เทคนิคการเขียนข้อเสนอโครงการวิจัยให้ได้ทุน และ การวิเคราะห์ความเสี่ยงข้อเสนอโครงการวิจัย

นพ. ประวิช ตัญญูสิทธิสุนทร
เครือข่ายวิจัยกลุ่มสถาบันแพทยศาสตร์ฯ
มูลนิธิส่งเสริมวิจัยทางการแพทย์

การประชุมชี้แจงกรอบการวิจัยสถาบันวิจัยระบบสาธารณสุข ปีงบประมาณ 2562
วันที่ 15 มกราคม 2561
ณ โรงแรมรามาการ์เดน กรุงเทพ

Presentation Outline

- Introduction
- Quality Standard in Research
  - Scientific and Ethical Standard
  - Quality Started from the Design
- Grant Proposal VS Research Protocol
- Risks & managing risks in Research

Challenging

Challenging

Innovation & Commercialization

- Development phase & Program planning
- Market analysis & product positioning
- Quality Standard
- Regulation & requirement
- Budgeting & resource

Risks & Cost Of Failure

- Financial & resource planning
- Risk management planning &
- Go – No go decision

Challenging

Challenging

Scientific Quality Standard

- EXTERNAL & INTERNAL VALIDITY
- RELIABILITY

Ethical Quality Standard

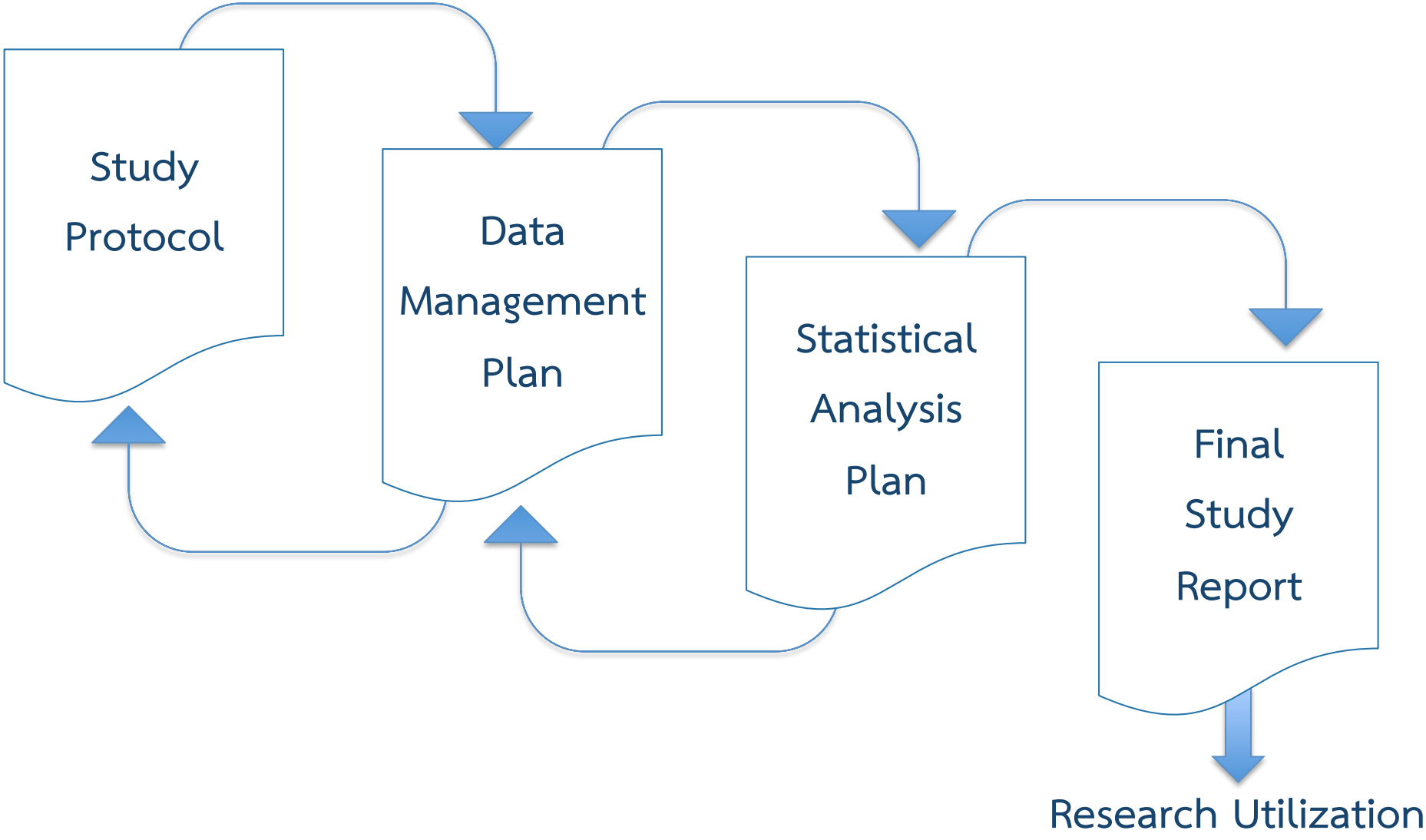
Protect

- Rights: self-determination, confidentiality & privacy
- Safety and continuing medical care
- Well-being

Research/Study Protocol

- Protocol is not research grant proposal
- Protocol is scientific plan & scientific communication
- Protocol should be completed before study started
- Protocol provide specific details
- The study should be conducted in accordance with the protocol
- The protocol determines resource planning and budgeting

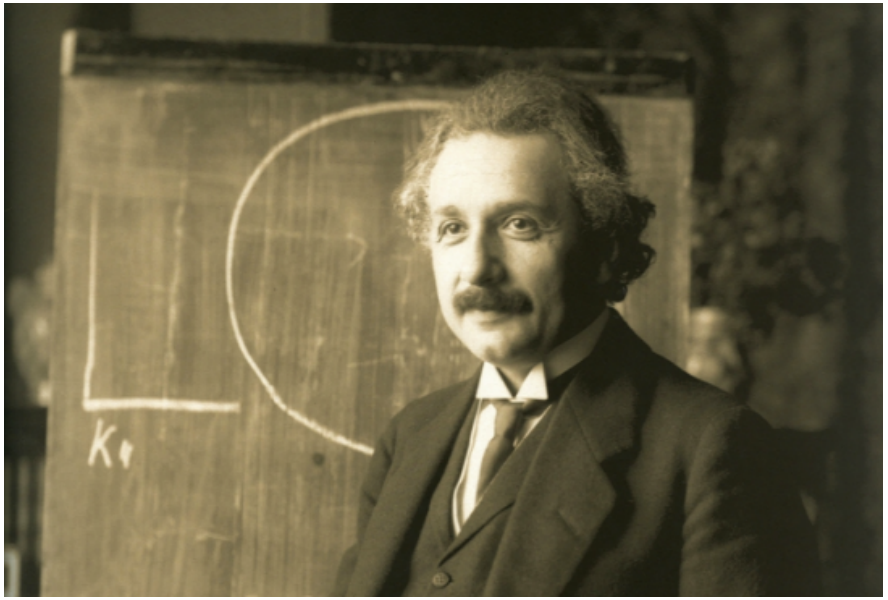
Quality by Design



Starting Research

- Research start from well defined problem and research question

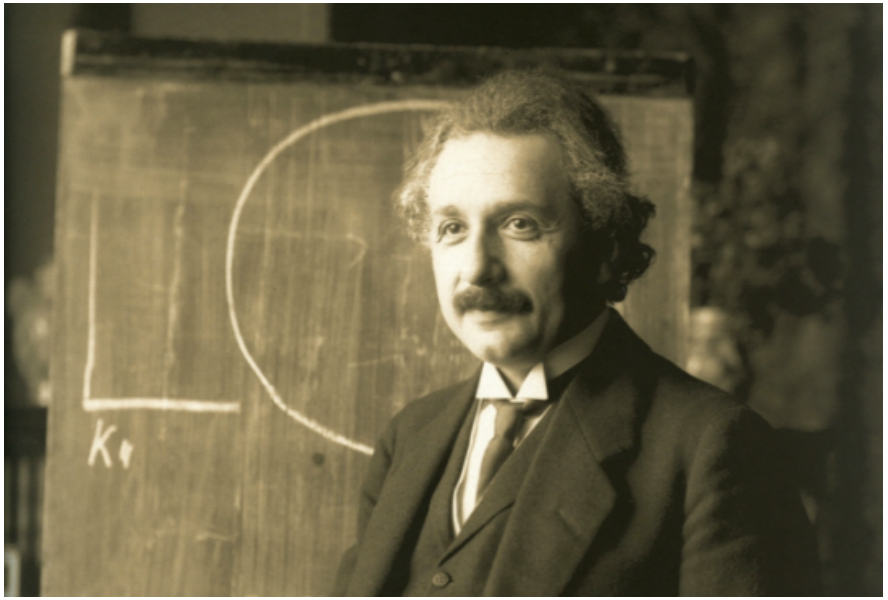
Research Question



Albert Einstein (1879 – 1955)

“...การตั้งคำถามส่วนใหญ่มีความสำคัญมากยิ่งกว่าการหาคำตอบ การหาคำตอบเป็นแค่เพียงการใช้ทักษะทางคณิตศาสตร์และการทดลอง...”

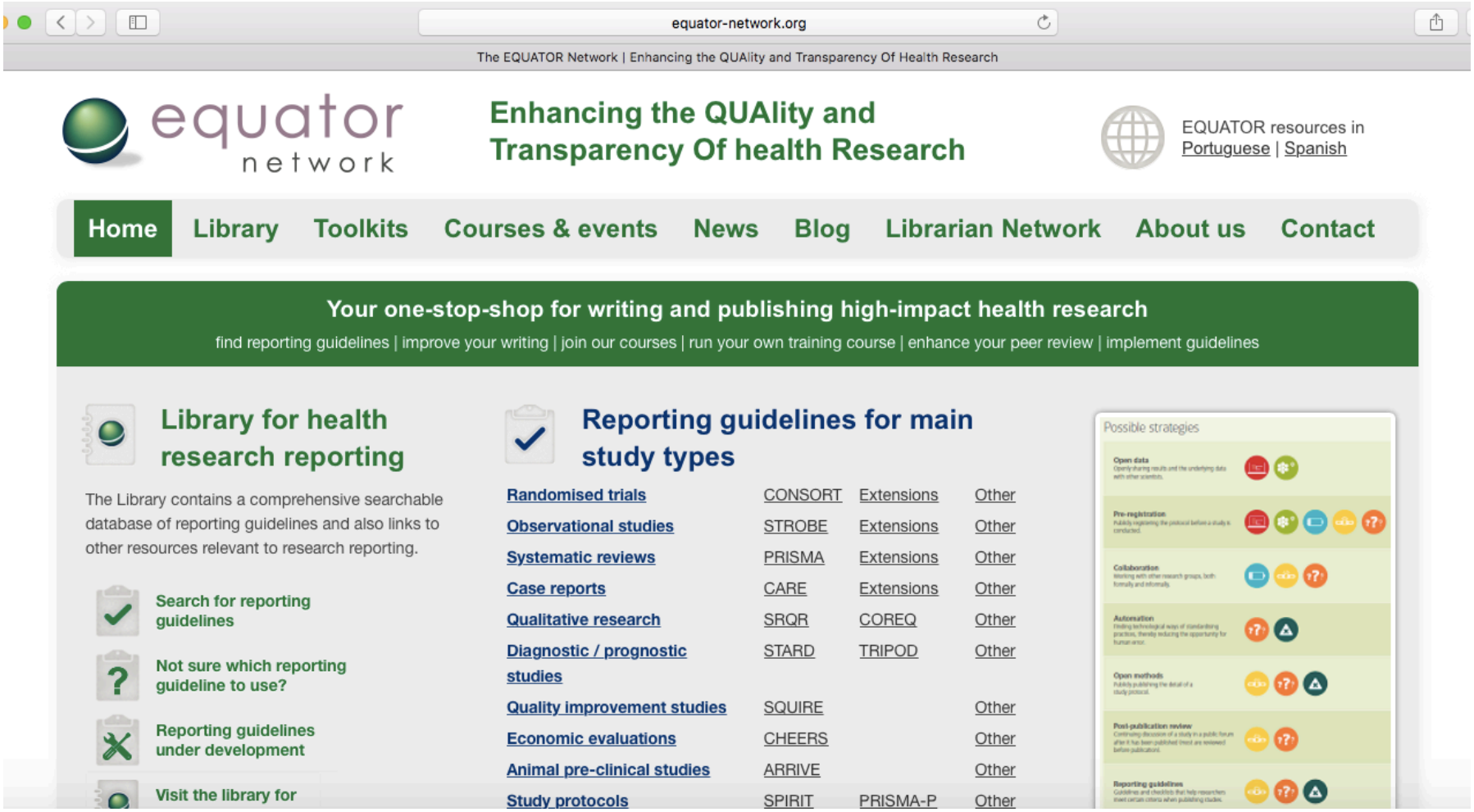
Research Question



Albert Einstein (1879 – 1955)

“...การสร้างคำถามใหม่ หรือการหาโอกาสหรือความเป็นไปได้ใหม่ เป็นการพิจารณาปัญหาเดิมจากมุมมองใหม่ ที่ต้องอาศัยจิตนาการสร้างสรร และก่อให้เกิดความก้าวหน้าทางวิทยาศาสตร์อย่างแท้จริง”

PROTOCOL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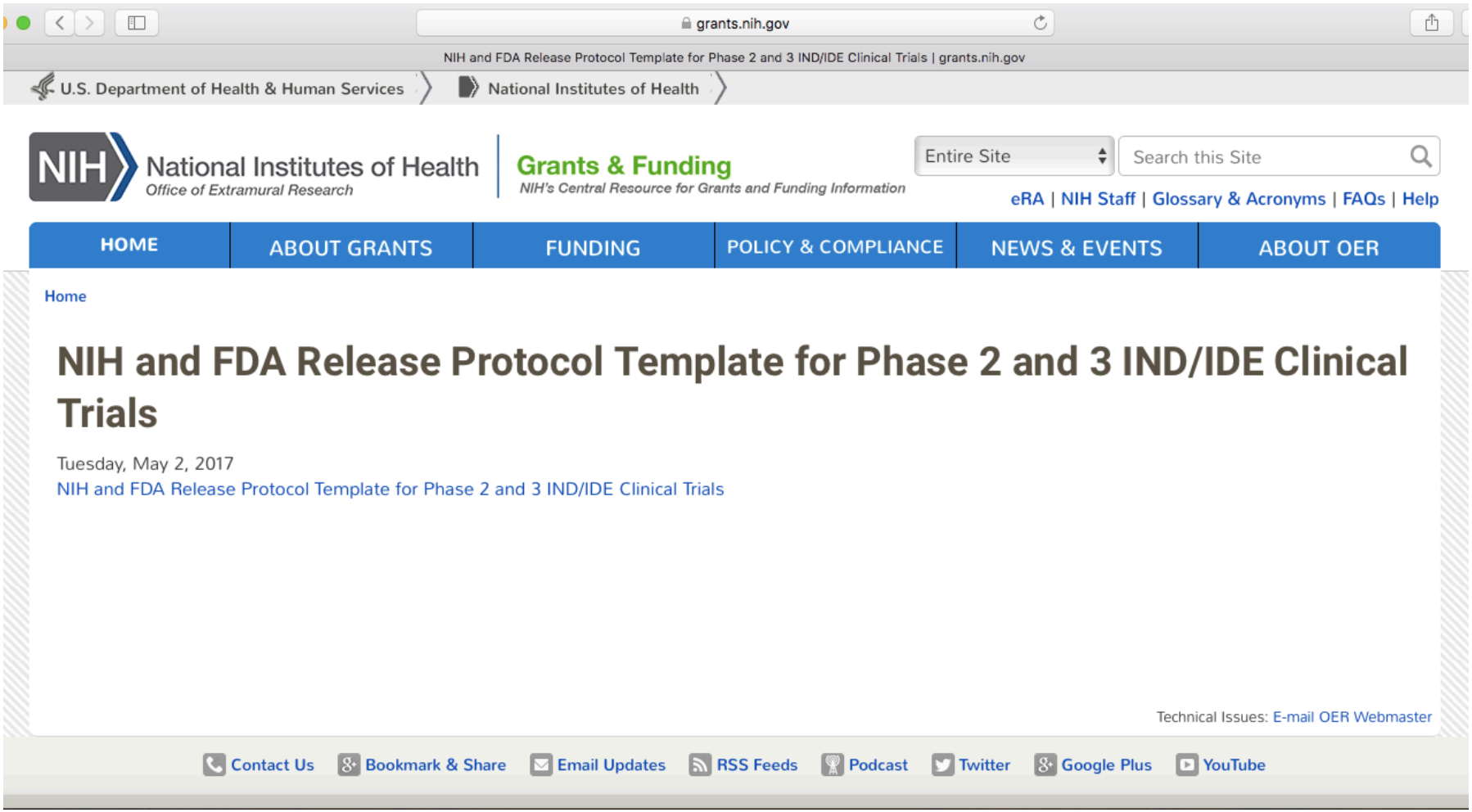
Diagnostic / prognostic studies STARD TRIPOD Other
Quality improvement studies SQUIRE Other
Economic evaluations CHEERS Other
Animal pre-clinical studies ARRIVE Other
Study protocols SPIRIT PRISMA-P Other
Possible strategies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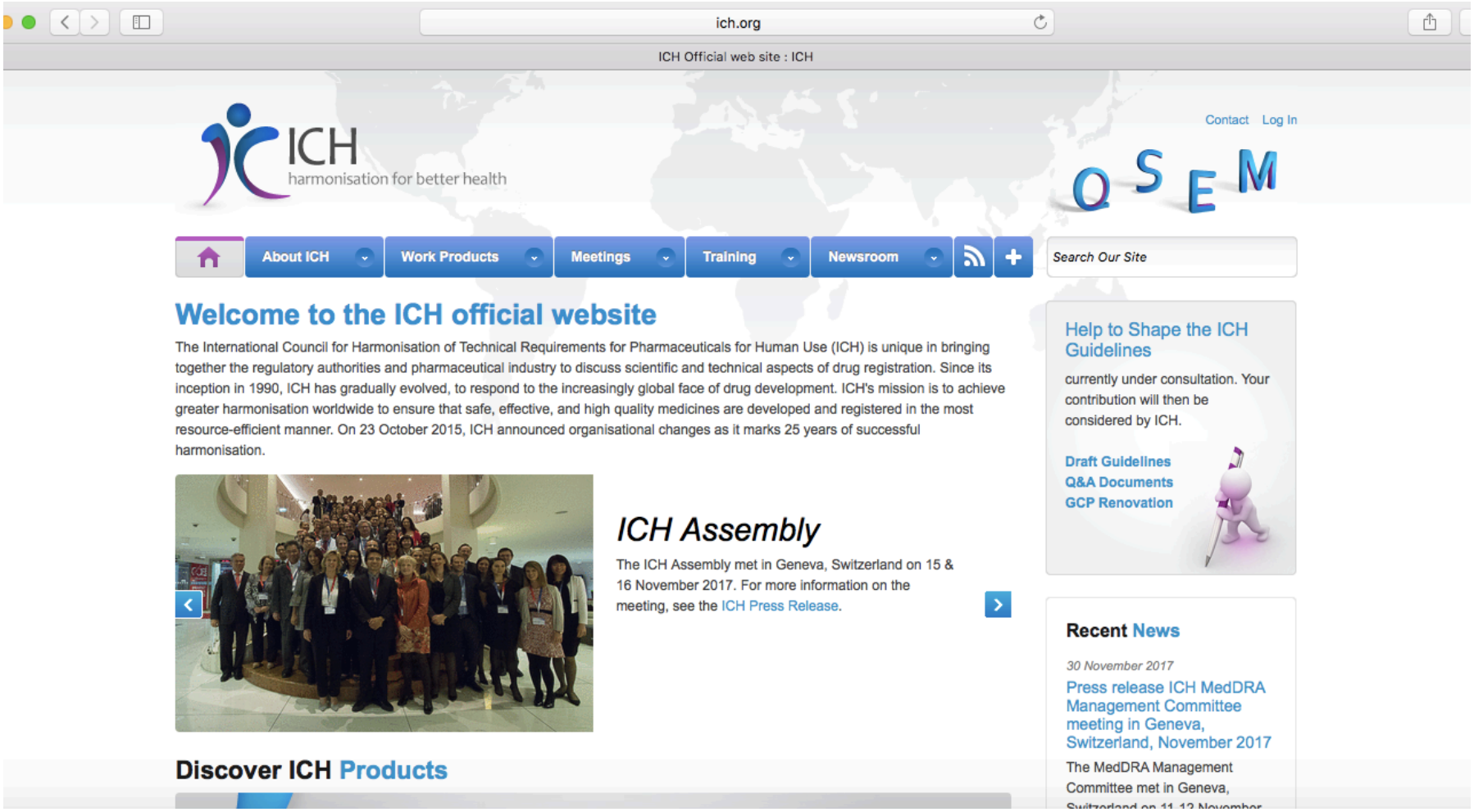
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The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved, to respond to the increasingly global face of drug development. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner. On 23 October 2015, ICH announced organisational changes as it marks 25 years of successful harmonisation.
ICH Assembly
The ICH Assembly met in Geneva, Switzerland on 15 & 16 November 2017. For more information on the meeting, see the ICH Press Release.
Help to Shape the ICH Guidelines
currently under consultation. Your contribution will then be considered by ICH.
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The MedDRA Management Committee met in Geneva,
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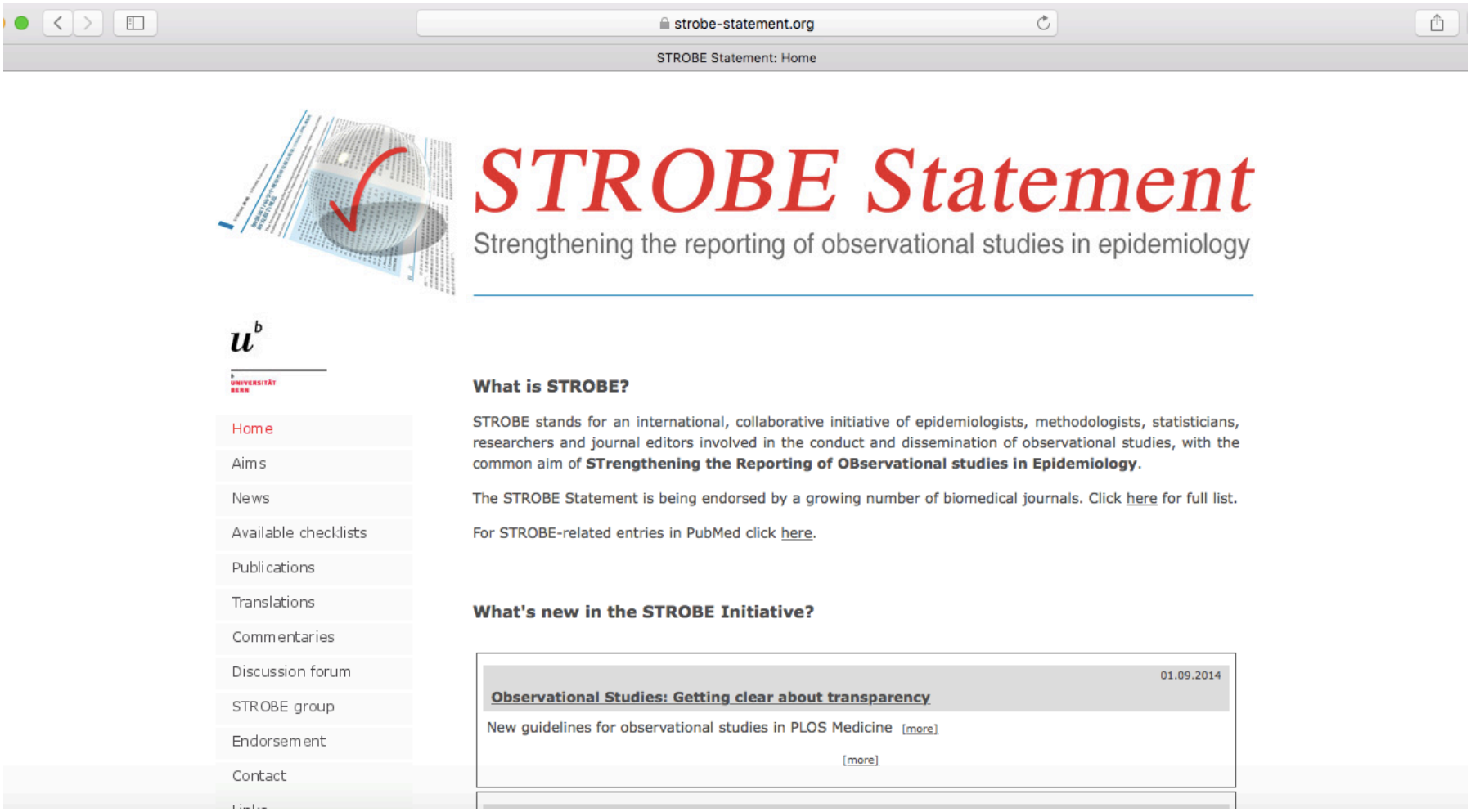
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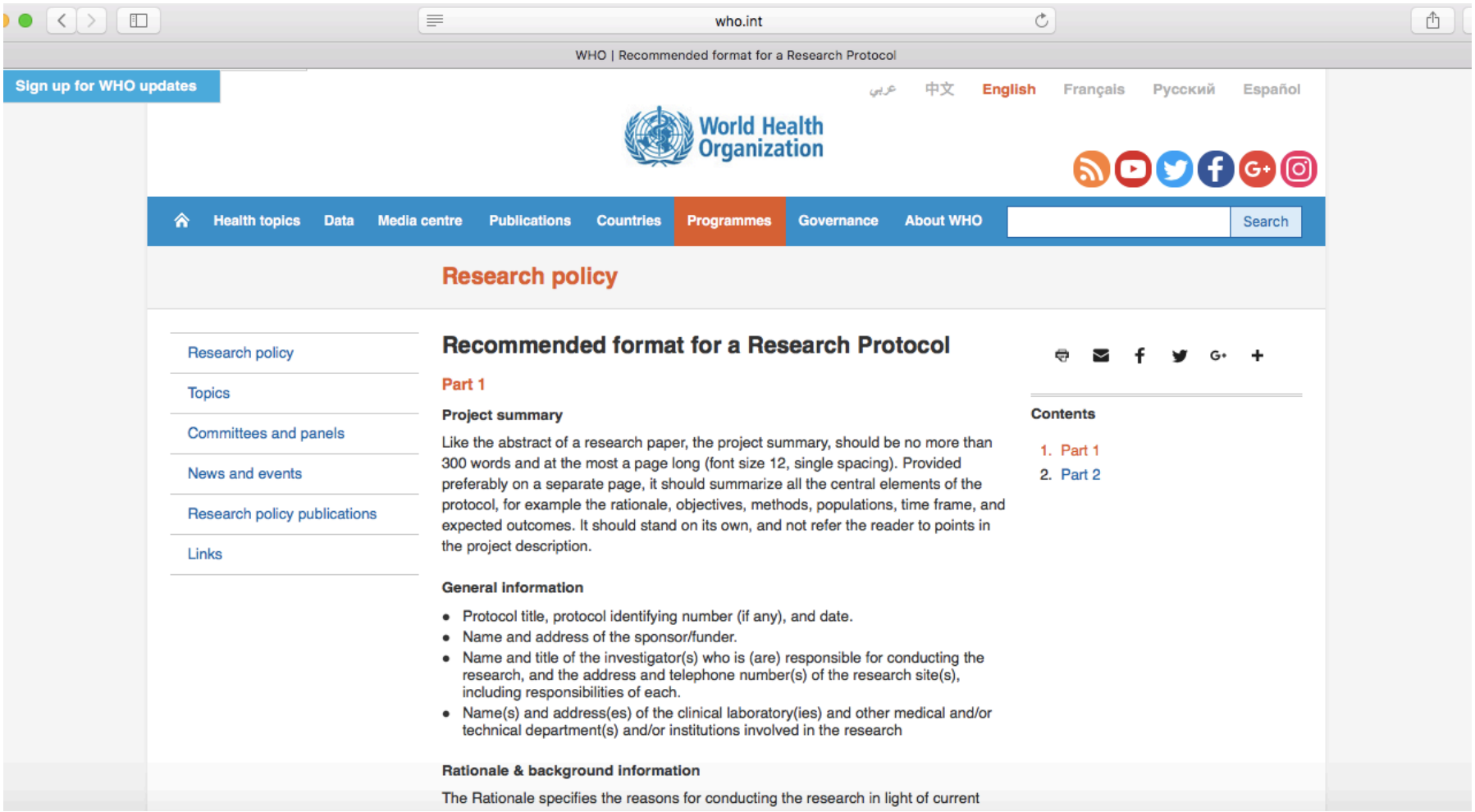
What is STROBE?
STROBE stands for an international, collaborative initiative of epidemiologists, methodologists, statisticians, researchers and journal editors involved in the conduct and dissemination of observational studies, with the common aim of STrengthening the Reporting of OBservational studies in Epidemiology.
The STROBE Statement is being endorsed by a growing number of biomedical journals. Click here for full list.
For STROBE-related entries in PubMed click here.
What's new in the STROBE Initiative?
01.09.2014
Observational Studies: Getting clear about transparency
New guidelines for observational studies in PLOS Medicine [more]
[more]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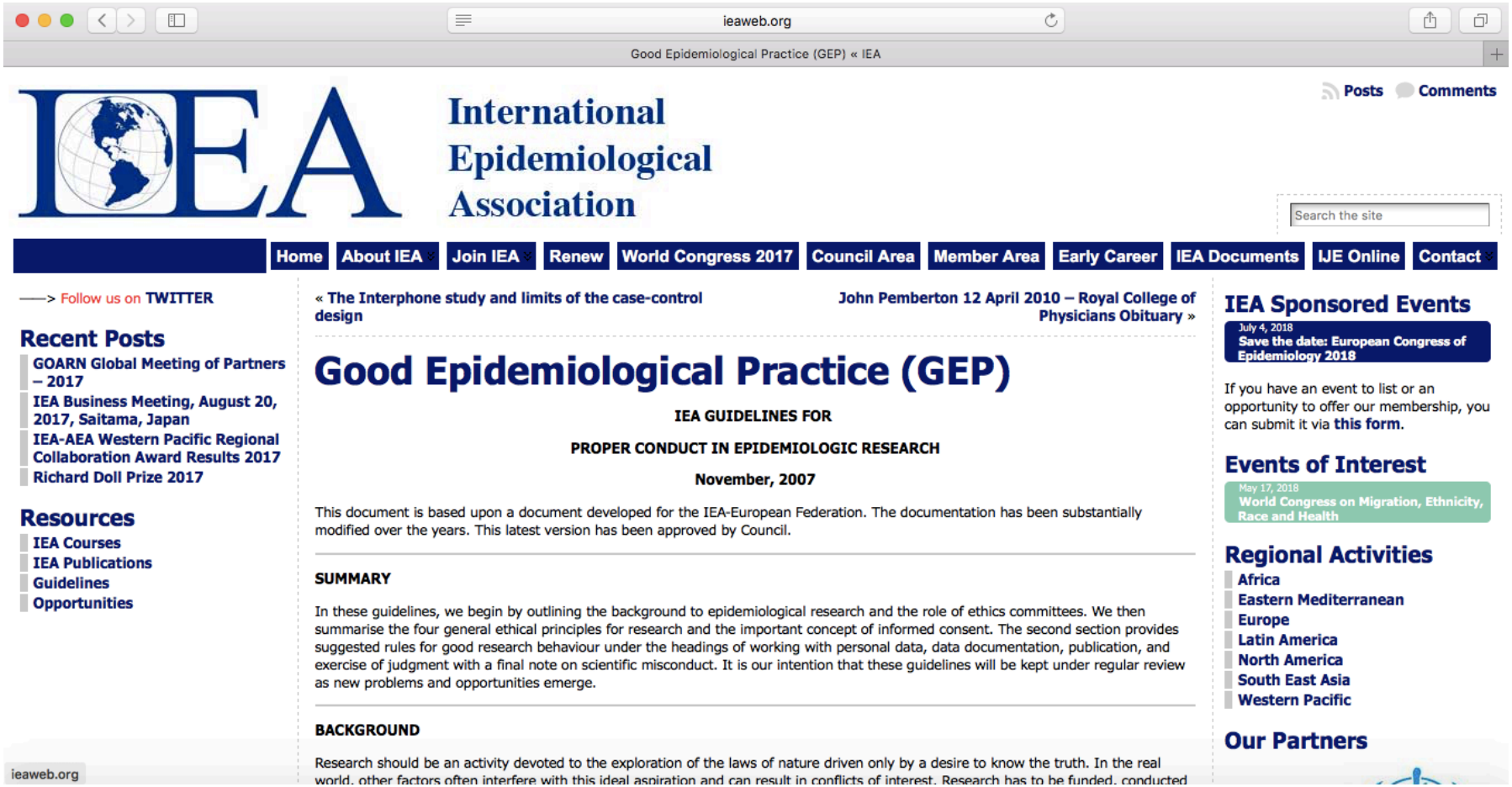
Recommended format for a Research Protocol
Part 1
Project summary
Like the abstract of a research paper, the project summary, should be no more than 300 words and at the most a page long (font size 12, single spacing). Provided preferably on a separate page, it should summarize all the central elements of the protocol, for example the rationale, objectives, methods, populations, time frame, and expected outcomes. It should stand on its own, and not refer the reader to points in the project description.
General information
Protocol title, protocol identifying number (if any), and date.
Name and address of the sponsor/funder.
Name and title of the investigator(s) who is (are) responsible for conducting the research, and the address and telephone number(s) of the research site(s), including responsibilities of each.
Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the research
Rationale & background information
The Rationale specifies the reasons for conducting the research in light of current
Contents
1. Part 1
2. Part 2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« The Interphone study and limits of the case-control design
John Pemberton 12 April 2010 – Royal College of Physicians Obituary »
Good Epidemiological Practice (GEP)
IEA GUIDELINES FOR
PROPER CONDUCT IN EPIDEMIOLOGIC RESEARCH
November, 2007
This document is based upon a document developed for the IEA-European Federation. The documentation has been substantially modified over the years. This latest version has been approved by Council.
SUMMARY
In these guidelines, we begin by outlining the background to epidemiological research and the role of ethics committees. We then summarise the four general ethical principles for research and the important concept of informed consent. The second section provides suggested rules for good research behaviour under the headings of working with personal data, data documentation, publication, and exercise of judgment with a final note on scientific misconduct. It is our intention that these guidelines will be kept under regular review as new problems and opportunities emerge.
BACKGROUND
Research should be an activity devoted to the exploration of the laws of nature driven only by a desire to know the truth. In the real
IEA Sponsored Events
July 4, 2018
Save the date: European Congress of Epidemiology 2018
If you have an event to list or an opportunity to offer our membership, you can submit it via this form.
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World Congress on Migration, Ethnicity, Race and Health
Regional Activities
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International Ethical Guidelines for Epidemiological Studies

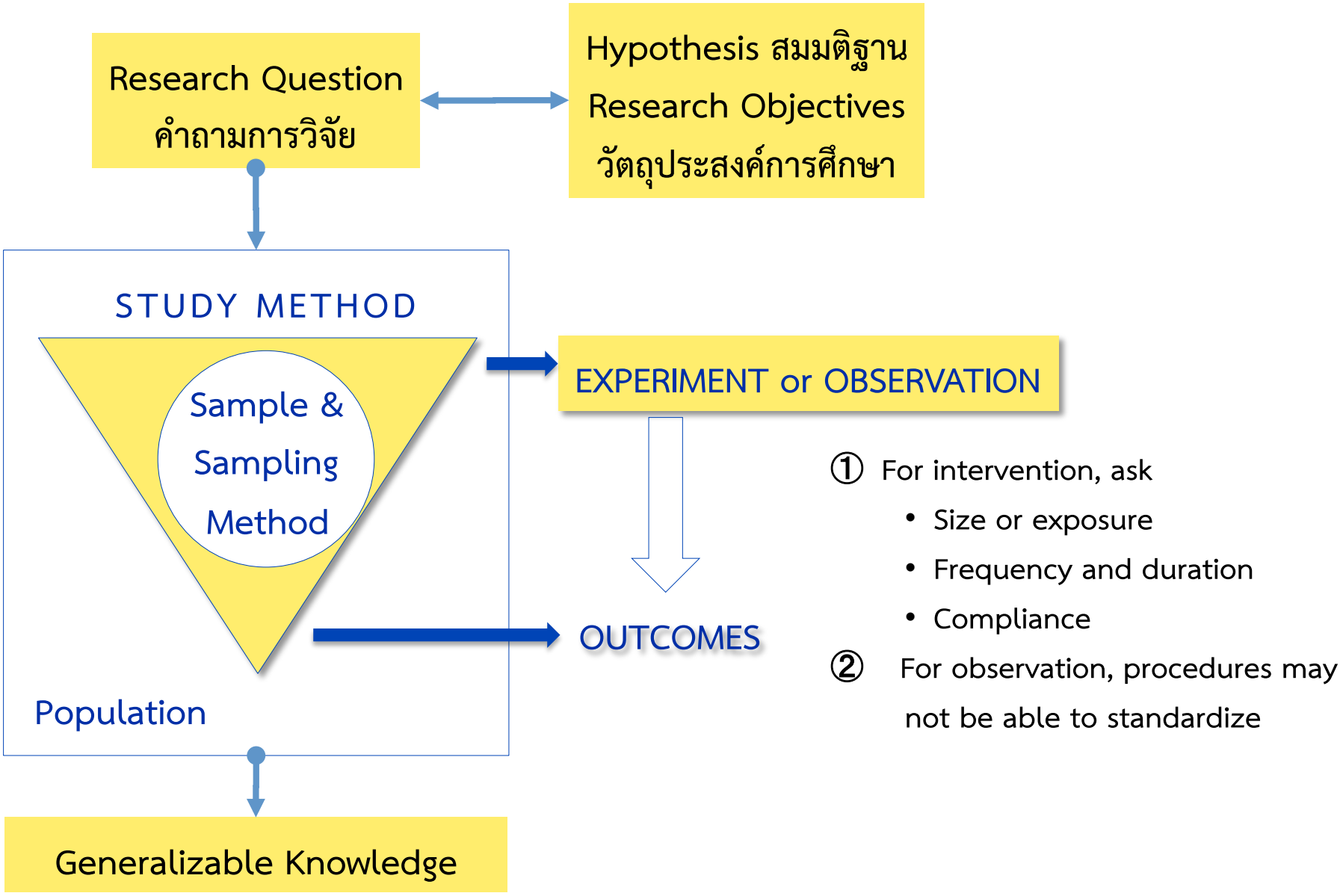
Prepared by the
Council for International Organizations
of Medical Sciences (CIOMS)
in collaboration with the World Health Organization
(WHO)

Geneva
2009

Protocol

- Background information and scientific rationale
- Study Objectives
  - Primary objectives
  - Secondary objectives
- Study Methodology
  - Study design (diagram would help)
  - Study population
  - Study method
    - Scheduling visit and procedures
    - Outcomes and methods of assessments
  - Data collection and analysis plan

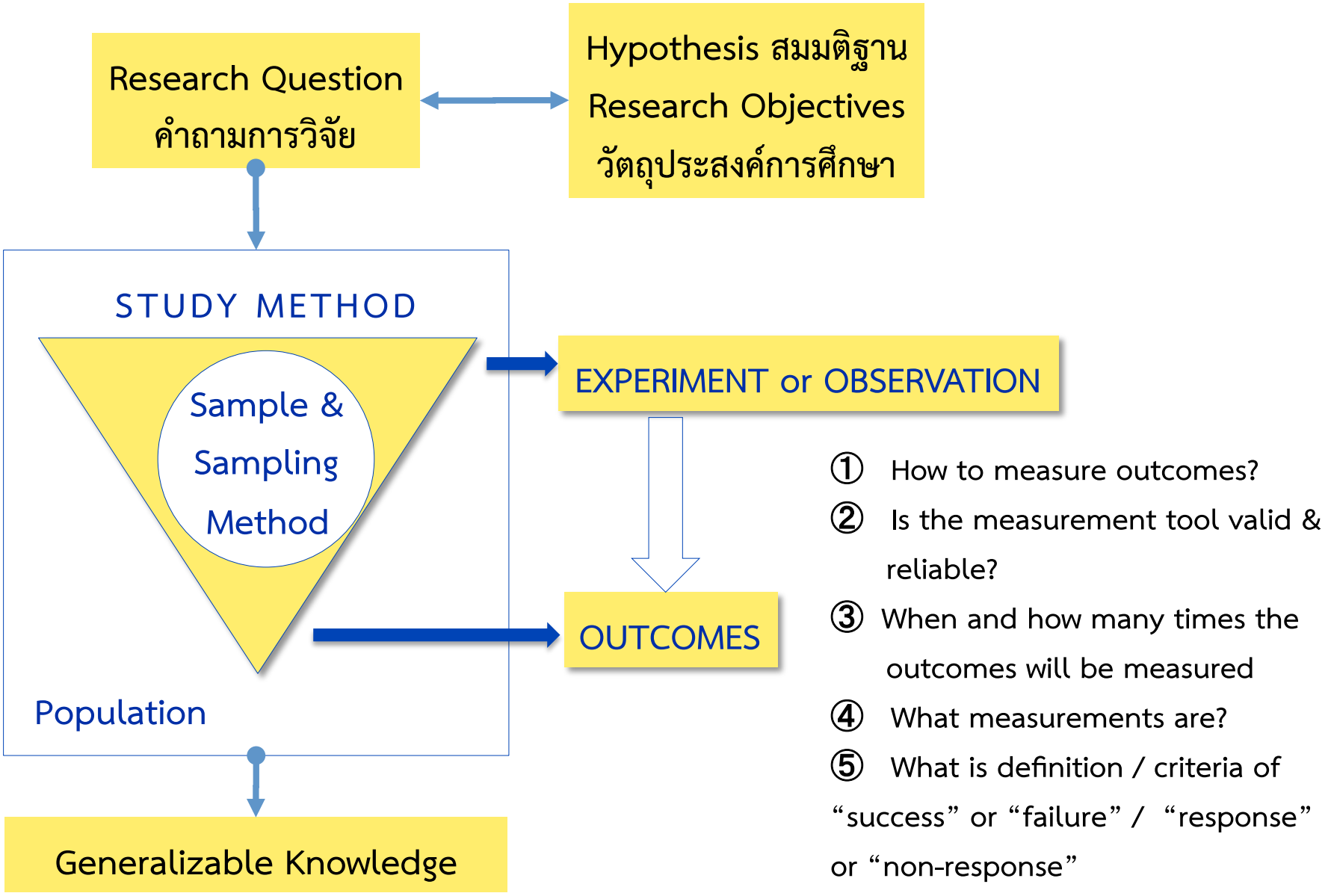
Research



① For intervention, ask
- Size or exposure
- Frequency and duration
- Compliance

② For observation, procedures may not be able to standardize

Research



① How to measure outcomes?

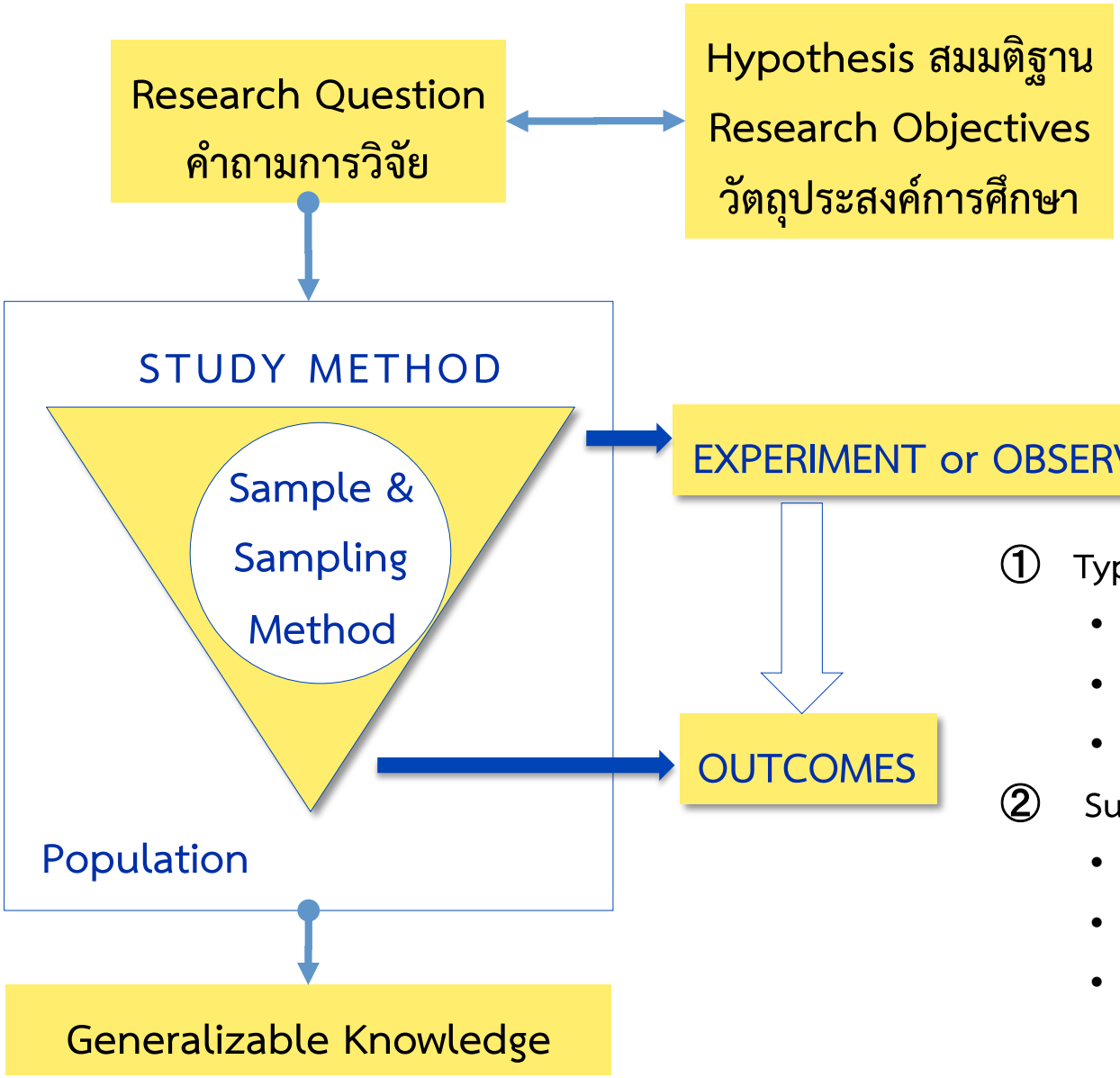
② Is the measurement tool valid & reliable?

③ When and how many times the outcomes will be measured

④ What measurements are?

⑤ What is definition / criteria of "success" or "failure" / "response" or "non-response"

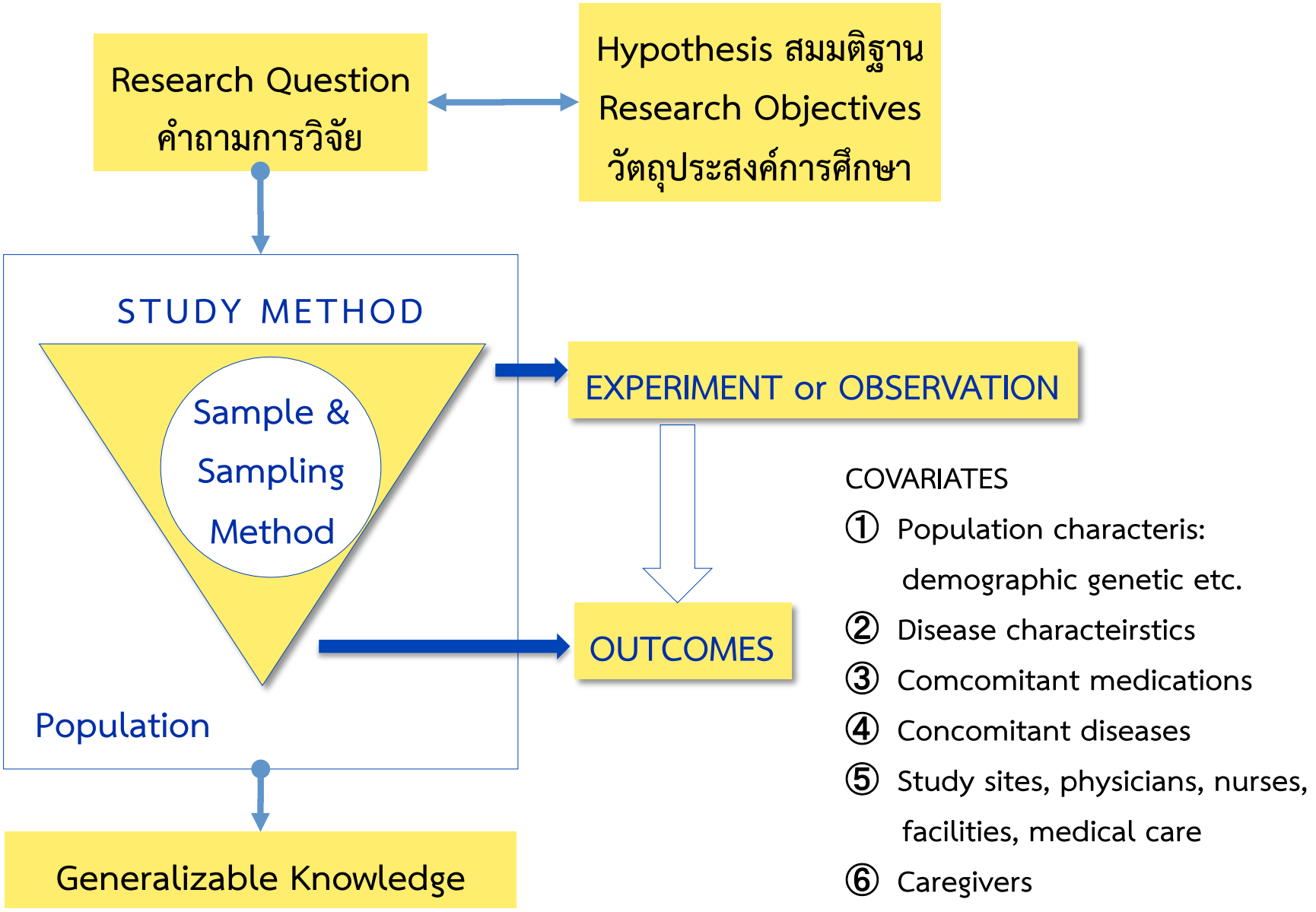
Research



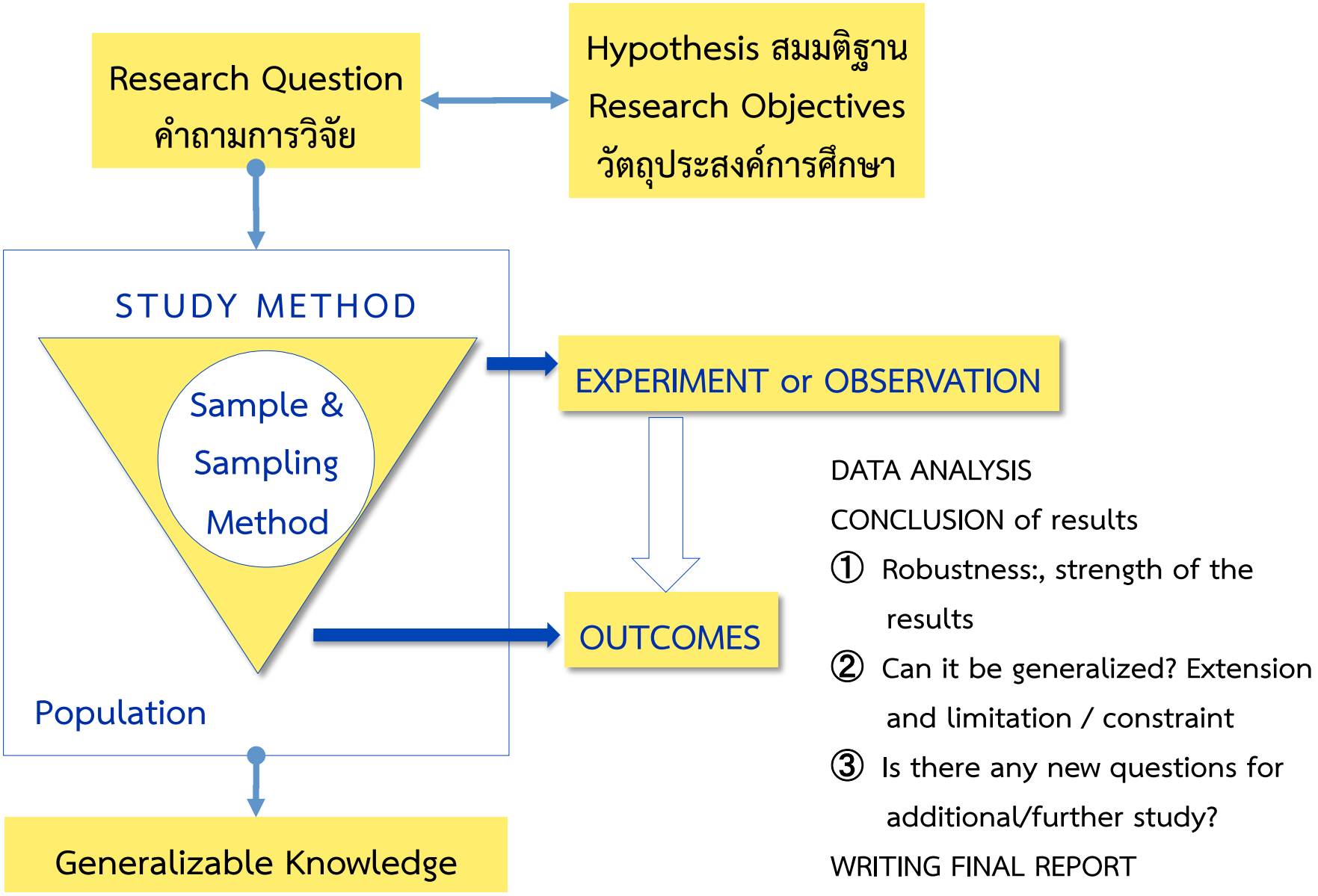
① Types of outcomes
- Clinical outcomes /endpoints
- Patient report outcomes
- Performance outcomes

② Surrogate outcomes
- Biomarker
- Physiological
- Process

Research


Research Question
คำถามการวิจัย
Hypothesis สมมติฐาน
Research Objectives
วัตถุประสงค์การศึกษา
STUDY METHOD
Sample &
Sampling
Method
Population
EXPERIMENT or OBSERVATION
OUTCOMES
Generalizable Knowledge
COVARIATES
① Population characteris:
demographic genetic etc.
② Disease characteirstics
③ Comcomitant medications
④ Concomitant diseases
⑤ Study sites, physicians, nurses,
facilities, medical care
⑥ Caregivers

Research



DATA ANALYSIS

CONCLUSION of results

① Robustness:, strength of the results

② Can it be generalized? Extension and limitation / constraint

③ Is there any new questions for additional/further study?

WRITING FINAL REPORT

Common Risks

- Protocol: not feasible, poor design, adaptive design
- Study site selection
- Research ethics committee review and approval
- Subject enrollment
- Data quality
- Budgeting