Strengthening the Occupational Health Expertise and Scientific Performance of Public Health Institution of Turkey

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Sağlık Bakanlığı
Türkiye Halk Sağlığı Kurumu

UNIVERSITEIT GENT

VU medisch centrum

TNO innovation for life

Houston, we have a problem

ptt A 4.2

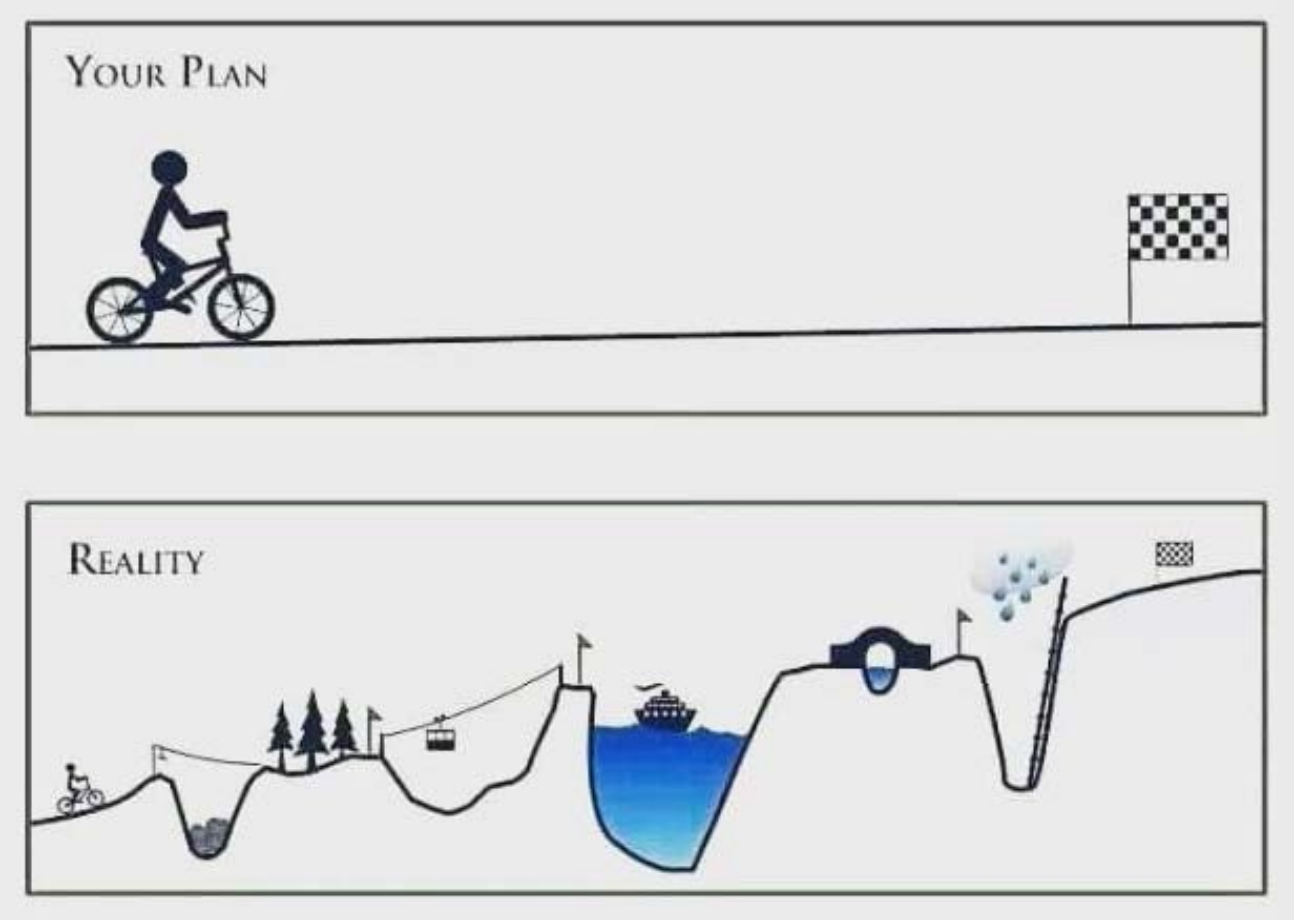
Learning Objectives

1. Identifying possible issues while preparing and conducting a research/surveillance
2. Preparing an informed consent for an institutional review board (IRB)
3. How to recruit and retain participants

Summary of presentation

- Possible issues in research/surveillance
- Code of ethics
- Informed consent
- Participation

Possible issues



Possible issues

What are the points to consider in preparing a study/surveillance?

What kind of problems you can expect during your research/surveillance?

Do you have solutions or alternatives?

Examples of possible issues

Finances	Ethics	Timeline
Participation	Bias	Confidentiality
Communication	Privacy	Legal aspects

Project management

- Principles of good management
  1) *Analysis of possible threats for the project*
     - Procedures and strategies based on the highest professional standards and ethical principles
     - Be pro-active and flexible : have a plan B
     - Learn from earlier projects and other reseachers
  2) *Good communication* with participants, stakeholders, key persons,…
  3) *Quality assurance*

Project management

- Legal aspects
  - Law on OHS, protection of privacy, rights of the patient,…
- Funding
  - Internal funding
  - Federal funding
  - International funding : Europe

Project management

- Data monitoring
  - Safety and confidentiality of data
  - Plan for statistical analyses

- Dissemination and implementation
  - Plan to share the study results in formats most useful to the different parties involved, including participants, scientific community, practitioners, policy makers,…

Project management

- Quality assurance
  - Research evaluations : check guidelines
    - For RCT (CONSORT)

      www.consort-statement.org
    - For observational studies (STROBE)

      www.strobe.statement.org

      http://www.strobe-statement.org/index.php?id=available-checklists
  - Ethics screening
  - Scientific integrity

Ethical aspects

- In general, scientific projects have to be presented and are evaluated by an Ethical Committee or an institutional review board (IRB)
- With this approval you may present the investigation to your local ethical commission/IRB
- Normally, they confirm the report of the other committee within a short time period.
- Please, inform yourself before which ethical approvals are needed for this type of study in your country : PHIT? Medical faculty of university xx ?

Ethics in the ESPrIT project

European Commission - Research - Participants

Proposal Submission Forms

Proposal ID **692188** *Acronym* **ESPrIT**

Declarations

1) The coordinator declares to have the explicit consent of all applicants on their participation and on the content of this proposal.	☒
2) The information contained in this proposal is correct and complete.	☒
3) This proposal complies with ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct).	☒

Ethics in the ESPrIT project

ARTICLE 34 — ETHICS

34.1 Obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[23] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

[22] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).

[23] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

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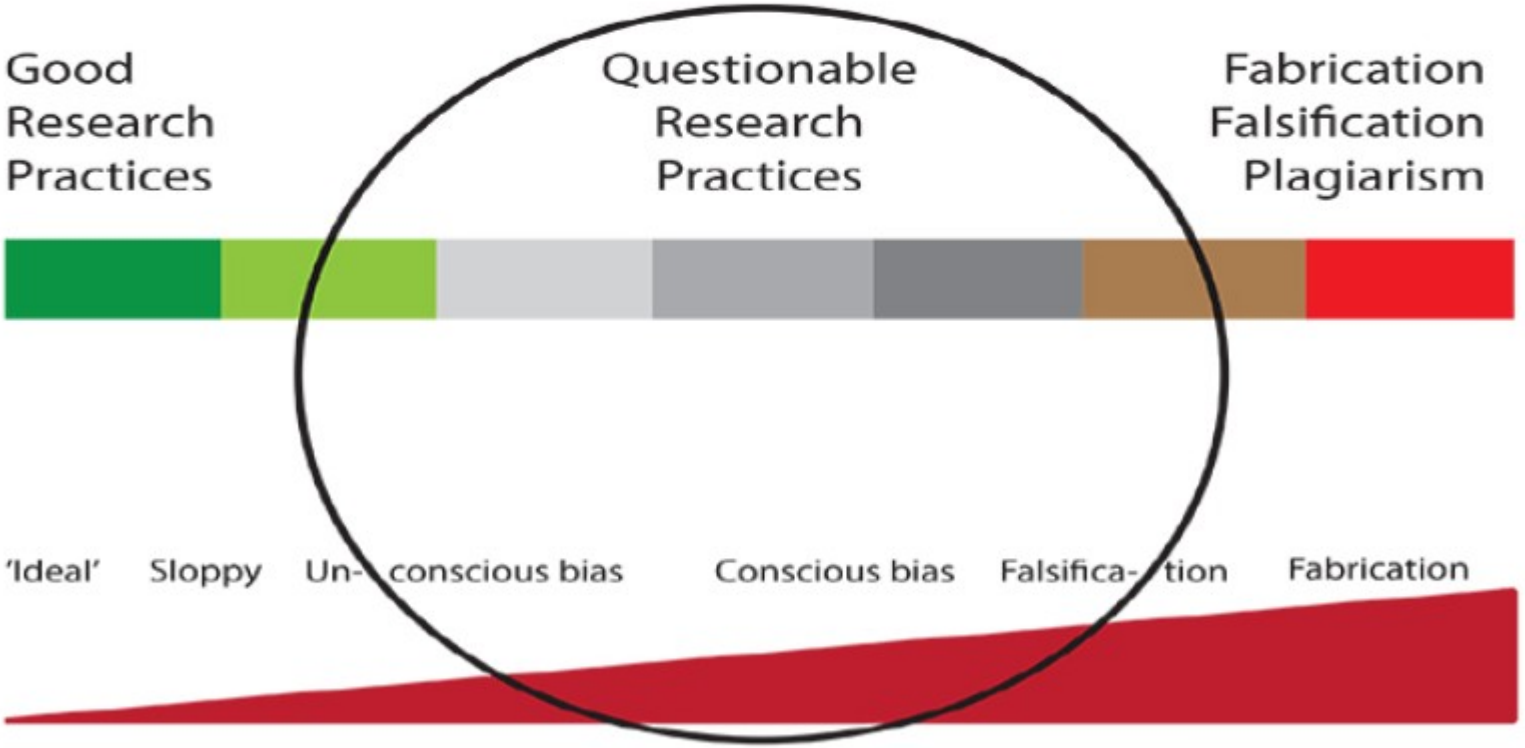
(b) applicable international, EU and national law.

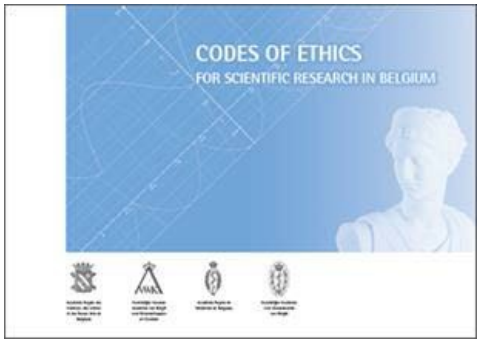
What are we talking about?

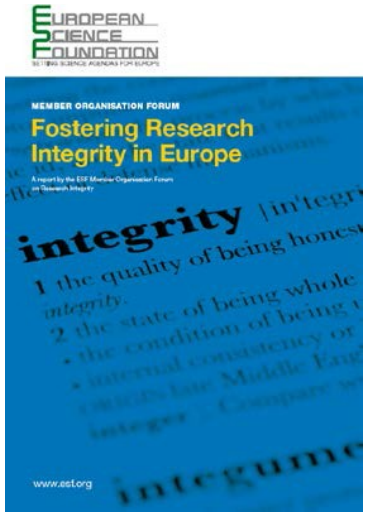


Source: Adapted from a presentation by Daniel Fanelli – by VIB

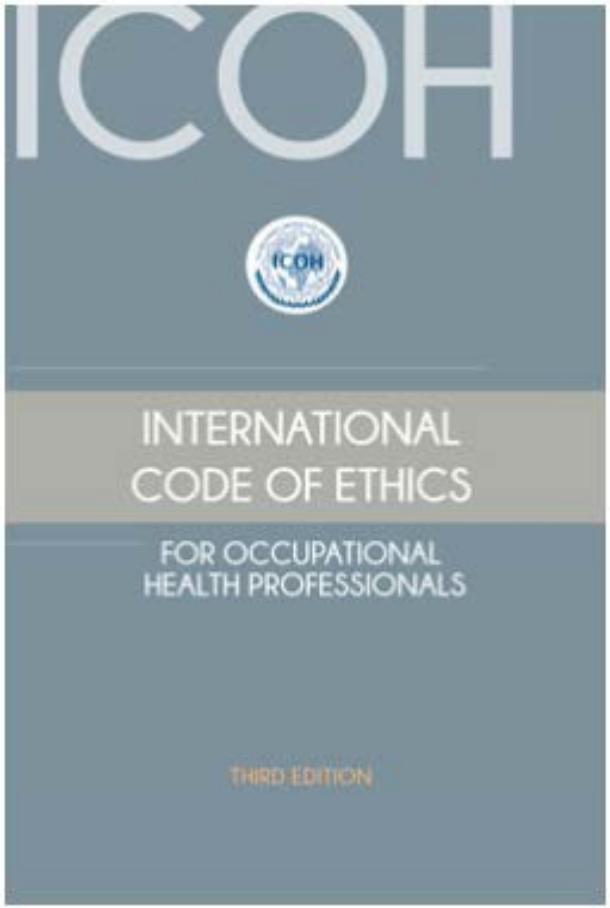
Scientific integrity

- Scientific integrity results from adherence to professional values and practices, when conducting and applying the results of science and scholarship.
- It ensures : objectivity, clarity, reproducibilty, utility
- It is important to avoid bias, fabrication, falsification, plagiarism, outside interference, censorship





International code of ethics



İŞ SAĞLIĞI PROFESYONELLERİ İÇİN

ULUSLARARASI ETİK KURALLAR

The duties of occupational health professionals include protecting the life and the health of the worker, respecting human dignity and promoting the highest ethical principles in occupational health policies and programmes. Integrity in professional conduct, impartiality and the protection of the confidentiality of health data and of the privacy of workers are part of these duties.

ÜÇÜNCÜ SÜRÜM

International code of ethics

Contribution to scientific knowledge

15. Occupational health professionals must report objectively to the scientific community as well as to the public health and labour authorities on new or suspected occupational hazards. They must also report on new and relevant preventive methods. Occupational health professionals involved in research must design and carry out their activities on a sound scientific basis with full professional independence and follow the ethical principles relevant to health and medical research work. These include social and scientific value, scientific validity, fair subject selection, favourable risk benefit ratio, informed consent, respect for potential and enrolled subjects, review of protocols and potential conflicts of interest by an independent and competent ethics committee and protection of confidential data. The occupational health professionals have a duty to make their research results publicly available. They are accountable for the accuracy of their reports.

www.icohweb.org/site/multimedia/code_of_ethics/code-of-ethics-en.pdf

International code of ethics

Collective health data

22. When there is no possibility of individual identification, information on aggregate health data on groups of workers may be disclosed to management and workers' representatives in the undertaking or to safety and health committees, where they exist, in order to help them in their duties to protect the health and safety of exposed groups of workers. Occupational injuries and work-related diseases must be reported to the competent authority according to national laws and regulations.

www.icohweb.org/site/multimedia/code_of_ethics/code-of-ethics-en.pdf

Informed consent

- Participants must understand the nature of the research
- Participants must be able to voluntarily decide whether or not to participate
- Participants must understand the risks and benefits of participation
- Participants must have the opportunity to ask questions

Informed consent

What are the elements to address in an informed consent form?

Consent form requirements

- Description of study (purpose, duration, procedures)
- Description of foreseenable risks/discomforts
- Description of benefits
- Disclosure of alternative procedures
- Description of confidentiality of records and anonymity
- Statement of who to contact for 1) research questions 2) research related illness or injury 3) rights for research subjects
- Statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits
- Most cases require that informed consent be documented in writing (two forms – one for the subject and one for the resaercher). Assent forms are needed for vulnerable persons (eg children)

World Health Organization

ntre | Publications | Countries | Programmes | Governance | About WHO

Research policy

Informed Consent Form Templates

(language used throughout form should be at the level of a local student of class 6th/8th)

Notes to Researchers:

1. Please note that these are templates developed by the WHO ERC to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. **The logo of the Institution must be used on the ICF and not the WHO logo.**
2. The informed consent form consists of two parts: the information sheet and the consent certificate.
3. Do not be concerned by the length of these templates. They are long only because they contain guidance and explanations which are for you and which you will not include in the informed consent forms that you develop and provide to participants in your research.
4. These templates include examples of key questions that may be asked at the end of each section, that could ensure the understanding of the information being provided, especially if the research study is complex. These are just examples, and suggestions, and the investigators will have to modify the questions depending upon their study.

http://www.who.int/rpc/research_ethics/informed_consent/en/

[Informed Consent form for _____ _____]

Name the group of individuals for whom this informed consent form is written.Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

(Example: This Informed Consent Form is for men and women who attend clinic Z, and who we are inviting to participate in research on X. The title of our research project is "……")

You may provide the following information either as a running paragraph or under headings as shown below.

[Name of Principal Investigator]
[Name of Organization]
[Name of Sponsor]
[Name of Proposal and version]

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant_____

Signature of Participant _____

Date _____
Day/month/year

Anonymous data

- By some ethics committee , the project must be made completely anonymous:
- Take care not to realize a study
    - **Pseudo anonymous:** the investigator knows the identification of the participants and in a given case, the investigator may award the participant!
    - If you want to research pseudo anonymous, we need a new vote of the local ethics commission!

Recruitment and retention issues

Recruitment and retention issues

What are the points to consider in the recruitment and retention of participants?

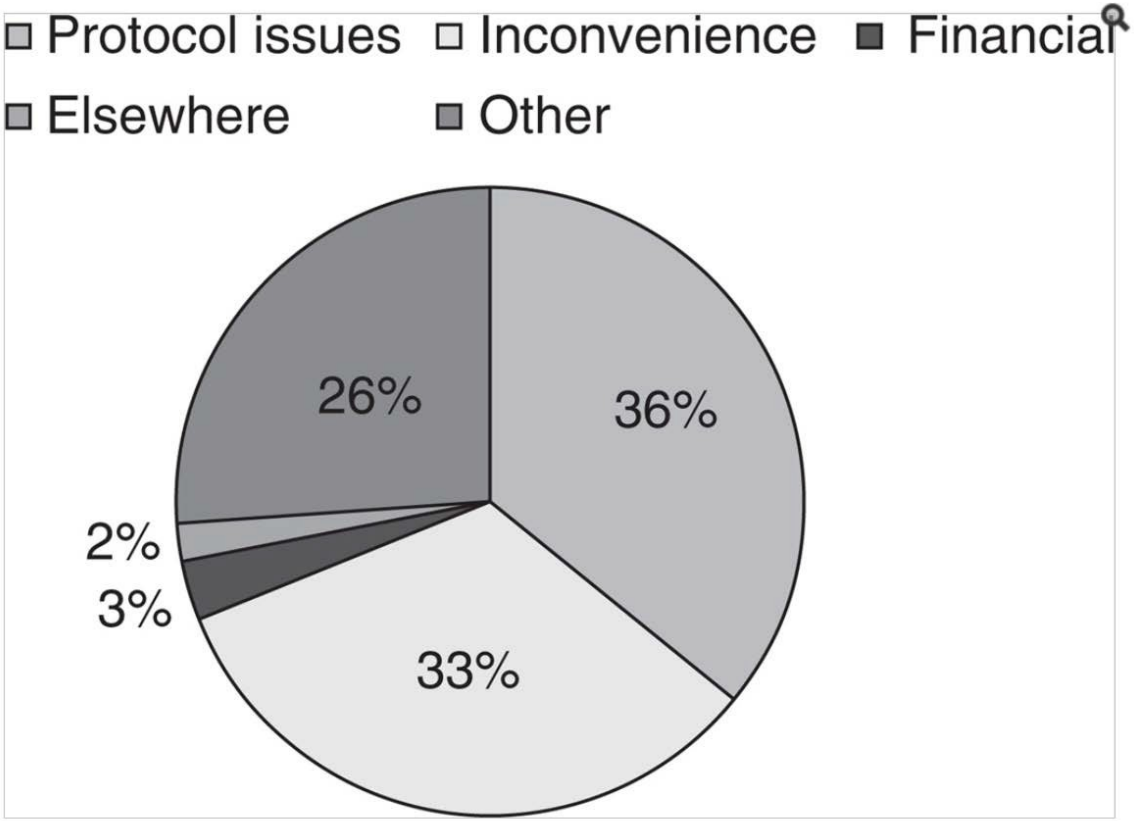
Do you have strategies to increase participation?

Participation rate

Some points to consider

- Engagement : how are the relationships with your potential participants?
- Methods of contact : telephone, face to face,…
- Benefits for participation
- Barriers to participation
- Informational materials
- Planning and timing
- Staff : training and accessibility

Participation rate



Also :

- Sociodemographic factors (age, race, education,…)
- Increasing number of request to participate in studies
- Length of questionnaire
- Collection of bio-specimens, …

Figure 1 : Reasons to decline

J Empir Res Hum Res Ethics. 2011 Mar; 6(1): 69–74.

Participation rate

Some strategies

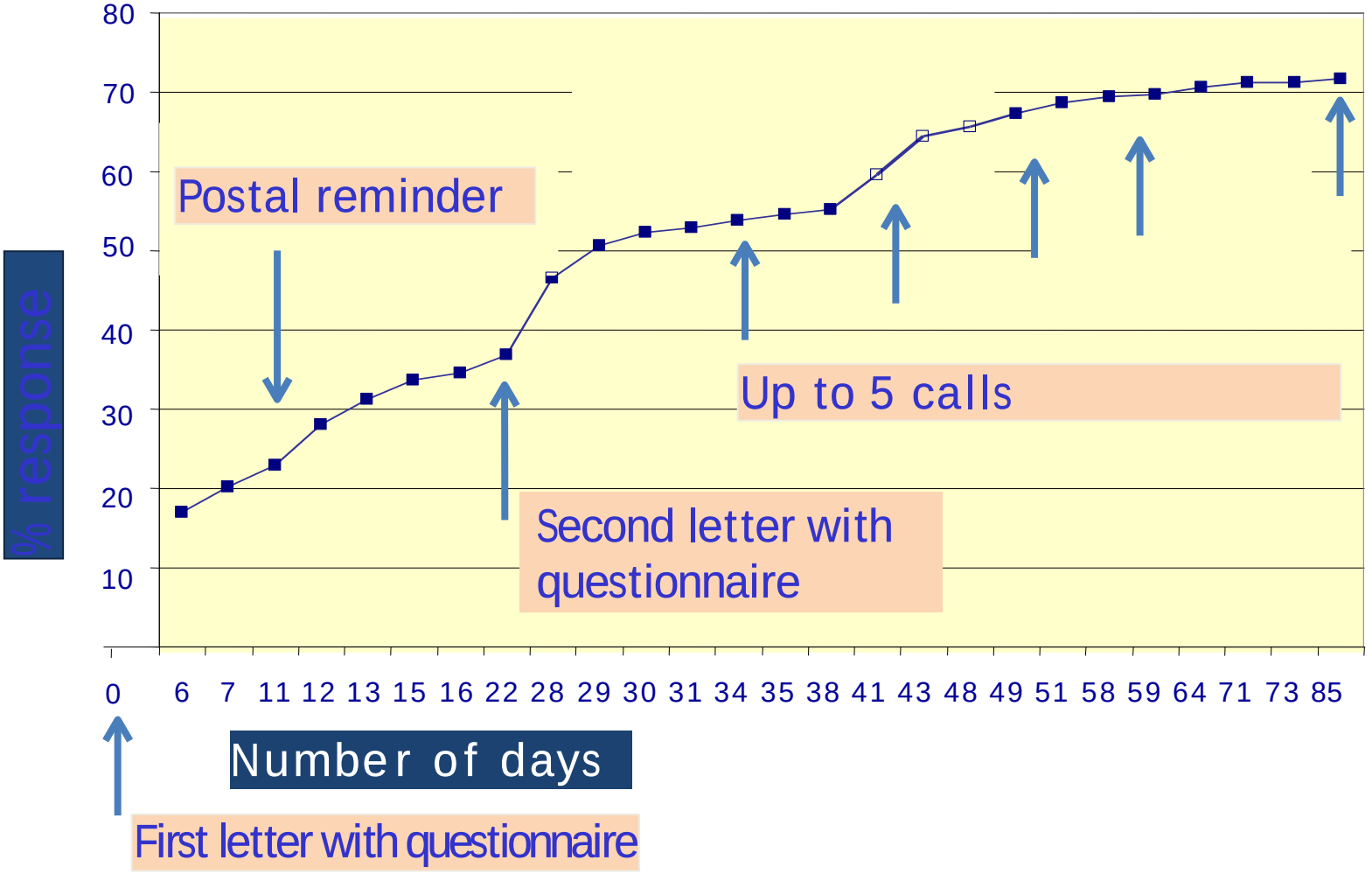
- Recruitment tools, tailored to the target audience: flyers, newspaper, interviews, websites,…
- Incentives (monetary and others)
- Have a point of contact : telephone number, email
- Be flexible when scheduling appointments
- Report results in appropriate formats to participants

Maximize the participation

Example questionnaire sent by post or e-mail

Day 1	First letter of invitation with the questionnaire
Day 8	Postal reminder
Day 22	Reminder letter with another questionnaire
From day 32	Telephone contact

Maximize the participation/ response rate



Maximize the participation/ response rate: interview

- Do not replace the participant
- Plan the visits in a period in which it is probable to meet the worker(s)
- Example: do not plan the field work during the holiday period, religious free days, etc.

Participation rate

Cochrane Library

Cochrane Database of Systematic Reviews

2016

Strategies designed to help healthcare professionals to recruit participants to research studies (Review)

Preston NJ, Farquhar MC, Walshe CE, Stevinson C, Ewing G, Calman LA, Burden S, Brown Wilson C, Hopkinson JB, Todd C

Authors' conclusions:

There is no strong evidence for any single strategy to help healthcare professionals to recruit participants in research studies. Additional visits or information did not appear to increase recruitment by healthcare professionals. The most promising strategies appear to be those with a dedicated resource (e.g. a clinical recruiter or automated alert system) for identifying suitable participants that reduced the demand on healthcare professionals, but these were assessed in studies at high risk of bias.