Mahidol University
Faculty of Medicine
Siriraj Hospital

มหาวิทยาลัยมหิดล
คณะแพทยศาสตร์
ศิริราชพยาบาล

Conducting Educational Activities Among Research Stakeholders: HRPU Staff

Peeraya Chaowalitwong, Supattra Dakham, Adun Bunsi, Julaporn Pooliam, Sompol Tapechum, Woraphat Ratta-apha, Naraporn Prayoonwiwat

Siriraj Institutional Review Board
Bangkok, Thailand

หน่วยจริยธรรมการวิจัยใน

Speaker : Emeritus Prof.Naraporn Prayoonwiwat, MD

EDUCATION:

- B.Sc., M.D., Diploma in Medical Sciences (Medicine), Thai Board in Internal Medicine, Thai Board in Neurology, Certificate of Proficiency in Stroke and Neurosonology

PROFESSIONAL EXPERIENCE:

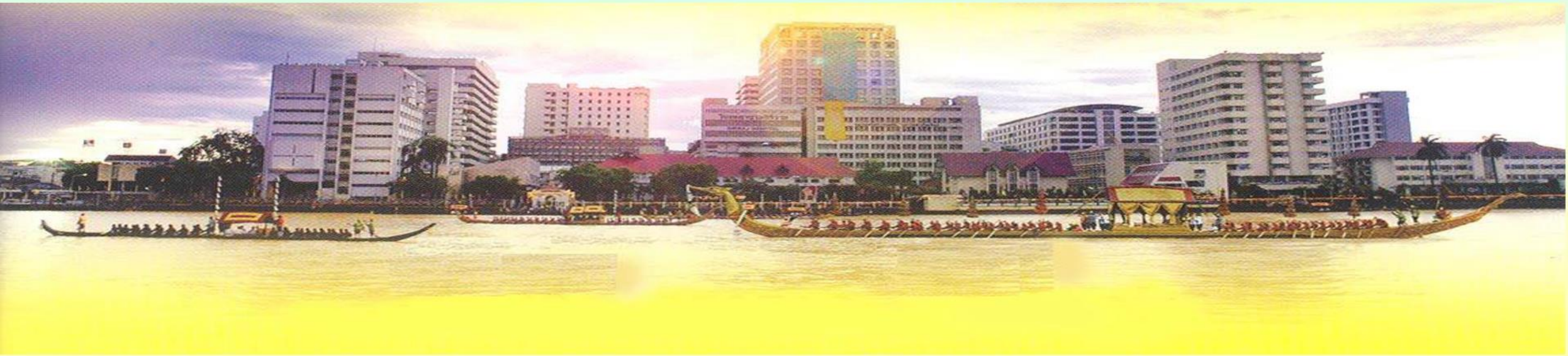
- Intern, Resident in Internal Medicine and Resident in Neurology, Siriraj Hospital;
- Visiting Scientist at Department of Neurology, Mayo Clinic, USA

Administrative position

- Chairperson
  Siriraj Institutional Review Board (SIRB), Faculty of Medicine Siriraj Hospital (since 2023)

Affiliation

- Division of Neurology, Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University



Introduction

HRPU Administration and Committees

Steering Committee

Policies in Culture, Good Governance and Ethics

Coordination Committee

HRPP Human Research Participant Protection

Steering Committee

Ethics in Human Subject Research

Administrative Committee

Human Research Protection Unit HRPU

Institutional Review Board IRB	Quality Assessment and Improvement	Education in Human Research Ethics	Research Participant Outreach Program
4 IRB Panels	QA/QI Subcommittee	Edu./Training Subcommittee	Outreach Subcommittee

Human Research Protection Office

IRB/HRPU Staff

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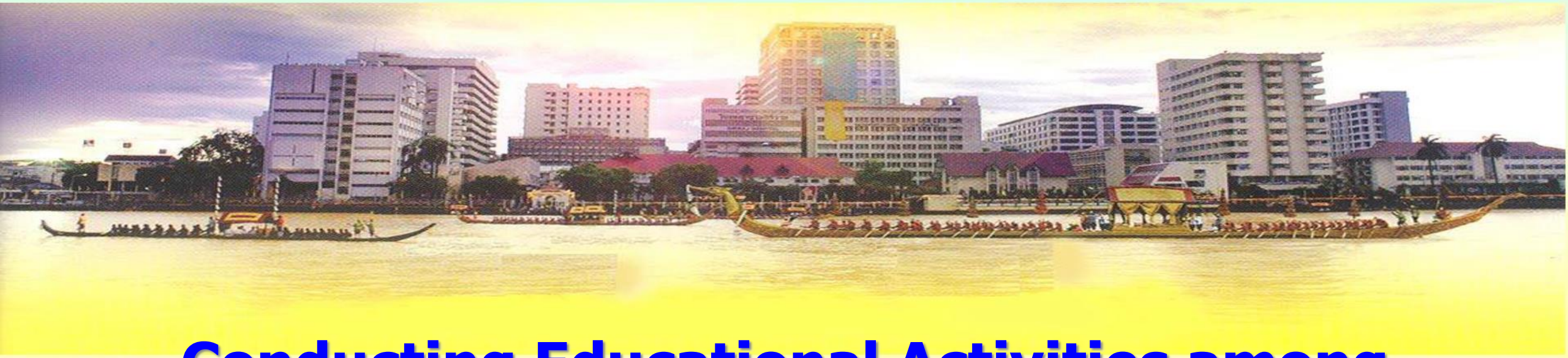
Roles and Responsibilities of HRPU Officers

- **Support protection of the rights and welfare of research participants by providing assistance to the SIRB in ..**
  - **competent reviews of study protocols**
  - **evaluation of progress report, update report**
  - **evaluation of adverse event report**
- **Well-equipped with knowledge and understanding in ethics in human research**
- **Continuous improvement via appropriate training**

Effective Methods in Training

Knowledge sharing

- Problem-based learning: examples, case scenarios
- Group discussion:
  - sharing views and experiences
  - learning from one another as a teamwork
  - freely communicating in relaxed environment
  - reflecting knowledge obtained
- Work instruction generated from conclusions



Conducting Educational Activities among Research Stakeholders: The HRPU Staff

Siriraj Institutional Review Board
Bangkok, Thailand

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Rationale:

- To increase competency and understanding of HRPU staff in providing effective responses to enquiries on initial reviews and post approval reports from investigators
- To plan for course syllabus adjustment of educational sessions by focusing on common enquiries as pro-active strategy

Materials and Methods: Steps

- Collect and categorize consultation/enquires received from investigators (Feb to Apr 2023)
- Design a set of questions on common problems in initial protocols submission and in continuing reviews (i.e., adverse event reports, protocol deviation, protocol amendment, annual report, close-out report)
- Validate the questionnaires by 3 experienced SIRB members for index of Item Objective Congruence (IOC)

COA no. SI 077/2023

Materials and Methods: Steps (2)

- **Educational activities: 2 workshops**
  - **Session 1: Interactive lectures on SOP relevant to the collected enquiries**
  - **Session 2: Group discussion on case scenarios giving opinions freely in 'relaxed environment'; ethical issues related to each case scenario explained, conclusion made, action plans given**
- **Questionnaires: as pre-test (preceding Session 1) and post-test (following Session 2)**
- **Analysis of findings**

Timeline

Siriraj Institutional Review Board
Certificate of Approval

COA no. Si 077/2023

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SIRB Protocol No. : 749/2565(IRB2)
Principal Investigator/Affiliation : Miss Peeraya Chaowalitwong / Human Research Protection Unit
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Duration of research : 1 year
Approval date : January 31, 2023
Expired date : January 30, 2024

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(Prof.Apichat Asavamongkolkul, M.D.) Dean of Faculty of Medicine Siriraj Hospital — 6 FEB 2023 date

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Submission to SIRB
20 Oct 2022

31 Jan 2023
SIRB Approval

Feb-Apr 2023
Data Collection, Categorize

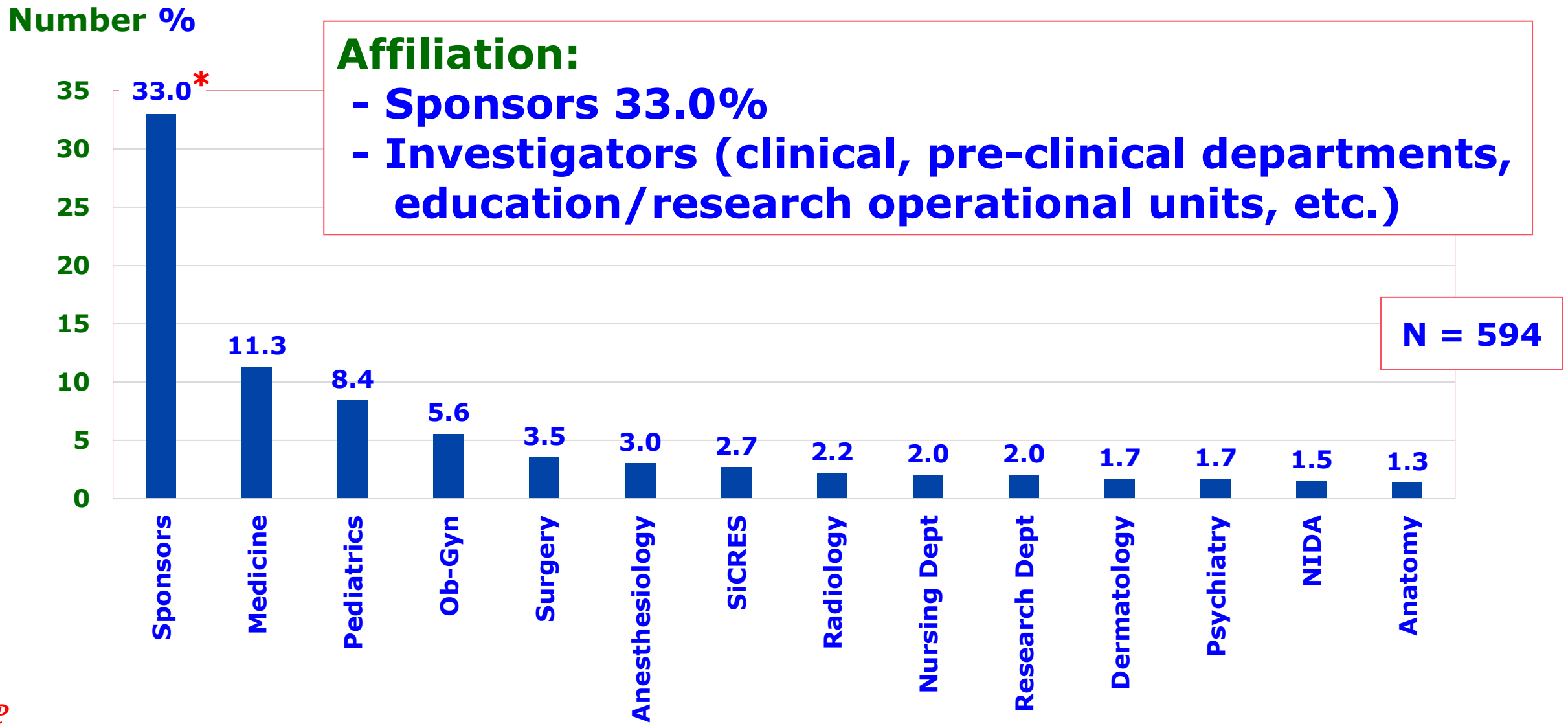
COA no. SI 077/2023

Ω NP

Results: Initial Survey (Feb-Apr 2023)

- Number: 594 questions (received within 60 working days)
- Contact type: telephone calls 98.5%, in person 1.5%
- Average time per contact: 4 minutes
- Review type: initial (50.8%), continuing (49.2%)

Results: Characteristics of Enquirers



Affiliation:

- Sponsors 33.0%
- Investigators (clinical, pre-clinical departments, education/research operational units, etc.)

N = 594

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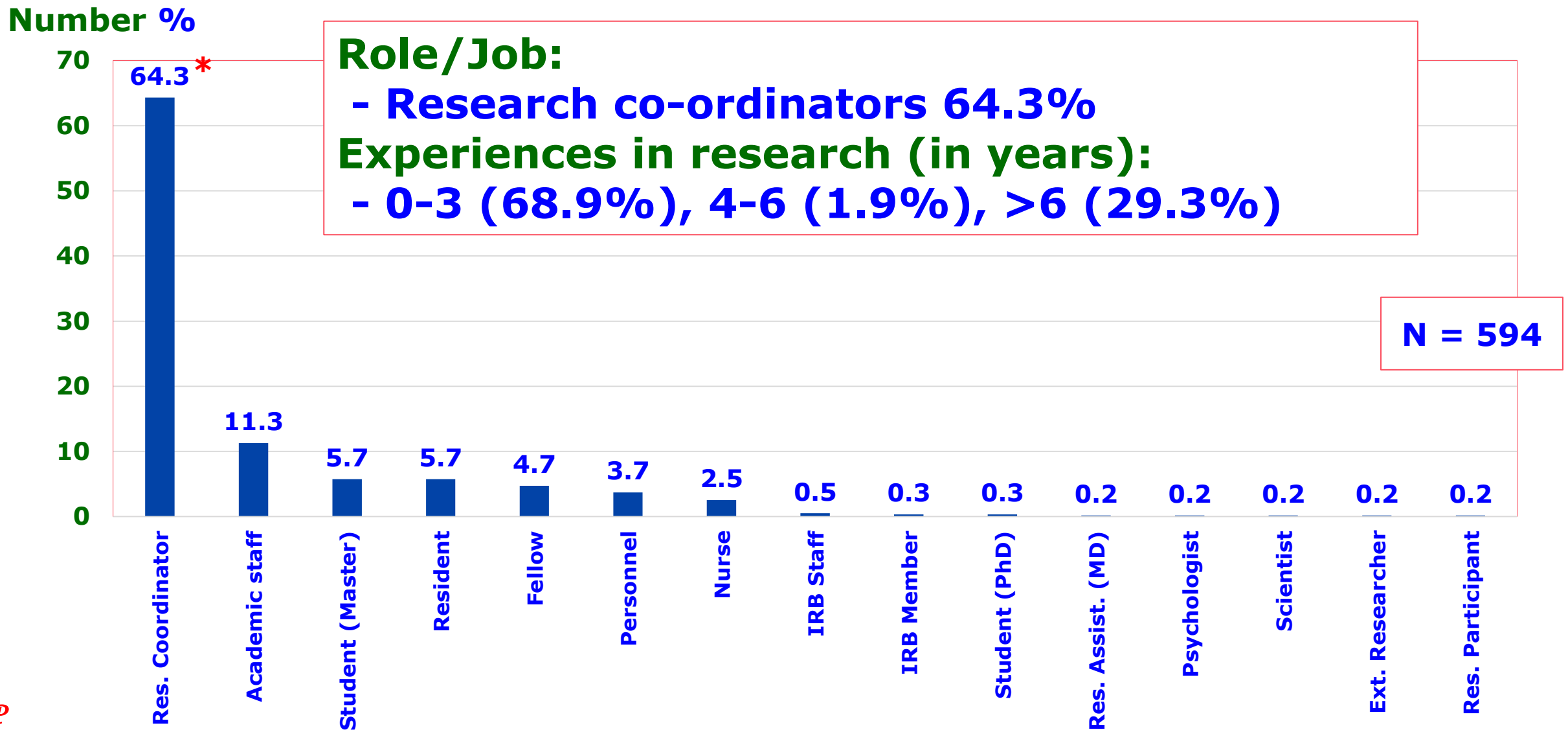
Results: Characteristics of Enquirers (2)



Role/Job:
- Research co-ordinators 64.3%

Experiences in research (in years):
- 0-3 (68.9%), 4-6 (1.9%), >6 (29.3%)

N = 594

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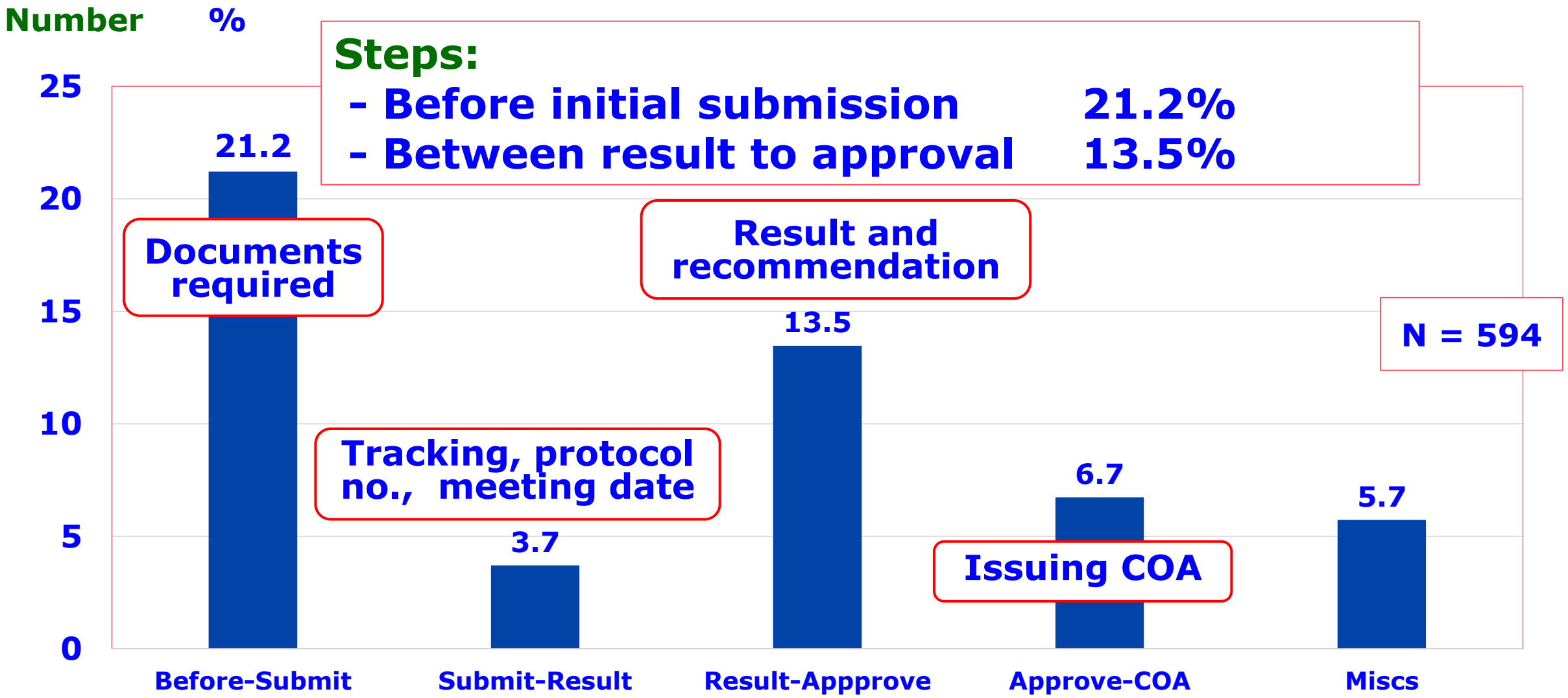
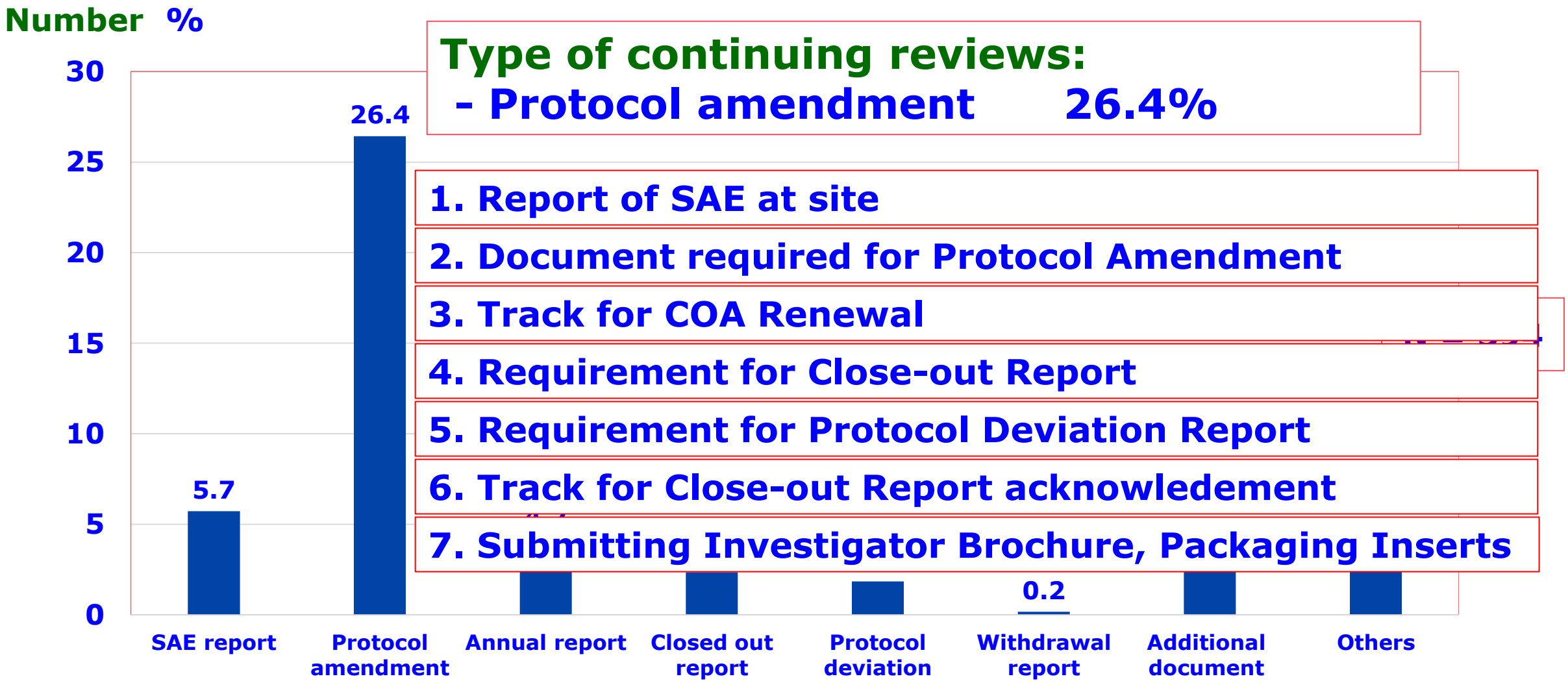
Results: Initial Review Process Enquired



Results: Continuing Review Enquired



Type of continuing reviews:
- **Protocol amendment 26.4%**

1. Report of SAE at site
2. Document required for Protocol Amendment
3. Track for COA Renewal
4. Requirement for Close-out Report
5. Requirement for Protocol Deviation Report
6. Track for Close-out Report acknowledement
7. Submitting Investigator Brochure, Packaging Inserts

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Timeline

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20 Oct 2022

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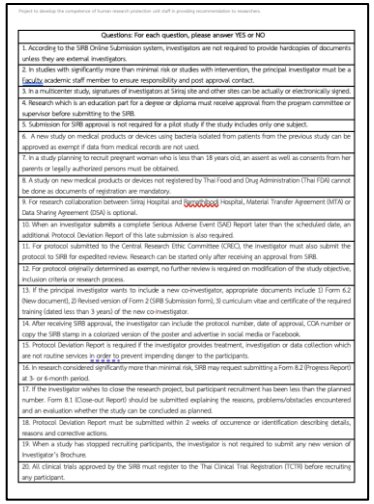

Questions: For each question, please answer YES or NO

1. According to the SIRB Online Submission system, investigators are not required to provide hardcopies of documents unless they are external investigators.
2. In studies with significantly more than minimal risk or studies with intervention, the principal investigator must be a Faculty academic staff member to ensure responsibility and post approval contact.
3. In a multicenter study, signatures of investigators at Siriraj site and other sites can be actually or electronically signed.
4. Research which is an education part for a degree or diploma must receive approval from the program committee or supervisor before submitting to the SIRB.
5. Submission for SIRB approval is not required for a pilot study if the study includes only one subject.
6. A new study on medical products or devices using bacteria isolated from patients from the previous study can be approved as exempt if data from medical records are not used.
7. In a study planning to recruit pregnant woman who is less than 18 years old, an assent as well as consents from her parents or legally authorized persons must be obtained.
8. A study on new medical products or devices not registered by Thai Food and Drug Administration (Thai FDA) cannot be done as documents of registration are mandatory.
9. For research collaboration between Siriraj Hospital and Secondary Hospital, Material Transfer Agreement (MTA) or Data Sharing Agreement (DSA) is optional.
10. When an investigator submits a complete Serious Adverse Event (SAE) Report later than the scheduled date, an additional Protocol Deviation Report of this late submission is also required.
11. For protocol submitted to the Central Research Ethic Committee (CREC), the Investigator must also submit the protocol to SIRB for expedited review. Research can be started only after receiving an approval from SIRB.
12. For protocol originally determined as exempt, no further review is required on modification of the study objective, inclusion criteria or research process.
13. If the principal investigator wants to include a new co-investigator, appropriate documents include 1) Form 8.2 (New document), 2) Revised version of Form 2 (SIRB Submission form), 3) curriculum vitae and certificate of the required training (dated less than 3 years) of the new co-investigator.
14. After receiving SIRB approval, the investigator can include the protocol number, date of approval, COA number or copy the SIRB stamp in a colorized version of the poster and advertise in social media or Facebook.
15. Protocol Deviation Report is required if the investigator provides treatment, investigation or data collection which are not routine services in order to prevent impending danger to the participants.
16. In research considered significantly more than minimal risk, SIRB may request submitting a Form 8.2 (Progress Report) at 3- or 6-month period.
17. If the investigator wishes to close the research project, but participant recruitment has been less than the planned number. Form 8.1 (Close-out Report) should be submitted explaining the reasons, problems/obstacles encountered and an evaluation whether the study can be concluded as planned.
18. Protocol Deviation Report must be submitted within 2 weeks of occurrence or identification describing details, reasons and corrective actions.
19. When a study has stopped recruiting participants, the investigator is not required to submit any new version of Investigator's Brochure.
20. All clinical trials approved by the SIRB must register to the Thai Clinical Trial Registration (TCTR) before recruiting any participant.

31 Jan 2023
SIRB Approval

Feb-Apr 2023
Data Collection, Categorize

Jul 2023
May 2024
Questionnaires, Workshop designs, Amend protocol x2

Ω NP

Timeline

Number: 7
Working experiences: >10 years (6/7)
Incomplete participation (1/7)

Submission to SIRB
20 Oct 2022

Siriraj Institutional Review Board
Certificate of Approval

COA no. Si 077/2023

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Recruitment and informed consent processes
Jun 2024

31 Jan 2023
SIRB Approval

Feb-Apr 2023
Data Collection, Categorize

Jul 2023
Questionnaires, Workshop designs, Amend protocol x2

May 2024

12 SIRB staff
3 investigators
2 general chores
7 participants

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Timeline

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Recruitment and informed consent processes
Jun 2024

31 Jan 2023 — **SIRB Approval**

Feb-Apr 2023 — **Data Collection, Categorize**

Jul 2023 — **Questionnaires, Workshop Design Amend protocol x2**

May 2024

14 Jun — **Workshop 1, 2**

8 Jul 2024

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Results:

Design for learning activities

: 20-item questionnaires

- validated for IOC

: interactive sessions

- Workshop 1: lectures
- Workshop 2: case scenarios

Time	
10	Registr
5	Overvie
20	Pre-tes
10	Coffee
60	Interac
15	Q & A

Case	Scenari
1	Types of protocol re
2	Paper-based and or
3	Consent from paren
4	Research on blood
5	Recruiting more pa

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Timeline

Items correctly answered <4 participants:
#1, 5, 6, 8, 9, 13, 19

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Jun 2024

14 Jun
8 Jul 2024
Workshop 1, 2

Data analysis
Aug 2024

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Timeline

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Jun 2024

14 Jun
Workshop 1, 2

8 Jul 2024

Data analysis
Aug 2024

Sep 2024
Conclusion

Ω NP

Conclusions:

- A study to assess pattern of consultation from investigators received by SIRB office
- Mostly from new investigators (≤ 3-year experience)
- Common problems as a base in generating and validating questions and case scenarios for effective learning experiences of HRPU staff
- Area of improvement among staff identified

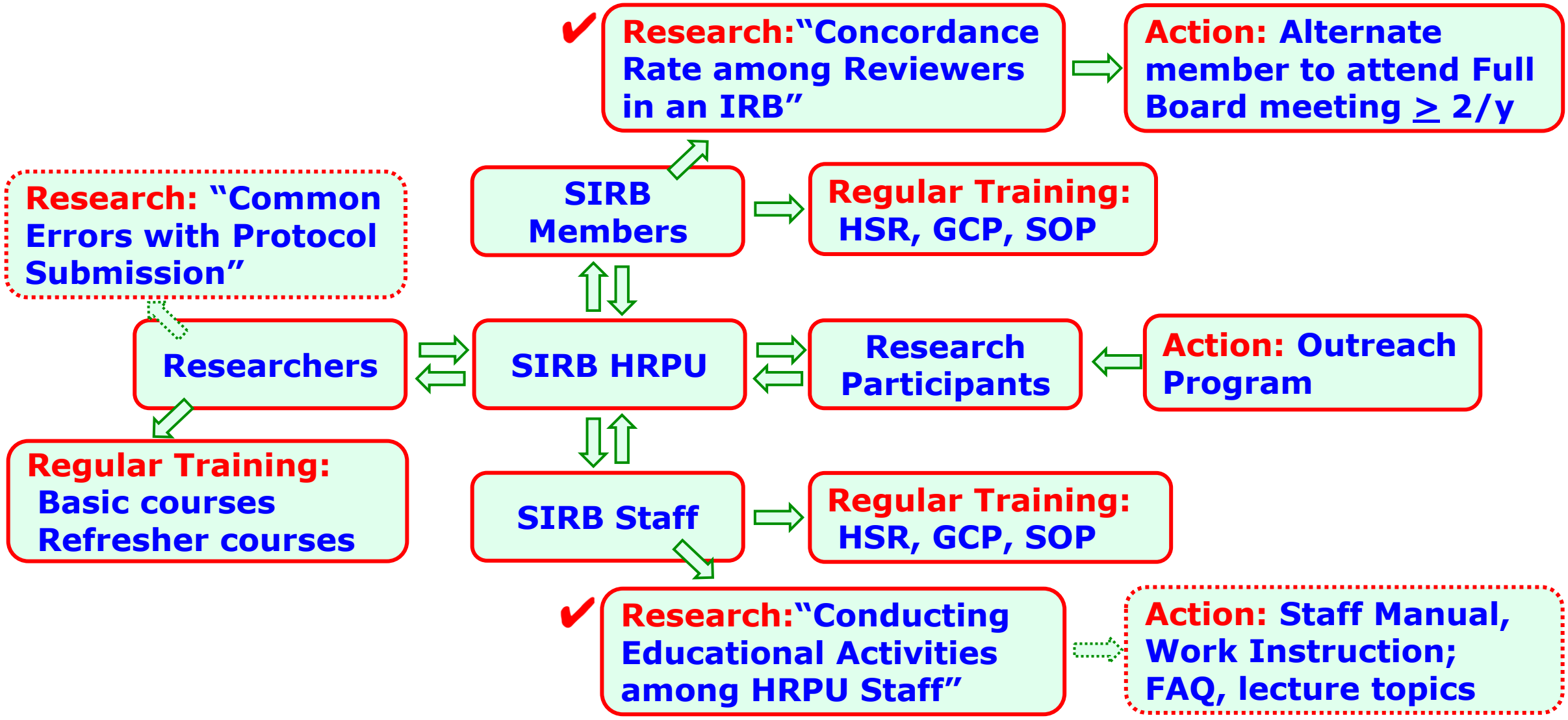
HRPU: Human Research Protection Unit;
SIRB: Siriraj Institutional Review Board

Application:

- Common problems to be mentioned in future educational courses and Frequently Asked Questions (FAQ) handbook for investigators
- Work instructions for HRPU staff to be generated that include topics frequently misunderstood

HRPU: Human Research Protection Unit;

SIRB: Educational Activities among Research Stakeholders



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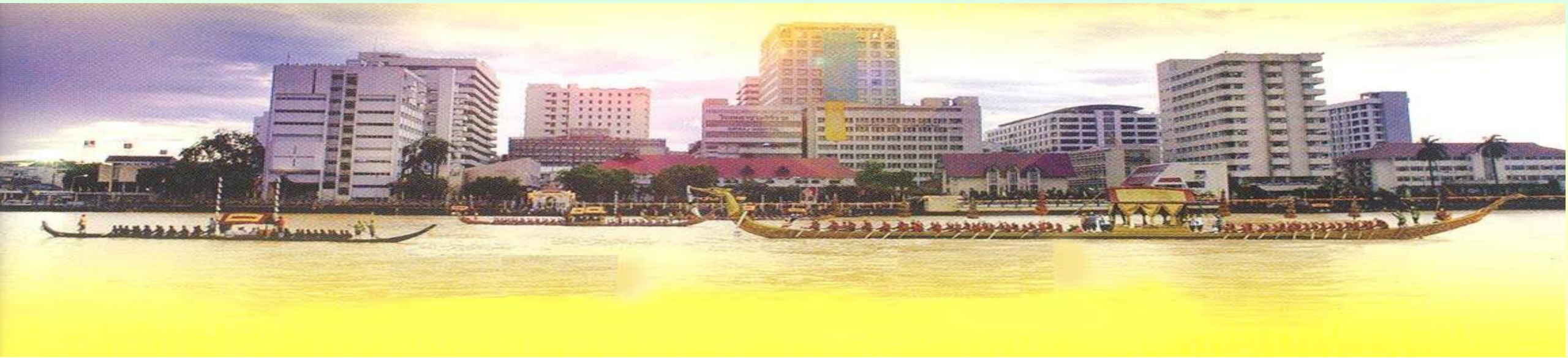

Thank You for Your Attention

Ω NP

Siriraj Hospital
Mahidol University

นพ. จอมพล มุสิกวงศ์

Ω NP

naraporn.pra@mahidol.ac.th