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Data Management and REDCap Presentation

BPAL OR Training of Trainers

May 19-21, 2021

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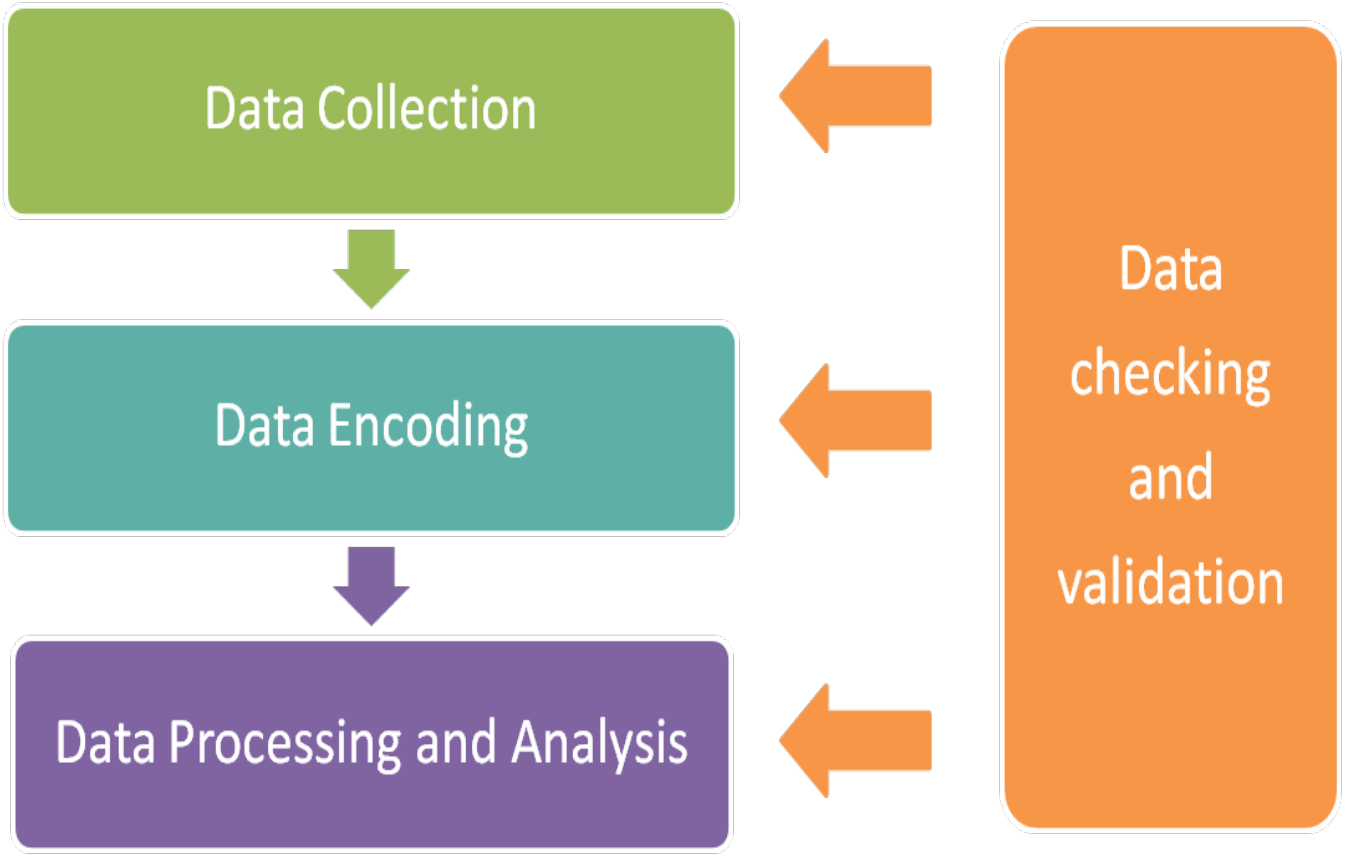
Research Specialist

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.

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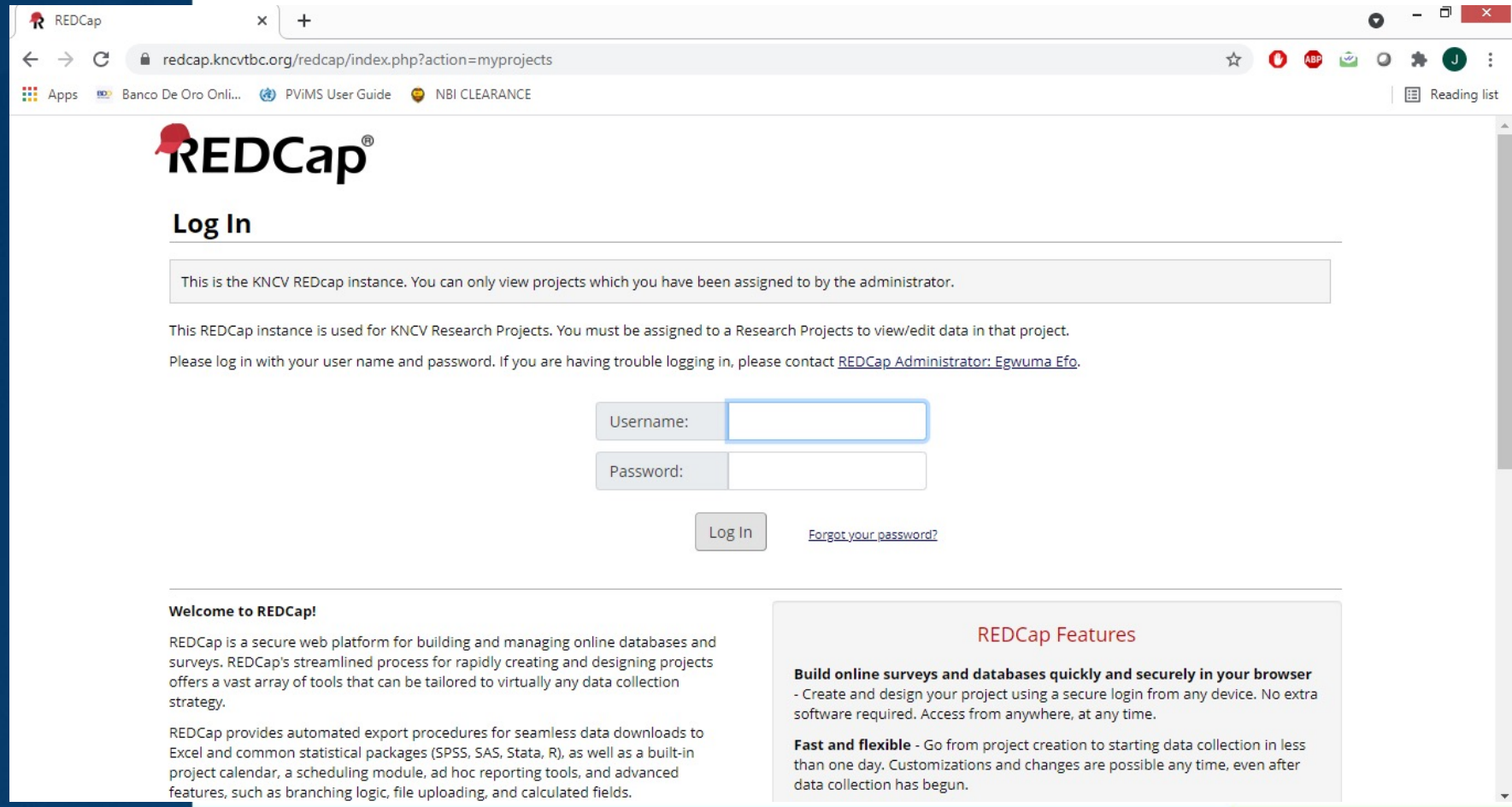
Data Encoding

What is REDCap?

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

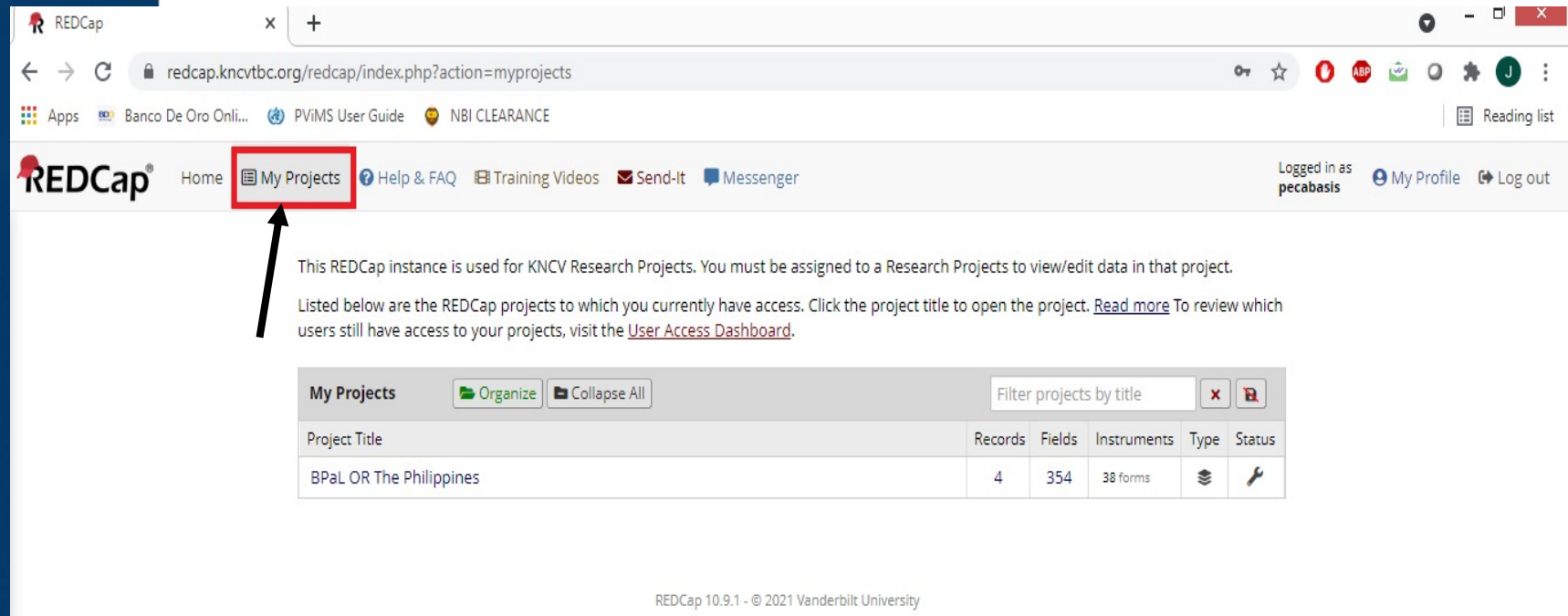
Steps on how to access REDCap?

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



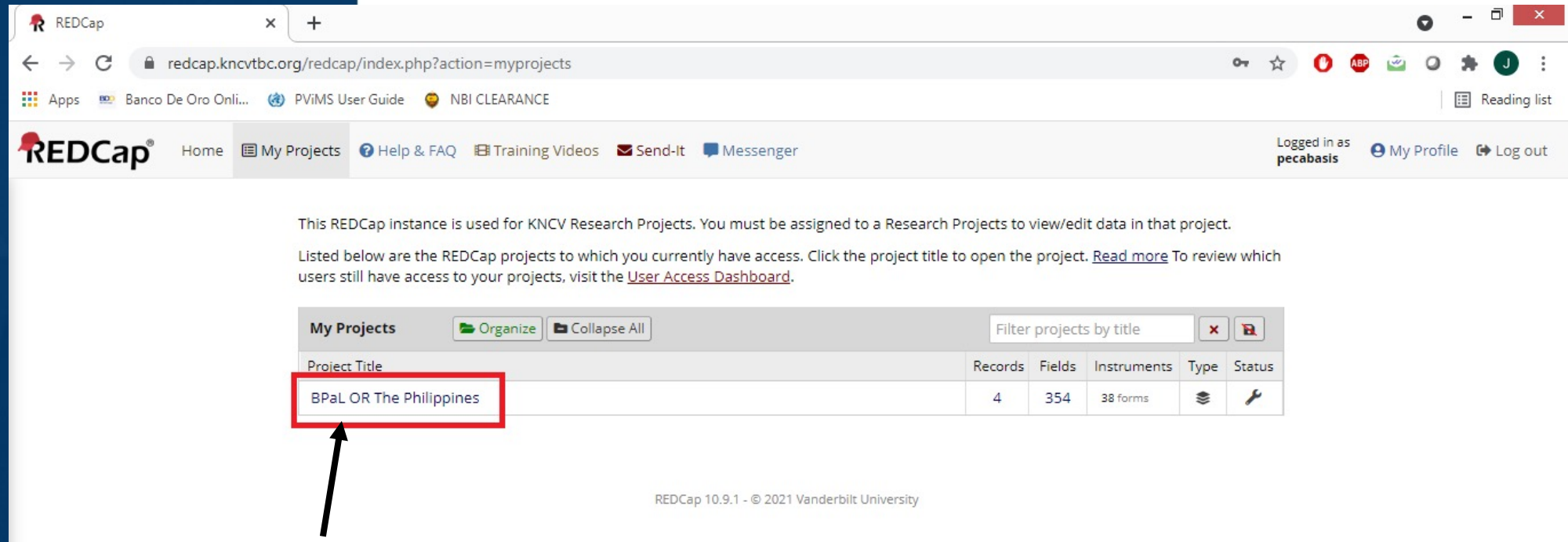
Steps on how to access REDCap?

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



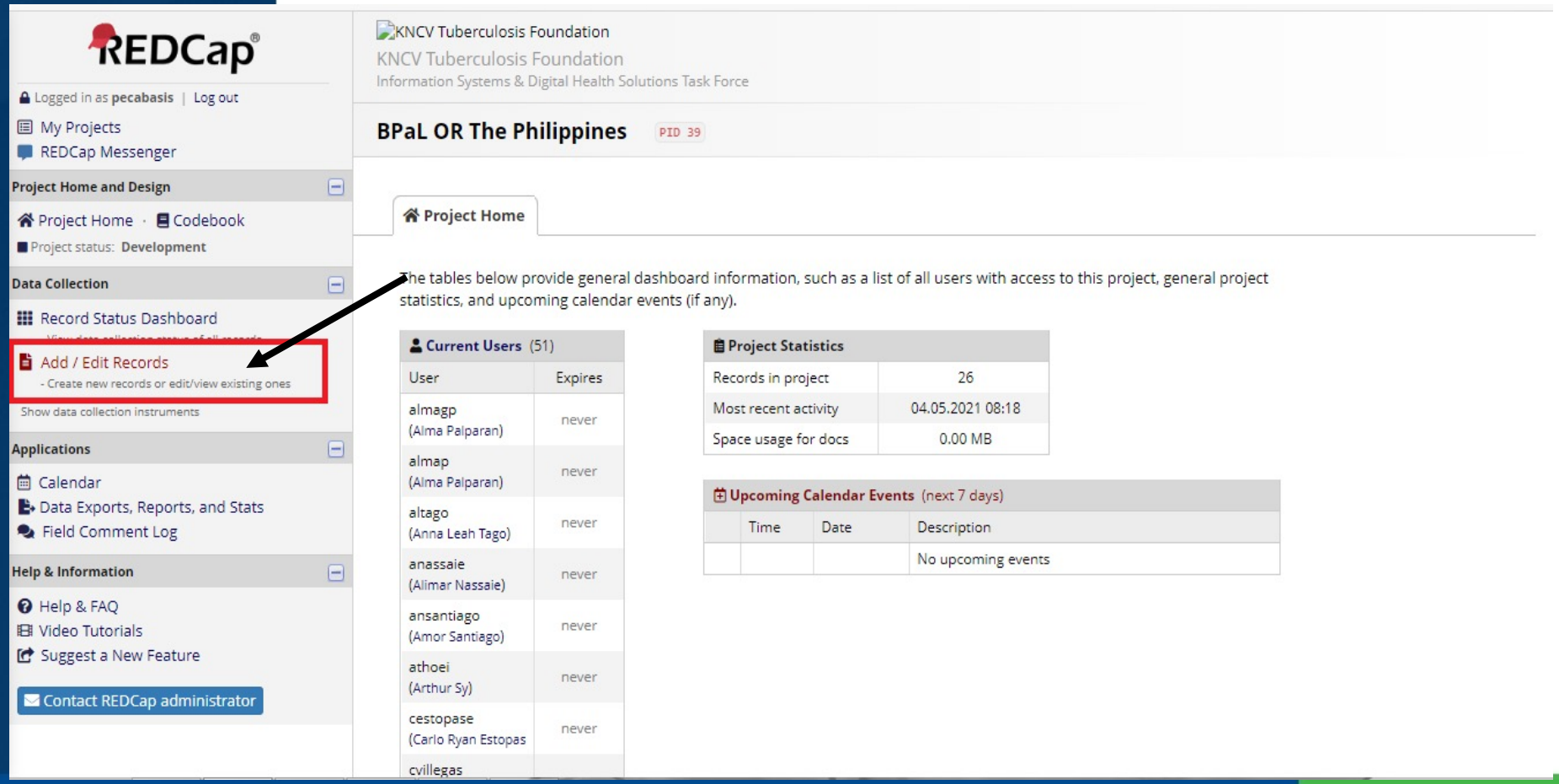
Steps on how to access REDCap?

3. Click the “BPaL OR in the Philippines”



Steps on how to add new patients

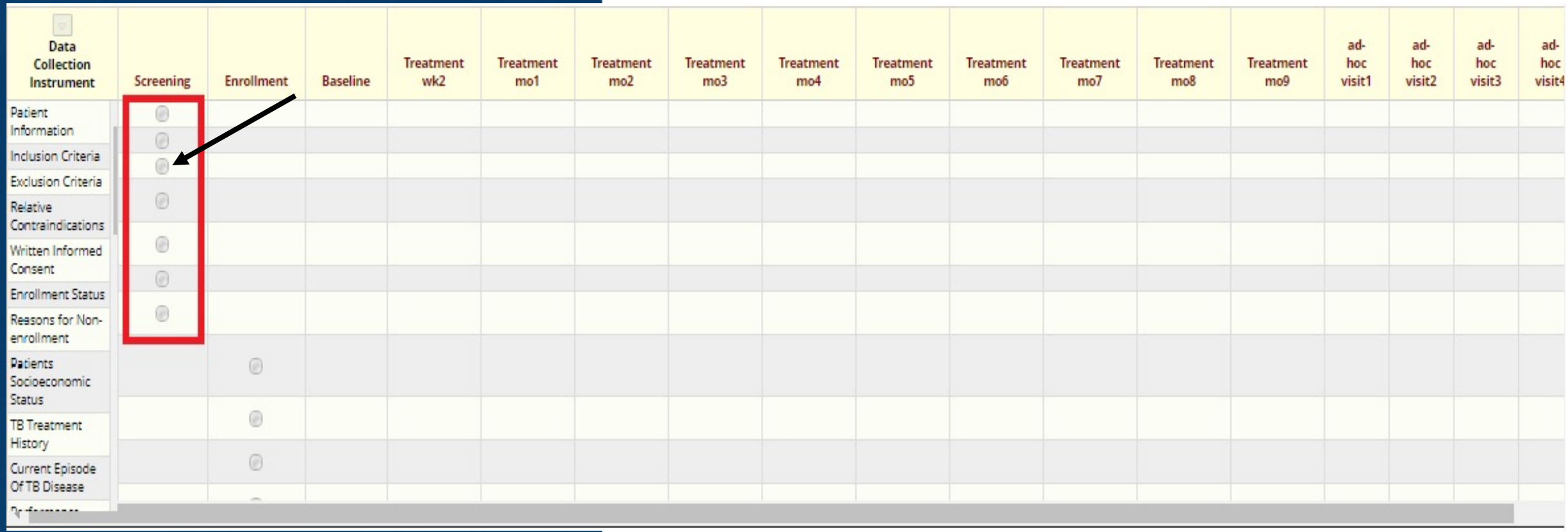
1. On the left side of the screen, under the data collection section, click on the “Add/Edit Records”



Steps on how to add new patients

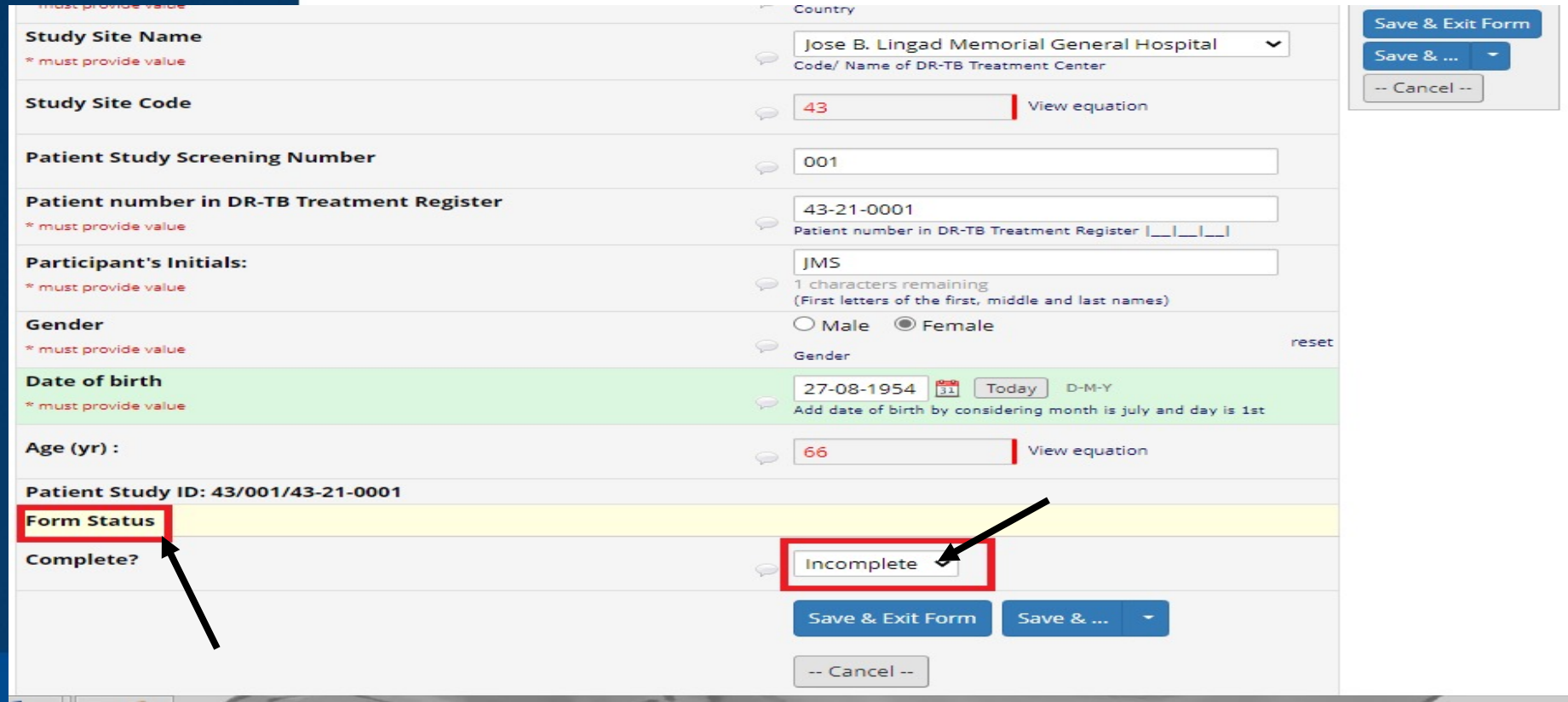
2. For the screening/patient information, encode all required data. Date format is mm/dd/yyyy.
Please do take note of the Record ID number of each patient that you are encoding.

3. Click the circle under status for each data collection instrument.



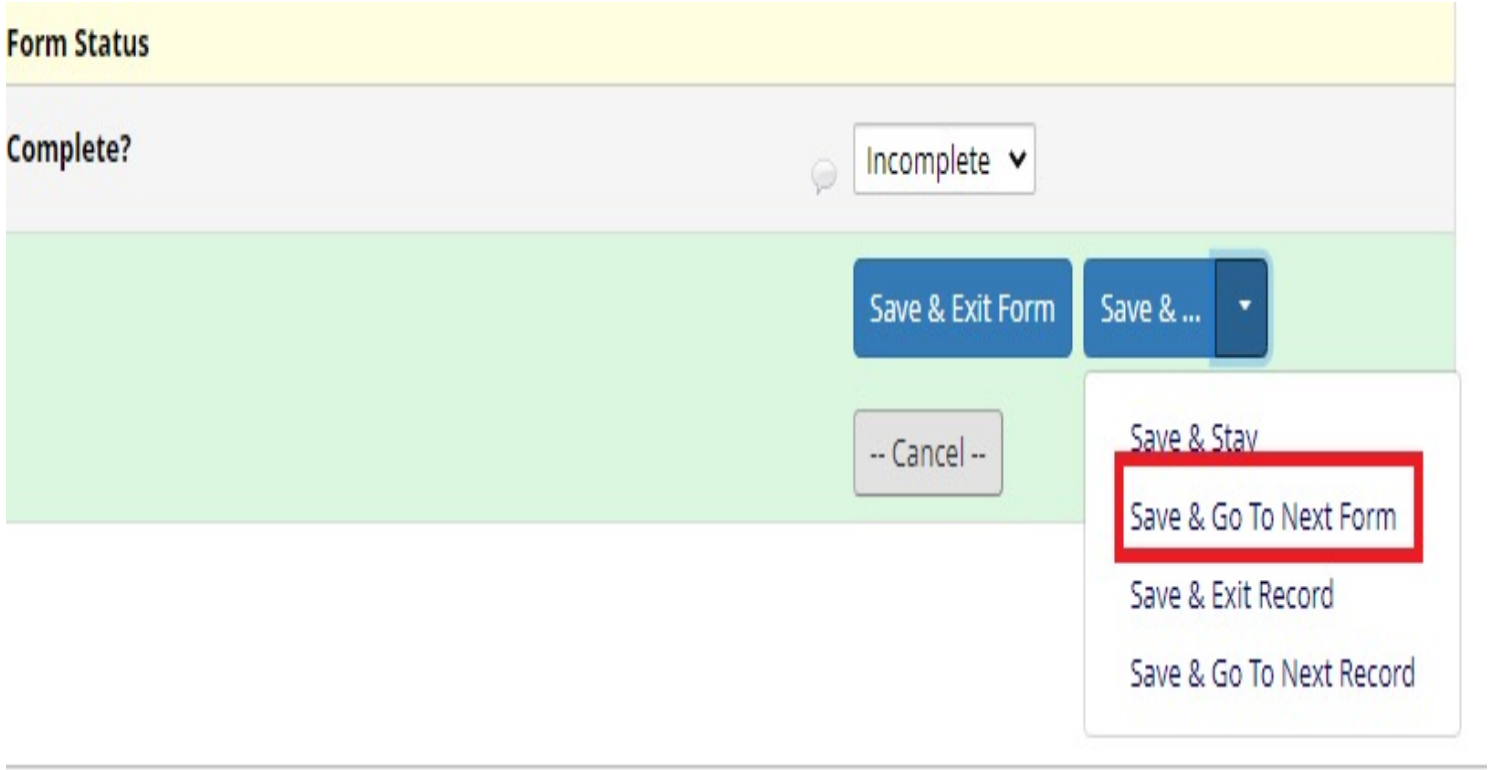
Steps on how to add new patients

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”.



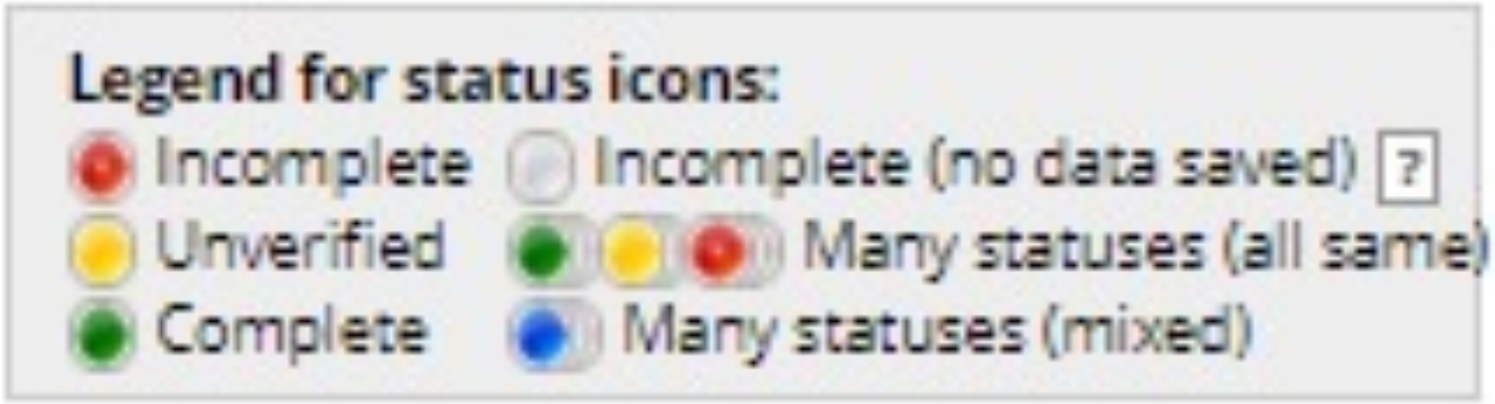
Steps on how to add new patients

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



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:



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

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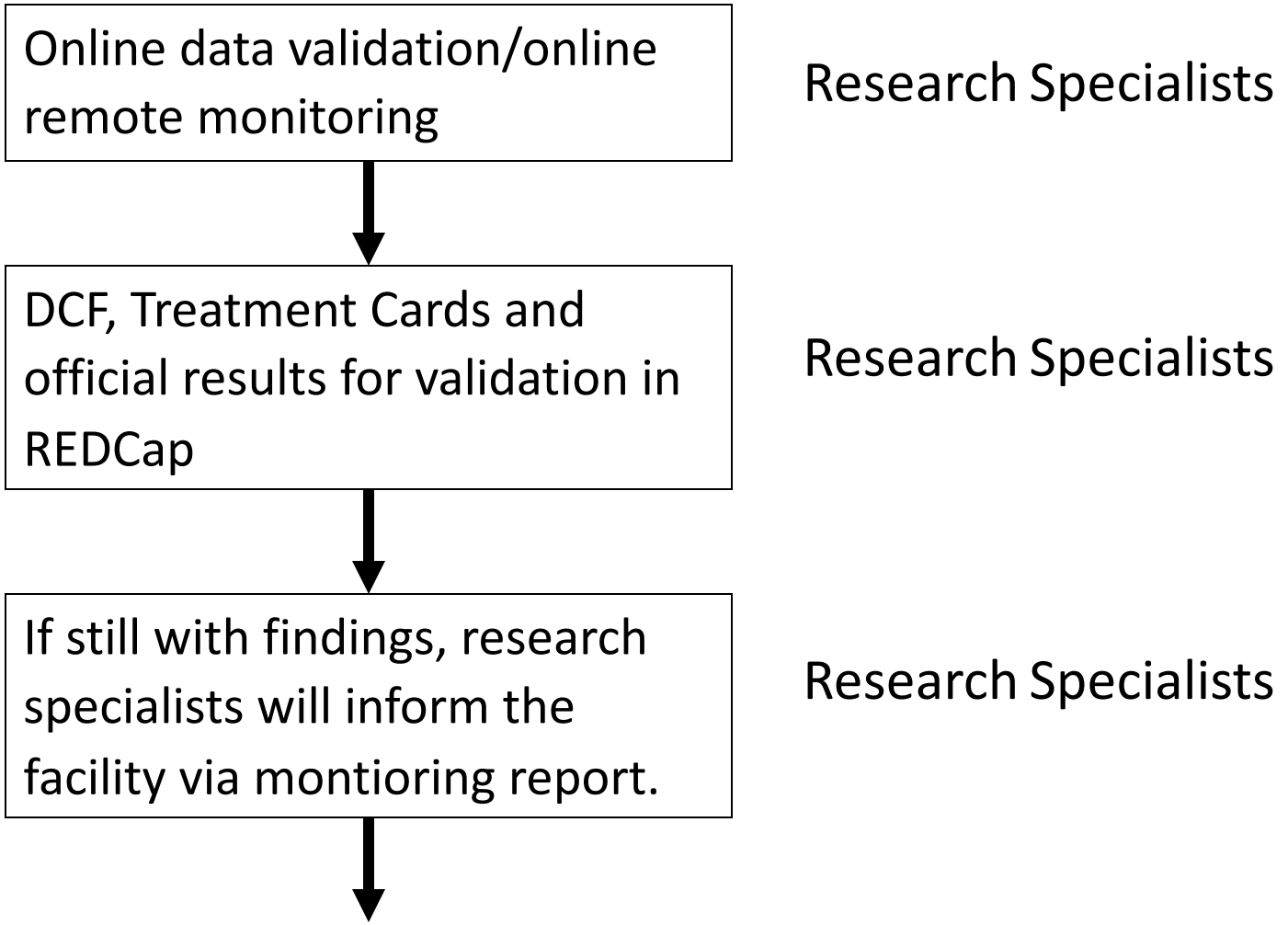
Data Checking and Validation



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.

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

OR site staff

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 cc the assigned research specialist to your facility

  - Jamie Cabasis (pecabasis.pbsp@gmail.com) – LCP, R1MC, BATMC, ECS, ZCMC and SPMC

  - Ma. Rhoda Torres-Cervas (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

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