Yes
☐ Tidak / No

[reset](#)

* must provide value

1.1 Sistem informasi geografis lokasi kerja (Lintang GPS) / GIS Place of Work Location information (GPS Latitude)

-6.1959864

[update](#) [reset](#)

1.2 Sistem informasi geografis lokasi kerja (Bujur GPS) / GIS Place of Work Location information (GPS Longitude)

106.8236567

[update](#) [reset](#)

Form Status

Complete? Incomplete

[Save Record](#)

REDCap – Tablet Data Entry

INA-RESPOND: Schistosomiasis
Record - 1235
UNMOD = Unmodified | MOD = Modified | NEW = New | [BLANK] = Empty
Select Record
1235
Create New Record
NEW
1234

Subject



INA-RESPOND: Schistosomiasis
Record - 1009
UNMOD = Unmodified | MOD = Modified | NEW = New | [BLANK] = Empty
Select Event
Screening / Enrollment
MDA Round 1 - Day 1
Week 8 F/U
MDA Round 2 - Day 1
End of Study

Visit



INA-RESPOND: Schistosomiasis
Record - 1009 Event - Screening
Incomplete | Unverified | Complete | No data saved
Select Instrument
Demografi / Demographics
Kriteria Inklusi Eksklusi / Inclusion Exclusion Criteria
Sistem Informasi Geografis Location Information
Tanda Vital / Vital Signs

Collection Form

REDCap – Tablet Data Entry

INA-RESPOND: Schistosomiasis
Screening / Enrollment
Demografi / Demographics

Show instrument controls

Subject Identification Number 1009

DEMOGRAFI / DEMOGRAPHICS

Inisial Subyek / Subject Initials BCE

1. Tanggal lahir / Date of Birth 11-10-1978

dd/mm/yyyy Today D-M-Y

2. Jenis kelamin saat lahir / Sex at birth

☒ Laki-laki / Male
☐ Perempuan / Female

3. Identitas gender saat ini / Current gender identity:

☒ Laki-laki / Male
☐ Perempuan / Female
☐ Waria / Transgender
☐ Tidak tahu atau tidak mau memberitahu / Unknow of unwilling to disclose

4. Jenjang pendidikan tertinggi / Highest education attainment

☒ Tidak sekolah / None
☐ Tidak tamat SD atau sederajat / Not graduated from elementary

5. Kategori Pekerjaan / Occupation category

☒ Tidak ada / None
☐ Pertanian / Agriculture
☐ Peternakan / Animal Husbandry
☐ Perikanan / Fishing
☐ Kehutanan / Forestry
☐ Pertambangan / Mining
☐ Energi & Tenaga / Energy & power
☐ Industri / Industry
☐ Sains + Teknologi / Science + technology
☐ Medis / Medical
☐ Pendidikan atau Akademia / Education or Academia
☐ Militer atau Kepolisian / Military or Police
☐ Lainnya / Other

**TANGGAL PERSETUJUAN SETELAH PENJELASAN & KODE SITE
INFORMED CONSENT DATE & SITE CODE**

1. Tanggal persetujuan setelah penjelasan / Informed consent date 11-10-2018

dd/mm/yyyy Today D-M-Y

2. Lokasi (Rumah) / Site (Home) 2

1-99

3. Lokasi (Tempat Kerja) / Site (Place of work) 3

1-99

Form Status

Questions

