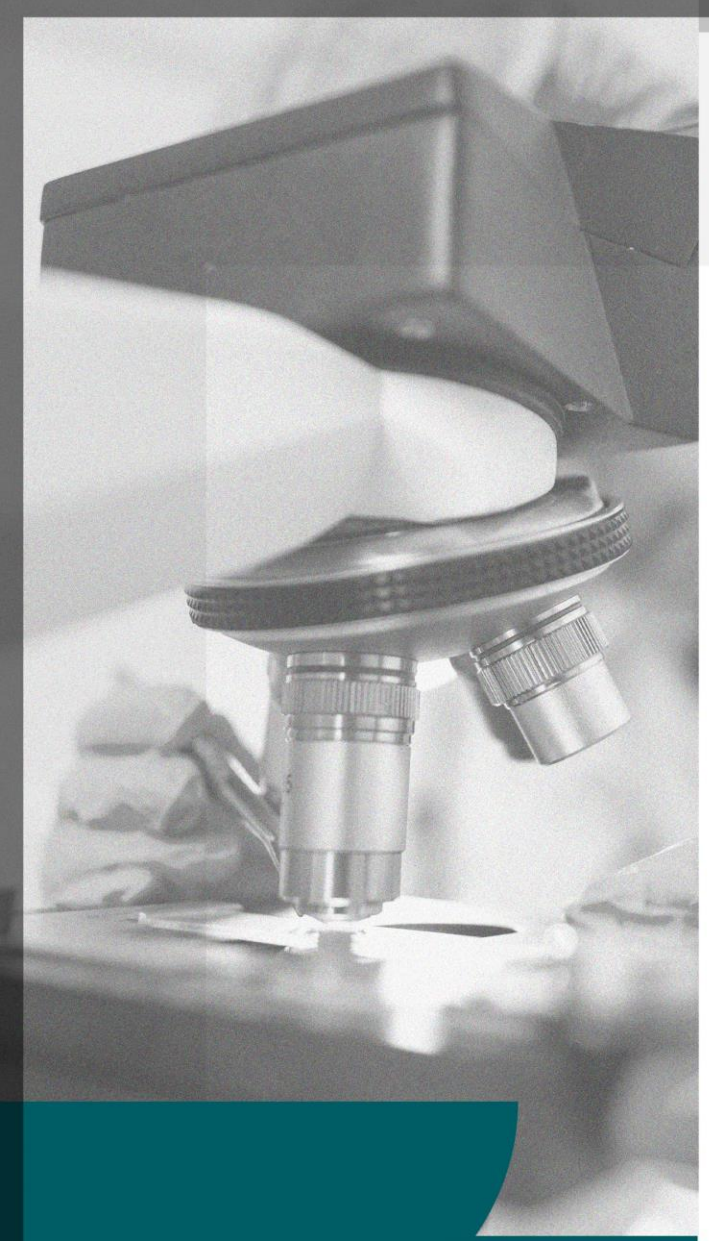


Philippine Clinical Research Professionals Inc.

GENERAL ASSEMBLY

PATIENTS, PURPOSE AND PASSION: HEART OF CLINICAL RESEARCH

Professional Subjects: Awareness, Recognition and Solutions

Prof Emeritus Lulu C Bravo, MD

University of the Philippines Manila

PCRP General Assembly 17 February 2023

Professor Emeritus Lulu Bravo MD

- Professor Emeritus at the College of Medicine, University of the Philippines Manila.
- Former Vice Chancellor for Research and Executive Director of the National Institutes of Health, University of the Philippines Manila (2005 – 2011)
- Convenor, Vaccine Study Group, UP National Institutes of Health
- President of the Immunization Partners in Asia Pacific (IPAP)
- Founding President and current Executive Director of the Philippine Foundation for Vaccination.
- 2018 Outstanding Professional in Medicine given by the Professional Regulation Commission of the Philippines. 2018 Pneumonia Fighter 2012 Asian Outstanding Pediatrician. 2011 Dr Jose Rizal Memorial Awardee for Academe.

Who are Professional Subjects?

- Primary:

Those who enroll in multiple clinical trials with the objective of generating income

Secondary:

- Special subset of subjects already enrolled who fake symptoms or illnesses to force an unscheduled visit or claim compensation to earn income from the study

Impact , Repercussions and Consequences of the presence of professional subjects in a Study:

- Patient safety is Threatened
- Data integrity are compromised
- Additional financial repercussions to the study sponsors
- Loss of confidence and credibility on the Country's Investigators

Case 1:

- Mr. V , 35 year old male, came for ICF discussion. During discussion, investigator noted that subject's first question was how much would he received after each visit, how often can he consult at site, and if site will cover all medical expenses of any illness and able to state the finer details of the study even before ICF discussion
- On further probing by sub-investigator, subject had slipped that he was included in another clinical trial similar to this trial

Case 2:

- Miss A , 25 year old female, was talking with Miss B, 24 year old female while waiting at the clinical trial site for their turn for ICF discussion.
- Miss A was narrating to Miss B what a clinical trial is about and how different the place of Site XYZ from Site LMN where she was assessed as screen failure.
- A study staff was seated nearby and heard the conversation thus investigators were discreetly alerted.

Case 3:

- During ICF discussion Ms. K, 25 year old female, relayed that she will give Php1000 of her Php2500 to Mr. T as he is the official recruiter for the study.

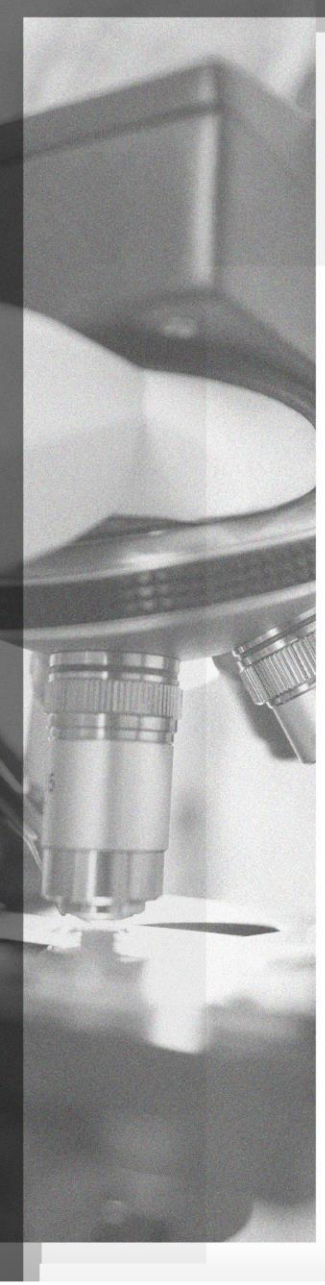
- This was referred by investigator to study coordinator who confirmed that there is no Mr. T. as part of the study team. Subject was informed.

Case 4:

- Mr. J, a 74 yr old male, had joined Clinical Study XYZ at site 1234 and agreed for monitoring for 1 year after 2 doses of IP vaccine
- He came in for unscheduled visit as reported symptoms meet criteria for ILI swab
- Presented the subject card for Clinical Study XYZ for site 7890
- Subject was referred to the investigator discreetly

Case 5:

- Mrs. E, 35 year old female, and daughter, 6 yr old, are participants of a clinical trial and came in for unscheduled visit due to symptoms
- Symptoms relayed by mother during her reporting to safety nurse did not match the symptoms reported to investigator nor does it match the physical findings of subject.
- Investigator also noted subject came to site for unscheduled visit almost every 2 weeks regularly

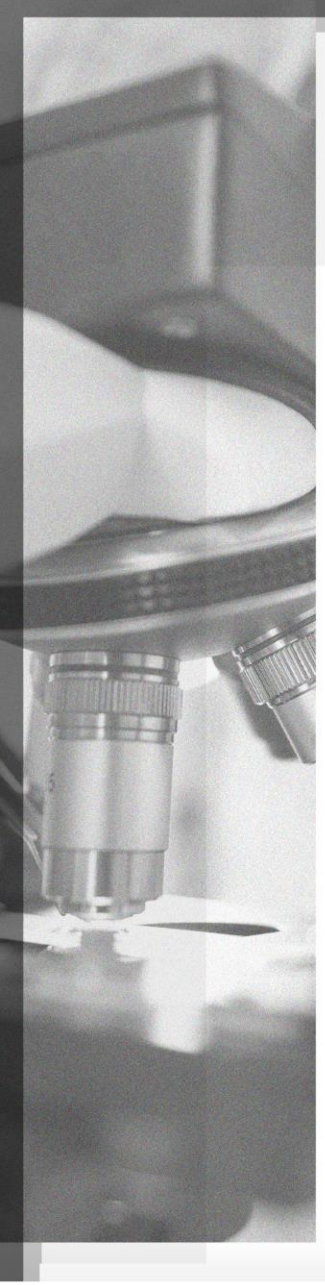


Red Flags

1. Inattentive to Informed Consent Process but more interested on the allowance to be given

2. Expressed certain fine details of trial procedures even before Investigators have provided them

3. Mention of other sites which Investigators know are doing similar trials

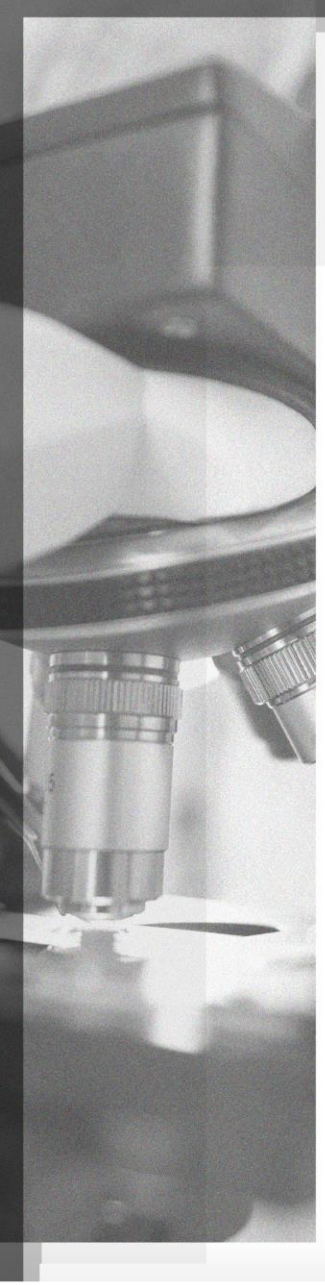


Red Flags

4. Mention of People who recruited them who are not involved in the study or not familiar with the site staff

5. Fake or Suspicious documents / Subject cards of Other sites presented

6. Multiple reports of symptoms for unscheduled visit that does not match details in reporting to safety nurse and investigators



Professional Subjects… SOLUTION/S

1. Avoid recruitment in high risk areas
2. Competitive recruitment is not beneficial
3. Vaccine Trial Registry - Data Base

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GENERAL ASSEMBLY
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Professional Subjects… SOLUTION/S

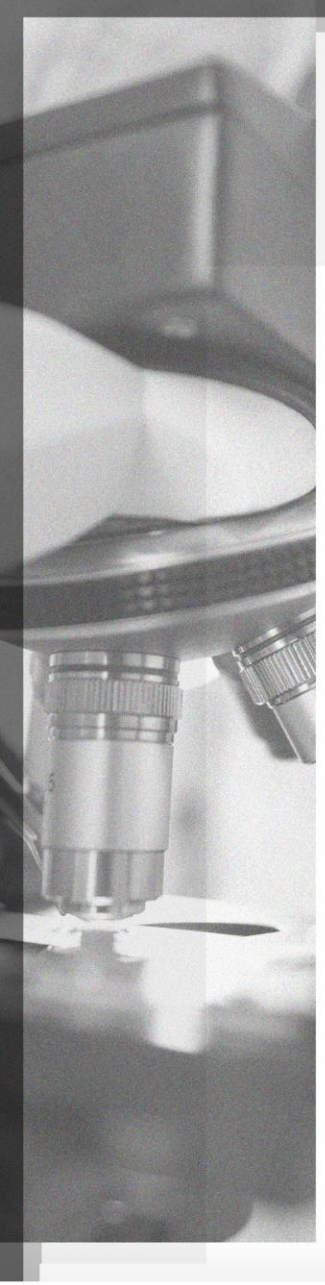
Vaccine Trial Registry - Data Base

Proposed By the National Clinical Trial and Translational Research Center (NCTTC) - National Institutes of Health-UPM

For Initiation in the COVID19 Vaccine Trials which are currently Voluminous !

REDCap : Research Electronic Data Capture

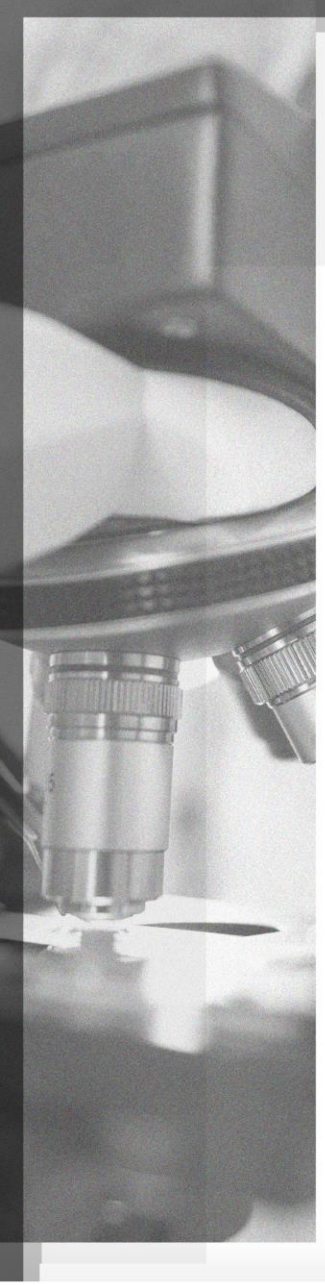
- Secure, web-based application used worldwide by a consortium of more than 3,000 research institutions in 126 countries, including Harvard, Yale and Oxford
- Used for collecting and managing research and administrative data to facilitate collaborative research activities



REDCap : Research Electronic Data Capture

- Designed to be used with minimal guidance even without technical knowledge on coding or prior experience with REDCap

- Has features of real-time data validation to ensure data quality and ready-to-use external modules for duplicate entry checks



Methodology : How it will be done

1. Invitation to Vaccine Trial Principal Investigators

- Including all incoming COVID-19 vaccine trials to utilize the registry
- NCTTC shall coordinate with the principal investigators (PI) of the vaccine trials being conducted in UP-PGH
- Letters will be sent to the principal investigators, their sponsors, and the contract research organization.
  - To state the purpose and design of the vaccine trial registry and suggested statement for the informed consent.

Methodology : How it will be done

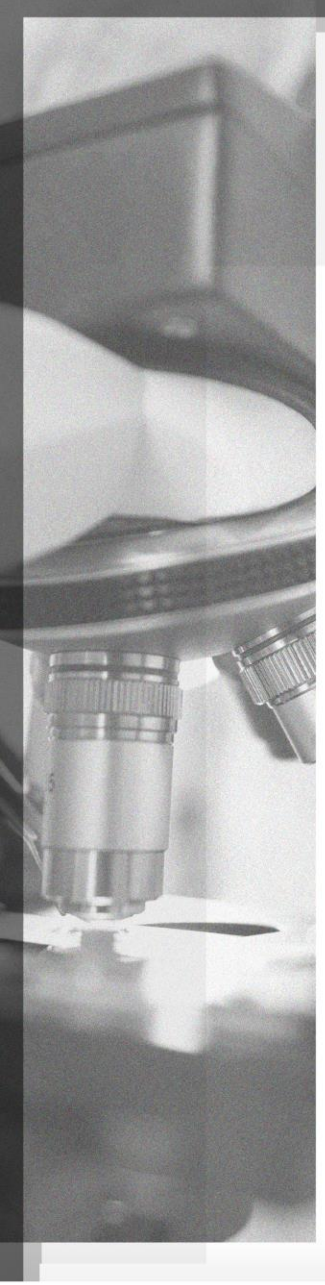
2. Accessing the Database

- Electronic data collection tool using REDCap
- Password-protected account and access to REDCap tool shall be granted to the identified data encoder of each clinical trial following submission of the signed REDCap Use and Users Responsibility Agreement.
- One data access group (DAG) will be created for each clinical trial to ensure that the trial only has access to its own data within REDCap.

Methodology : How it will be done

3. Data Entry

- Each designated data encoder of participating clinical trial shall undergo a short training with NCTTC for proper data entry using a REDCap mobile app or REDCap web browser.
- **Each clinical trial study shall provide subject data including full name (given name, middle name and surname), birthday and sex.**

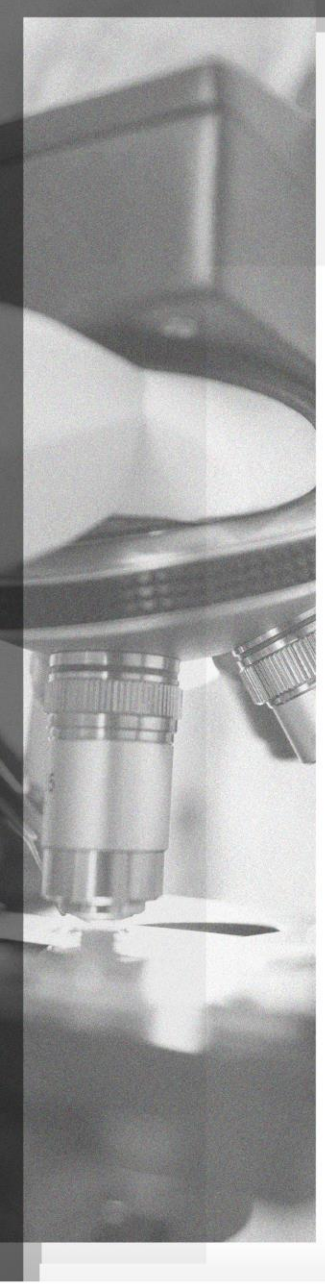


Methodology : How it will be done

4. Flagging for Duplicates

- Data entry will be considered a duplicate if ALL data fields are the same under one criteria group **OR** if ALL data fields are the same under another criteria group.

  Ex. data entry will be flagged as a duplicate if first name, last name and date of birth match an existing record.
- The database curator shall notify the designated trial data monitors of concerned studies via email within 24 hours of system flagging for potential participant duplicate.
- Data monitors/Principal investigators will evaluate further and ultimately decide if the participant is eligible.



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KEY MESSAGES

1. Be Aware : Subject Vigilance should be exercised especially during recruitment. Reporting of Professional Subjects would be Most Useful.

2. Give ample time for recruitment to avoid missing the “Red Flags”

3. Cooperation and working together of Sponsors, CROs, PIs and IRBs are essential

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Vaccine Study Group

VSG

1998

"Translating Science into Action"

Thank you!