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# Data Management and REDCap Presentation

**BPAL OR Training of Trainers**

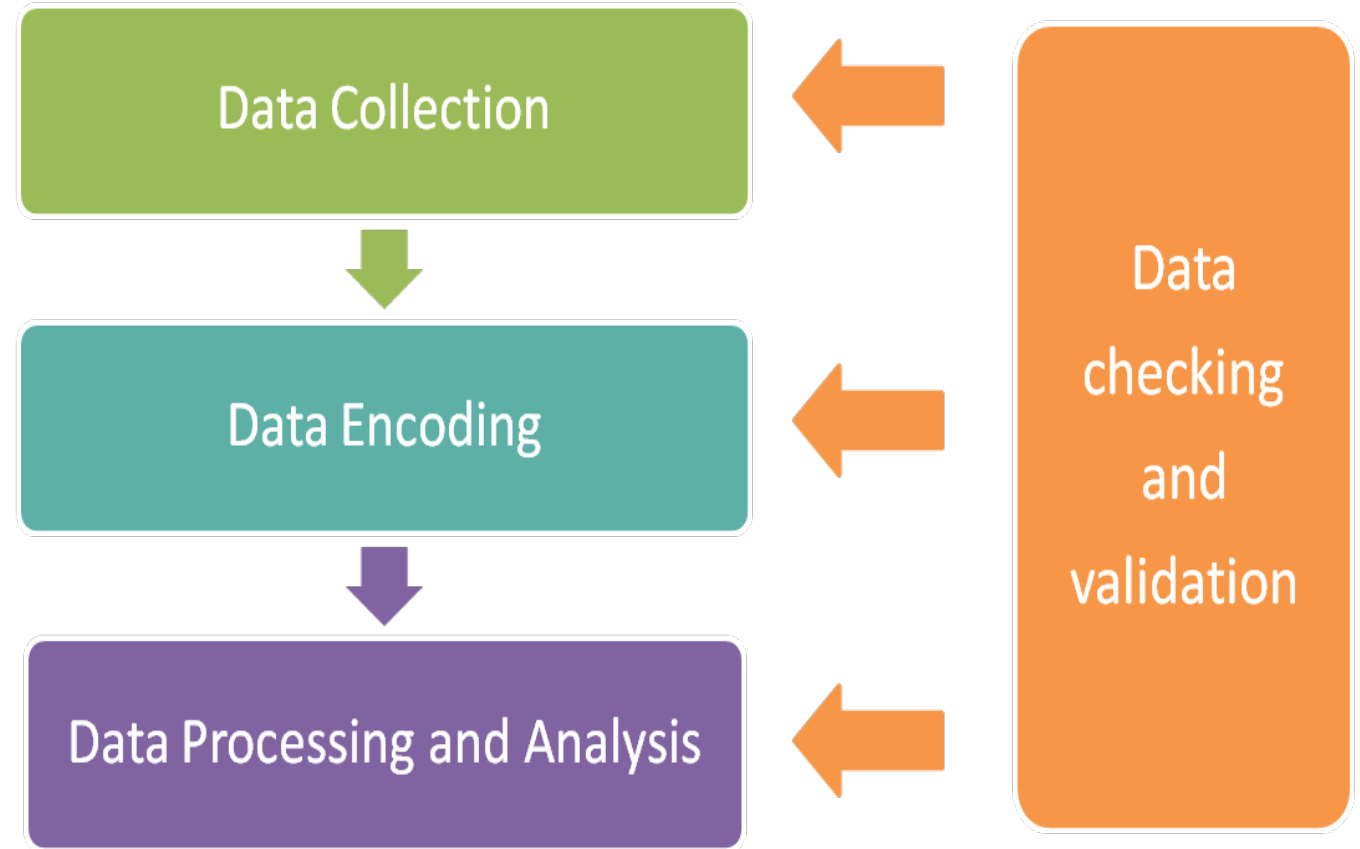
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**Research Specialist**

# Data Management Process

- There are 3 main areas in research where actual data are involved:



## Data Collection

- Data Sources
  - DR-TB Treatment Cards and other PMDT forms
  - Laboratory Results
  - IT IS
- Data of MDR/RR-TB patients satisfying the inclusion and exclusion criteria will be collected from all the patients enrolled in BPaL Operational Research.

## Data Collection

- 12 OR Sites in 10 Regions will participate:
  - NCR: Lung Center of the Philippines and Dr. Jose N. Rodriguez Memorial Hospital
  - Region 1: Region 1 Medical Center and Ilocos Training and Regional Medical Center
  - Region 3: Jose B. Lingad Memorial Regional Hospital
  - Region 4: Batangas Medical Center
  - Region 5: Sorsogon Medical Mission Group Hospital and Health Services
  - Region 6: Western Visayas Medical Center
  - Region 7: Eversley Childs Sanitarium and General Hospital

## Data Collection

- 12 OR Sites in 10 Regions will participate:
  - Region 9: Zamboanga City Medical Center
  - Region 10: Northern Mindanao Medical Center
  - Region 11: Southern Philippines Medical Center



## Procedures in the Collection and Management: Obtain Data Sources

- OR site staff must collect data from the data sources and **must ensure** the following:
  - patients included meet the inclusion and exclusion criteria. If this is not done, a written report should be submitted to the research team duly signed by the treatment center head.
  - completeness and consistency of data across all data sources for each patient.

# Procedures in the Collection and Management: Obtain Data Sources

- OR site staff must collect data from the data sources and **must ensure** the following:
  - scan the data sources (must ensure that the maximum size of every file is 50MB) and upload in REDCap. Make sure there is no identifier (e.g. name, address, etc.) of the patients.
  - All data sources must ensure compliance to the Data Privacy Act 2012.

# Procedures in the Collection and Management: **Fill- out Data Collection Forms**

- Guidelines in completing the Data Collection Forms
  - Must use black permanent pens and write legibly in print form and not script.
  - must ensure data completeness and accuracy by double checking that:
    - the data written in the forms are exactly the same as that in the data source/s
    - all due items are filled out
    - number of pages in each form are complete
  - All forms related to OR must be kept in a safe and secure location and OR site staff must observe strict data confidentiality.



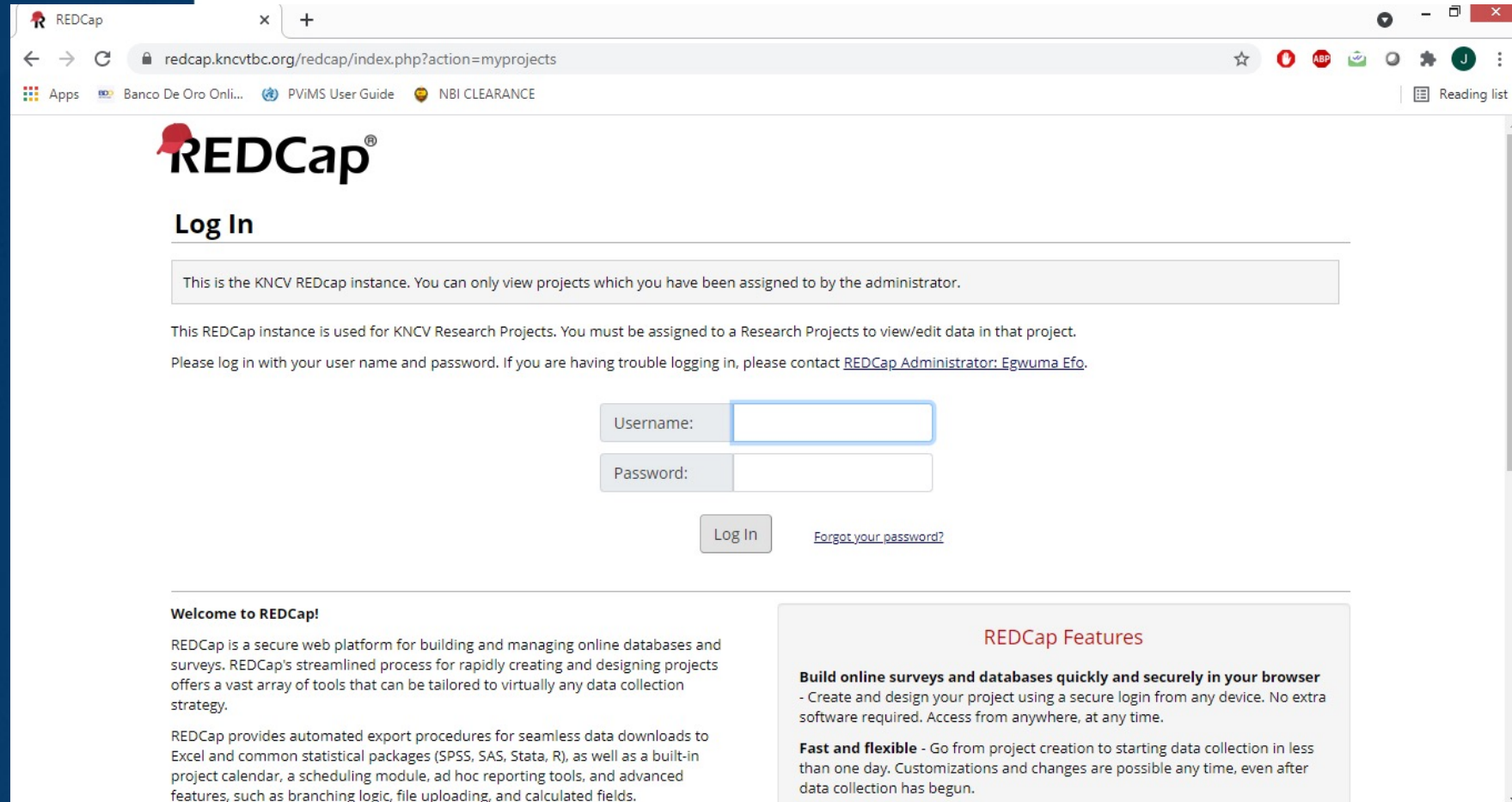
# Data Encoding

# What is REDCap?

- REDCap stands for Research Electronic Data Capture
- It is a browser based, meta data driven electronic data capture software.

# Steps on how to access REDCap?

1. Access through web link: <https://redcap.kncvtbc.org/redcap/index.php?action=myprojects> and key in your username and password.



The screenshot shows a web browser window with the URL [redcap.kncvtbc.org/redcap/index.php?action=myprojects](https://redcap.kncvtbc.org/redcap/index.php?action=myprojects). The page features the REDCap logo and a "Log In" section. A message box states: "This is the KNCV REDcap instance. You can only view projects which you have been assigned to by the administrator." Below this, a paragraph explains: "This REDCap instance is used for KNCV Research Projects. You must be assigned to a Research Projects to view/edit data in that project. Please log in with your user name and password. If you are having trouble logging in, please contact REDCap Administrator: Egwuma Efo." The login form includes fields for "Username:" and "Password:", a "Log In" button, and a link for "Forgot your password?". At the bottom, there are two informational sections: "Welcome to REDCap!" and "REDCap Features".

**Welcome to REDCap!**

REDCap is a secure web platform for building and managing online databases and surveys. REDCap's streamlined process for rapidly creating and designing projects offers a vast array of tools that can be tailored to virtually any data collection strategy.

REDCap provides automated export procedures for seamless data downloads to Excel and common statistical packages (SPSS, SAS, Stata, R), as well as a built-in project calendar, a scheduling module, ad hoc reporting tools, and advanced features, such as branching logic, file uploading, and calculated fields.

**REDCap Features**

**Build online surveys and databases quickly and securely in your browser** - Create and design your project using a secure login from any device. No extra software required. Access from anywhere, at any time.

**Fast and flexible** - Go from project creation to starting data collection in less than one day. Customizations and changes are possible any time, even after data collection has begun.

# Steps on how to access REDCap?

## 2. Once you logged in, go to “My Projects”

This REDCap instance is used for KNCV Research Projects. You must be assigned to a Research Projects to view/edit data in that project.

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

Project Title	Records	Fields	Instruments	Type	Status
BPAL OR The Philippines	4	354	38 forms		

REDCap 10.9.1 - © 2021 Vanderbilt University

# Steps on how to access REDCap?

## 3. Click the “BPaL OR in the Philippines”

This REDCap instance is used for KNCV Research Projects. You must be assigned to a Research Projects to view/edit data in that project.

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#) To review which users still have access to your projects, visit the [User Access Dashboard](#).

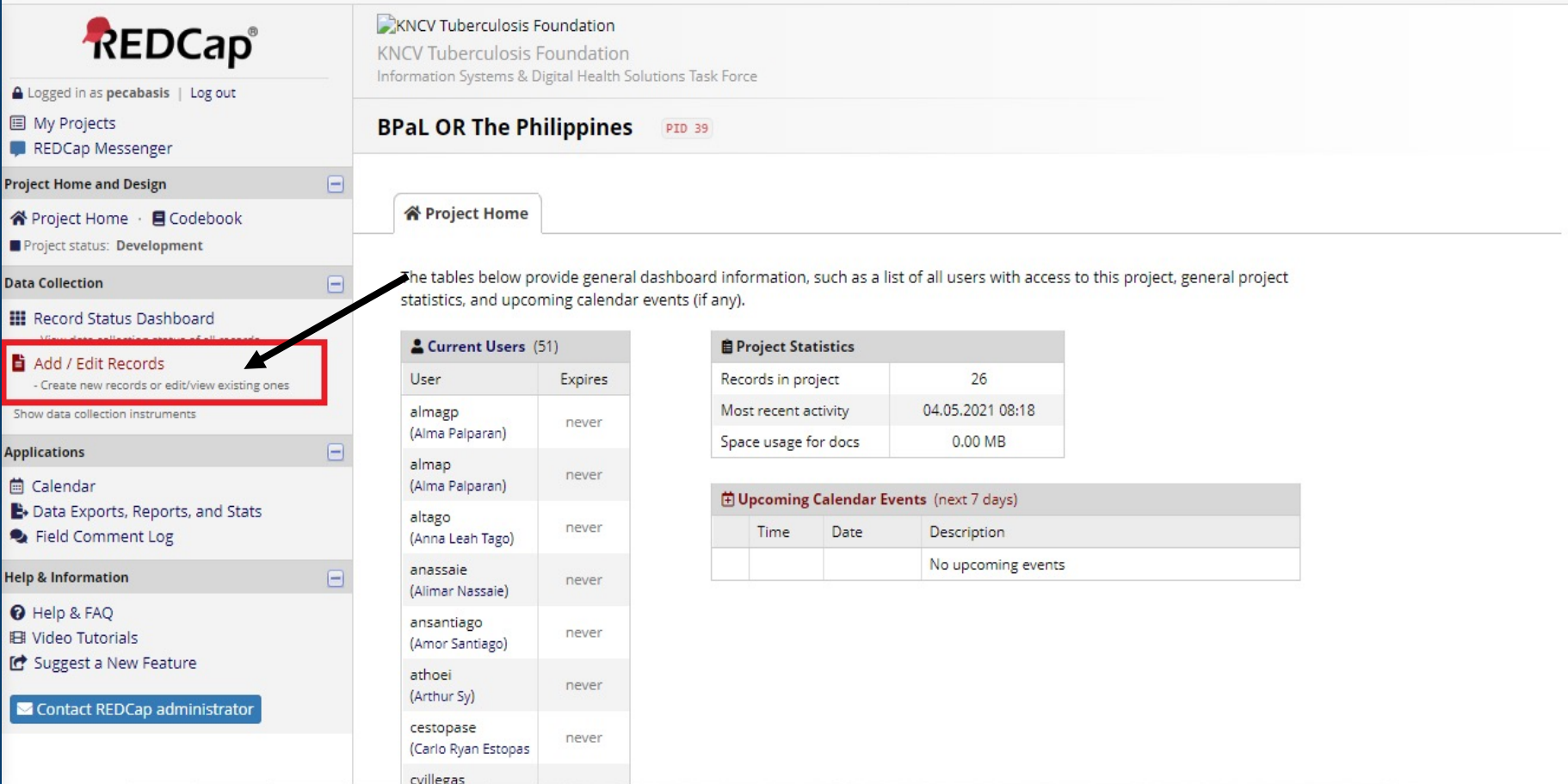
**My Projects** [Organize](#) [Collapse All](#)

Project Title	Records	Fields	Instruments	Type	Status
<b>BPaL OR The Philippines</b>	4	354	38 forms		

REDCap 10.9.1 - © 2021 Vanderbilt University

# Steps on how to add new patients

1. On the left side of the screen, under the data collection section, click on the “Add/Edit Records”



The screenshot displays the REDCap interface for the project "BPaL OR The Philippines" (PID 39). The left sidebar contains a navigation menu with sections: "Project Home and Design", "Data Collection", "Applications", and "Help & Information". The "Add / Edit Records" option is highlighted in the "Data Collection" section. An arrow points from this option to the main dashboard area.

The main dashboard area includes a "Project Home" button and a text box stating: "The tables below provide general dashboard information, such as a list of all users with access to this project, general project statistics, and upcoming calendar events (if any)."

The dashboard contains three tables:

- Current Users (51)**: A table listing users and their expiration dates.
- Project Statistics**: A table showing project metrics.
- Upcoming Calendar Events (next 7 days)**: A table showing upcoming events.

User	Expires
almagp (Alma Palparan)	never
almap (Alma Palparan)	never
altago (Anna Leah Tago)	never
anassaie (Alimar Nassaie)	never
ansantiago (Amor Santiago)	never
athoei (Arthur Sy)	never
cestopase (Carlo Ryan Estopas)	never
cvillegas	

Records in project	26
Most recent activity	04.05.2021 08:18
Space usage for docs	0.00 MB

Time	Date	Description
		No upcoming events







# Steps on how to add new patients

4. After encoding all the required data, nurses should leave the form status as “incomplete”. Doctors must review all the encoded data and be the one to mark it as “complete”.

The screenshot shows a patient registration form with the following fields and values:

- Study Site Name:** Jose B. Lingad Memorial General Hospital (dropdown menu)
- Study Site Code:** 43
- Patient Study Screening Number:** 001
- Patient number in DR-TB Treatment Register:** 43-21-0001
- Participant's Initials:** JMS
- Gender:** Female (radio button selected)
- Date of birth:** 27-08-1954
- Age (yr):** 66
- Patient Study ID:** 43/001/43-21-0001
- Form Status:** Incomplete (dropdown menu)

Arrows point to the 'Form Status' dropdown menu and the 'Incomplete' option. The form also includes 'Save & Exit Form', 'Save & ...', and '-- Cancel --' buttons.

# Steps on how to add new patients







5. Click the drop down arrow on the form status, save options. **Always choose "Save & Go To Next Form"**.

The screenshot shows a form interface with a yellow header labeled "Form Status". Below the header, there is a "Complete?" label and a dropdown menu currently set to "Incomplete". To the right of the dropdown are two blue buttons: "Save & Exit Form" and "Save & ...". Below these buttons is a grey button labeled "-- Cancel --". The "Save & ..." button is open, showing a dropdown menu with four options: "Save & Stay", "Save & Go To Next Form", "Save & Exit Record", and "Save & Go To Next Record". The "Save & Go To Next Form" option is highlighted with a red rectangular border.

## Steps on how to add new patients

Once you click the “save & go to the next form”, it will go to the inclusion criteria data collection instrument. On the left side of your screen, you will see a ‘red light’ or color in the circle. Color code means the following:

**Legend for status icons:**

 Incomplete	 Incomplete (no data saved) <input type="checkbox"/>
 Unverified	   Many statuses (all same)
 Complete	 Many statuses (mixed)



## Steps on how to add new patients

**6. Encode all the answers pertaining to certain Data Collection Instrument. Again, choose “Save & Go To Next Form”. Repeat step 5 and proceed to the next step.**

## Things to remember

1. Read the SOP on Data Collection and Management
2. Do not share your password to anyone.
3. ALWAYS REMEMBER/Write in the Data Collection Form the Record ID no. of your patient/s.
4. OR sites should encode within **48 hours**.
5. **Always choose “Save and Go to the Next Form”** to avoid getting to the next patient.

## Things to remember

6. OR sites can upload source document up to 50MB each file.
7. OR sites must redact all personal data of the patients.
8. OR sites must check the completeness and consistency of the data.
9. Form status:
  - Unverified – Nurses
  - Verified – Doctors
  - Complete – Research Team
10. All MDR TB patients must be entered to the REDCap regardless of their enrollment status in BPAL OR.

# Data Checking and Validation

- **Completeness**
  - The physical count of the Data Collection Forms (DCFs) should match the count of patients included in the study
  - Inspect each page of the data collection form and ensure that all items/fields were answered
- **Consistency**
  - Fields or variables in the data collection form that are related to each other should have consistent data

# Data Checking and Validation

## ■ Data validation and editing

- Identify and note the registration number/s of patients with data queries
- Obtain the paper data collection form of the patient and verify if the encoded data are the same. If the data issue is due to an **encoding error** (e.g. actual laboratory results written in the DCF is different from the encoded data in REDCap), correct the encoded data accordingly.
- If encoded data and data on the paper form have the same issue, then encoders should obtain the data source/s and verify the correct data. If the issue is due to a **recording error** (e.g. actual laboratory result is different from what is written in the DCF) based on the data source/s, revise the recorded information in the data collection form and edit the encoded data accordingly.
  - If revising an entry in the data collection form, strikethrough once the incorrect information and write the correct information beside it. The original information should still be legible in the data collection form so the changes made can be clearly identified. Any changes in the data collection form should be signed by the research team member who made the changes and the date of the change should be included.



# Data Checking and Validation

- Data validation and editing
  - If issues on the data are still not resolved after verifying the data sources, clarification should be immediately requested from staff of the health facility for further verification and resolution. Research Team should also be informed of any data queries on the data sources. Feedback regarding the data query and resolution from the health facility should be noted and recorded in the Resolution of Queries Log. OR site staff can use their initials.
  - No changes shall be made on the data collection form without data validation by the research specialists every week.



# Data Flow and Responsible Staff

- Data validation and editing
  - If issues on the data are still not resolved after verifying the data sources, clarification should be immediately requested from staff of the health facility for further verification and resolution. Research Team should also be informed of any data queries on the data sources. Feedback regarding the data query and resolution from the health facility should be noted and recorded in the Resolution of Queries Log. OR site staff can use their initials.
  - No changes shall be made on the data collection form without data validation by the research specialists every week.

# Data Checking and Validation

Online data validation/online remote monitoring

Research Specialists

DCF, Treatment Cards and official results for validation in REDCap

Research Specialists

If still with findings, research specialists will inform the facility via monitoring report.

Research Specialists

# Data Checking and Validation

Findings to be resolved by the OR site staff within 48 hours and they should use the resolution of queries log to indicate the status of the findings.

OR site staff

After resolving the findings, research specialists will validate the one week after the issuance of queries.

Research Specialists

# Data Checking and Validation

Once resolved, the research specialist will mark it as resolved in queries log.

OR site staff

If there are still findings, the research specialist will re-open the query and discuss it with the OR site.



Research Specialists to send a report to the OR site within 48 hours via email.


Research Specialists

## Things to remember

- OR site staff should send the Data Collection Forms to Research Team via email within 48 hours. Send it to [researchunit.lcpncpr@gmail.com](mailto:researchunit.lcpncpr@gmail.com) cc the assigned research specialist to your facility
  - Jamie Cabasis ([pecabasis.pbsp@gmail.com](mailto:pecabasis.pbsp@gmail.com)) – LCP, R1MC, BATMC, ECS, ZCMC and SPMC
  - Ma. Rhoda Torres-Cervas ([mtcervas.pbsp@gmail.com](mailto:mtcervas.pbsp@gmail.com)) – DJNRMH, ITRMC, JBL, SMMG, WVMC, NMMC

## Things to remember


- OR sites should expect a monitoring report from the research team within 48 hours.
- If there is a finding from the remote monitoring, OR site staff should resolve it within 48 hours upon receipt of the query.



## Guidelines in Sending Patients' Data via Email

- Make sure to redact the patients' identifier (e.g. name, birthday, address, etc.)
- Make sure it is on PDF File
- Write in the source documents the patient's unique identifier used in the BPAL OR
- Use the same email thread for each patient





## Guidelines in Sending Patients' Data via Email

- Use the patient's Record ID number as the subject of the email
- Use password when sending all DCFs.



## Archiving of Data Collection Forms

- All recording and reporting forms specific for the BPaL OR shall be kept and maintained by the LCP-NCPR research team after the all participants from all the facilities are done in post treatment follow up phase.

THANK YOU

