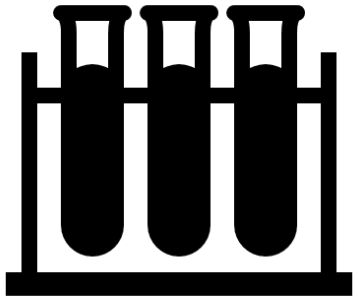
Designing a Research Study

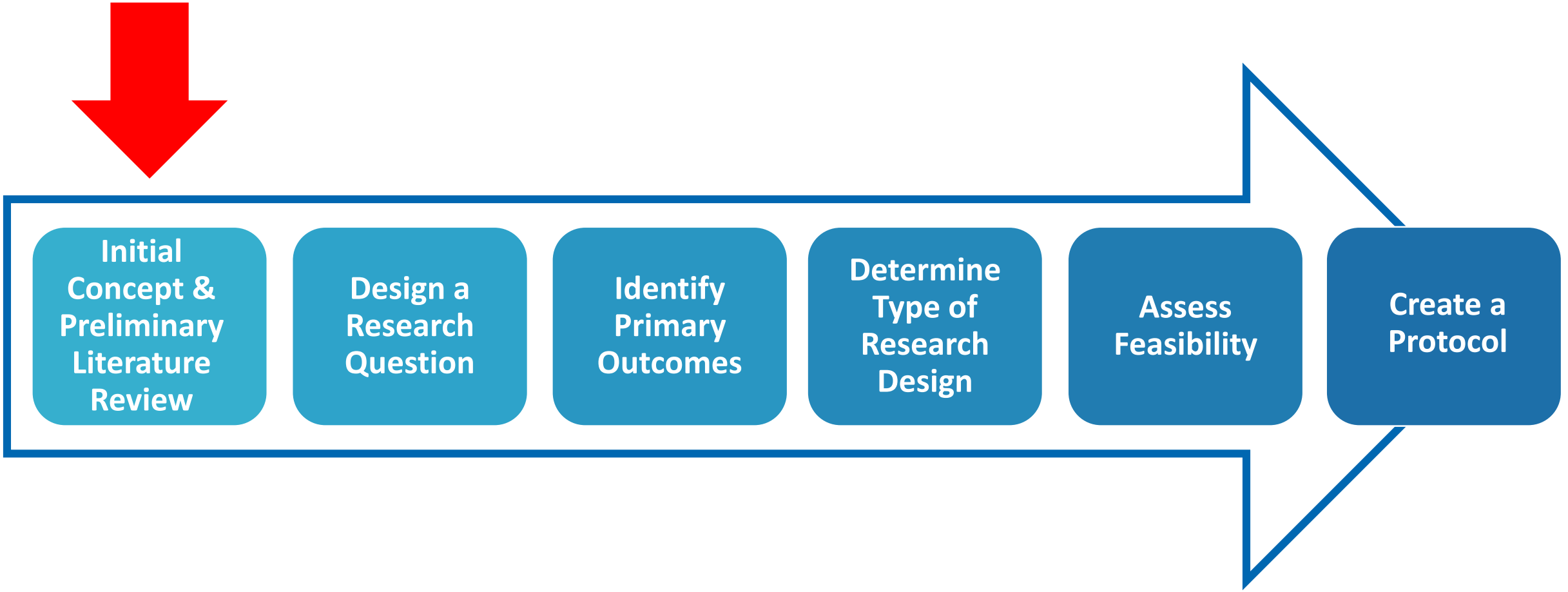
Presenter: Sarah Ibrahim, RN, PhD, CHSE



Learning Objectives

1. To identify best practices for developing a research question, defining outcomes of interest and assessing feasibility.
2. To describe various clinical research designs.
3. To differentiate between quality improvement projects and research projects.
4. To describe the key elements in a research study protocol.

Designing Your Study: From Idea to Execution



Designing a Study

STEP 1: THE CONCEPT

A) Addresses a gap
B) Contributes to a body of knowledge
C) Enhances health services and / or delivery
D) Ultimately, improves patient care or outcomes

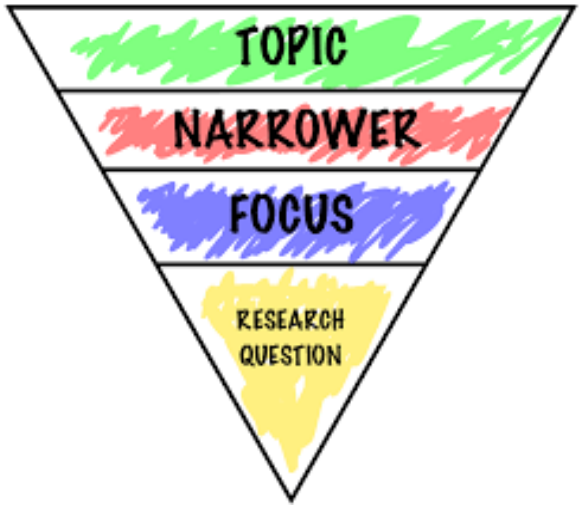
STEP 2: DUE DILIGENCE

Conduct a preliminary literature review:

A) What information currently exists on the research topic?
B) Are there any gaps in the literature?
C) Consider how the study will contribute to scientific literature?
D) Will the study refute current theories or generate a new one?

STEP 3: THE RESEARCH QUESTION

The development of a clear, focused, specific and feasible research question.



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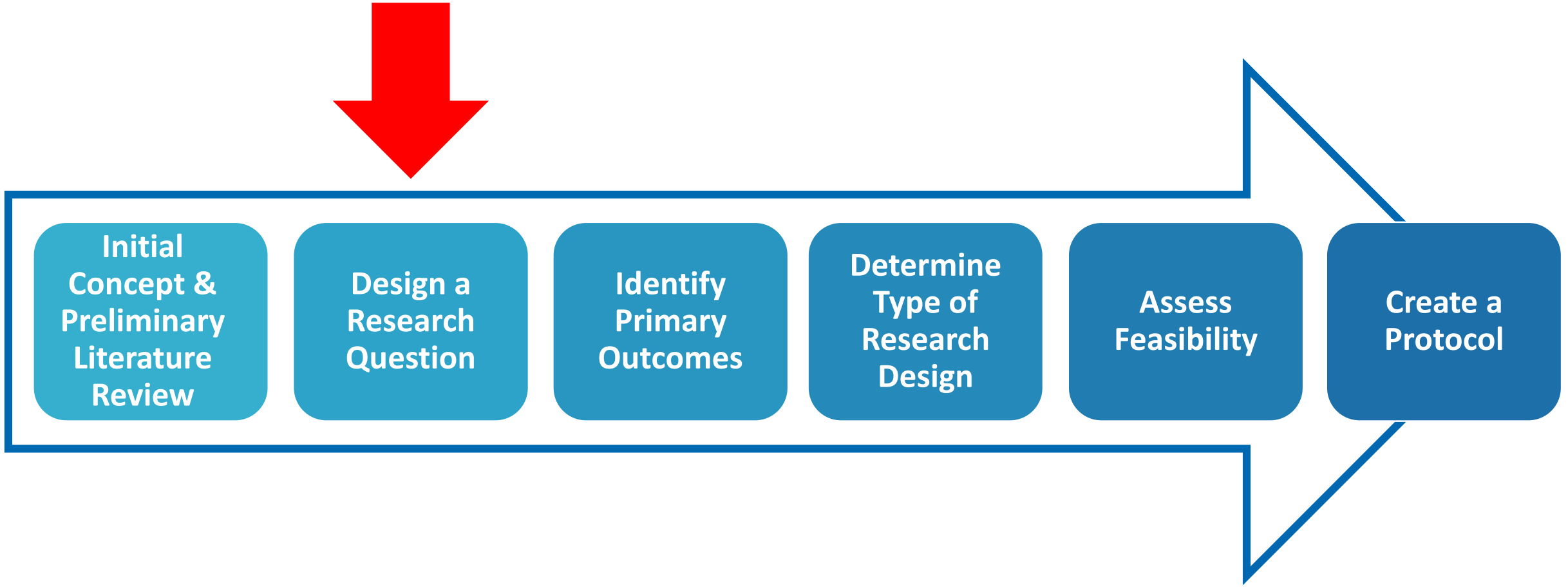

Formulating Research Questions

Two Types of Questions

Photo by pine watt on Unsplash

Background Questions

- Overall broad questions:
  - Often begin with ***what, when, where, how*** and ***why***

- Answers provide **general knowledge**

- **Examples:**
  - What is the best method to prevent pressure ulcers?
  - What is sepsis?
  - What is COVID-19?

Foreground Questions

- Specific questions, often related to a specific clinical issue
- Answers provide **evidence for clinical decision making**
- Foreground questions:
  - Arise from clinical uncertainty or clinical curiosity
  - Informs a clinical issue
- **Example:**

  In parents of hospitalized children, how does the presence of a parent compared to no presence of a parent affect the amount of nighttime sleep during a short-term hospital-stay on the pediatric unit?”

Background vs. Foreground Questions

Background Question	Foreground Question
A broad, basic-knowledge question that is commonly answered in textbooks. May begin with: what, when, how and why	A specific question that provides evidence for clinical decision making, when answered. Includes key elements: Population (P), Intervention or issue of interest (I), Comparison intervention or issue of interest (C), Outcome of Interest (O), Time (T).

Stillwell et al. (2010)

Question

Which type of question is most commonly asked in research?

a) Background

b) Foreground

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a) Background

b) Foreground

Foreground Question Component: PICO(T)

P	I	C	O	T
Population to be Assessed	**Interventions, Treatments or Tests**	**Comparison Group (if any)**	**Outcome – What do you want to measure?**	**Time – Duration of data collection**

Research Question Design Exercise

You work in a pediatrician's office in Toronto, Ontario and you routinely withdraw blood in young children (5-7 years of age) who are often afraid of needles.

You notice that some nurses use technological devices such as tablets to distract children. You want to know if using tablets as a distraction technique influences children's pain scores, compared to not using a distraction technique, over a one-year duration.

Let's use the PICOT tool to design the research question.

In _____(P), how does _____(I) compared to _____(C) affect _____(O) within _____(T)?

Research Question Design Exercise

You work in a pediatrician's office in Toronto, Ontario and you routinely withdraw blood in young children (5-7 years of age) who are often afraid of needles.

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In _____(P), how does _____(I) compared to _____(C) affect _____(O) within _____(T)?

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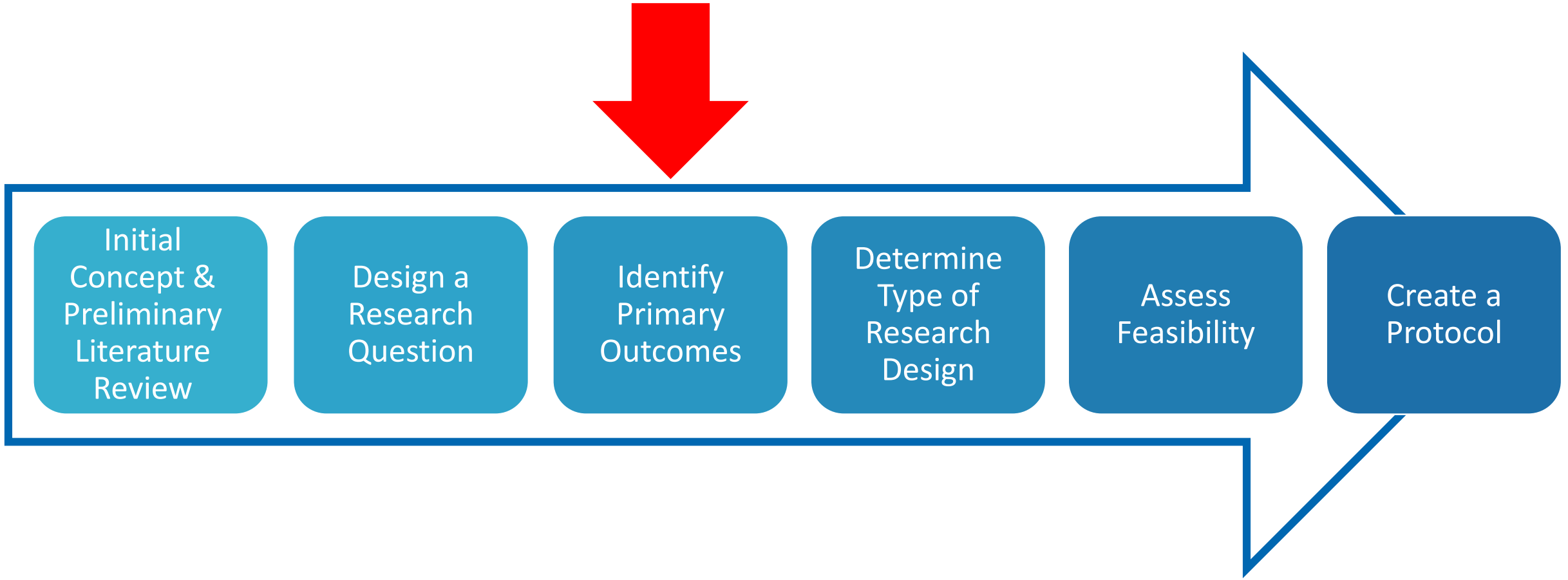
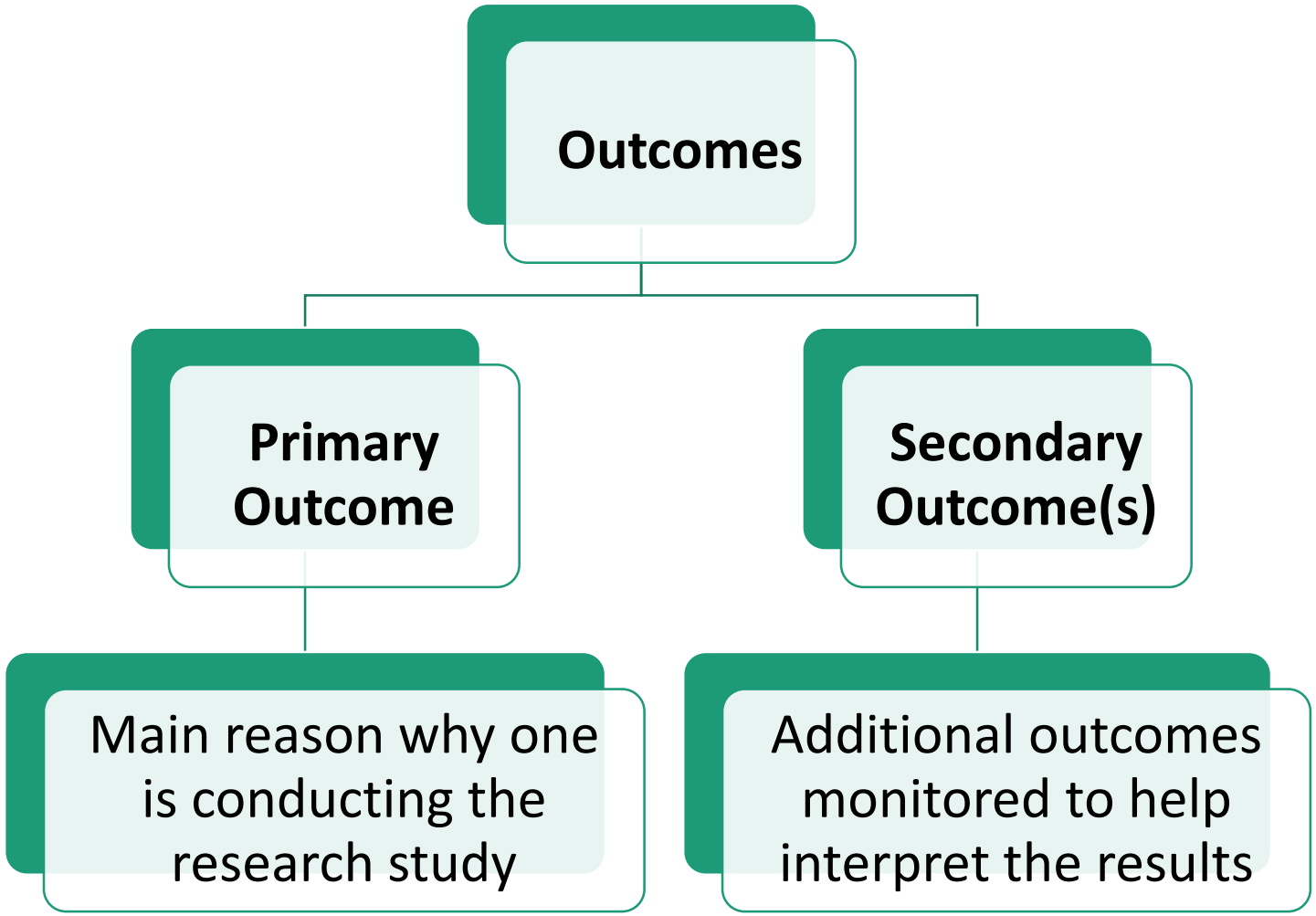


Outcomes of Interest



Outcomes of Interest

Theoretical / Conceptual Definition

- Indicates what the constructs of interest means (i.e., definition of pain, anxiety)

Operational Definition

- Indicates how the outcome of interest will be measured (i.e., use of psychometrically sound instrument, observations, checklist etc.)

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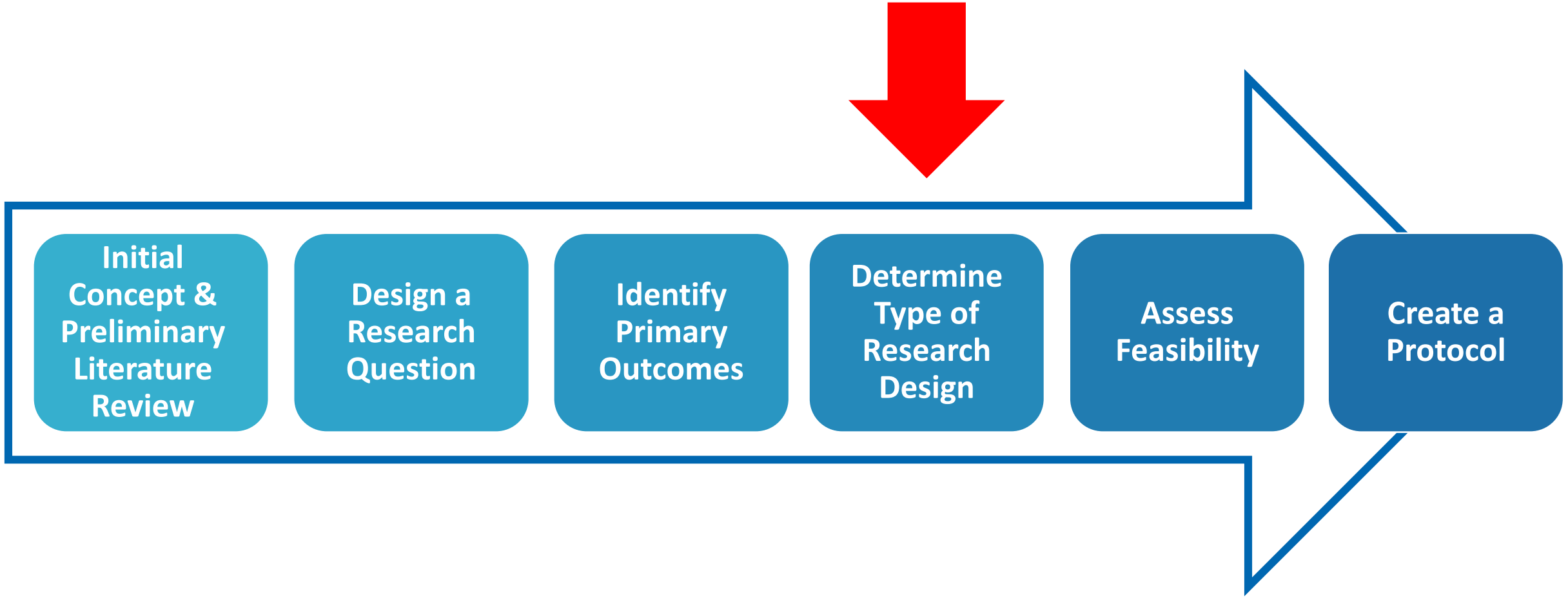
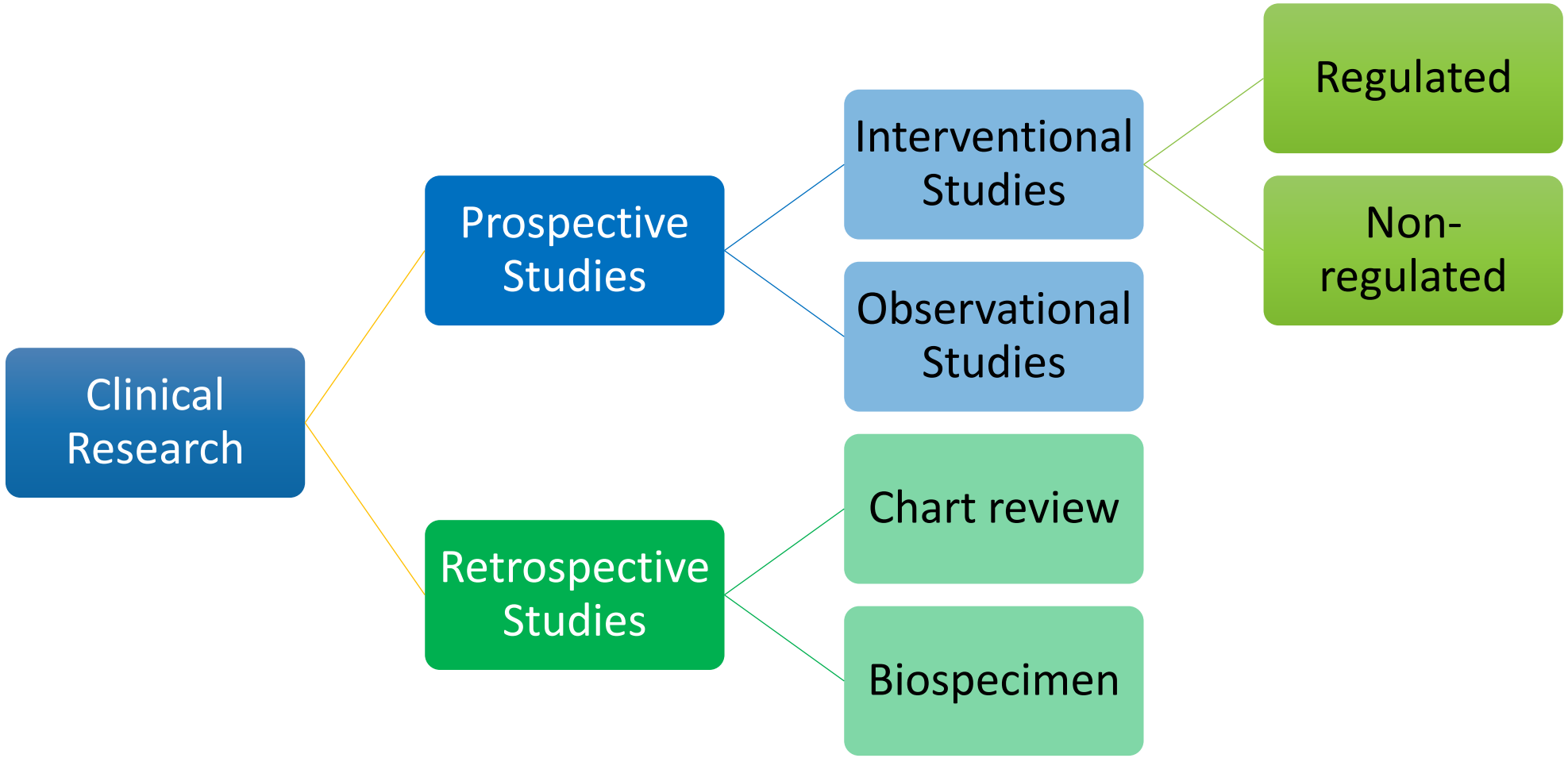


Types of Clinical Research Design



Types of Clinical Research Designs

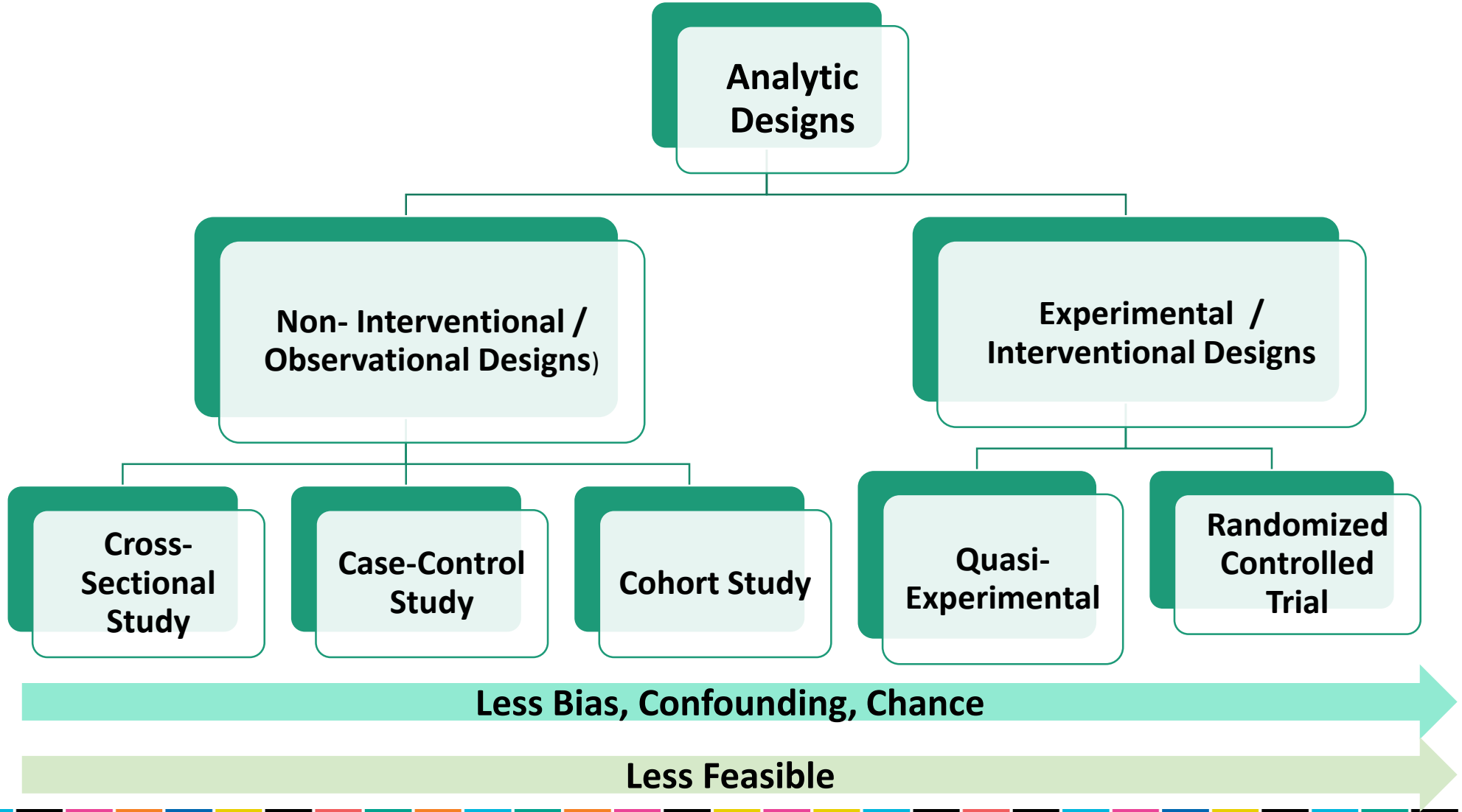
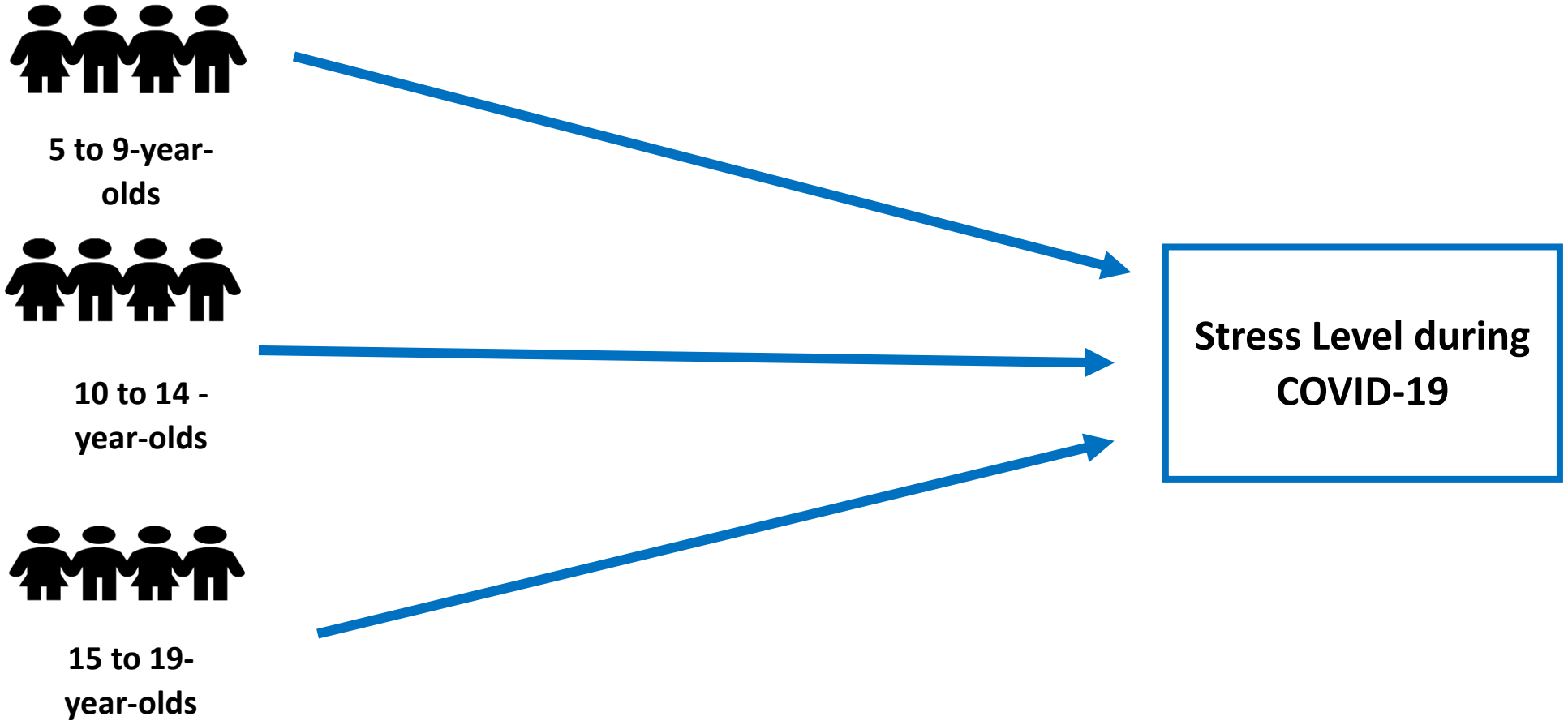
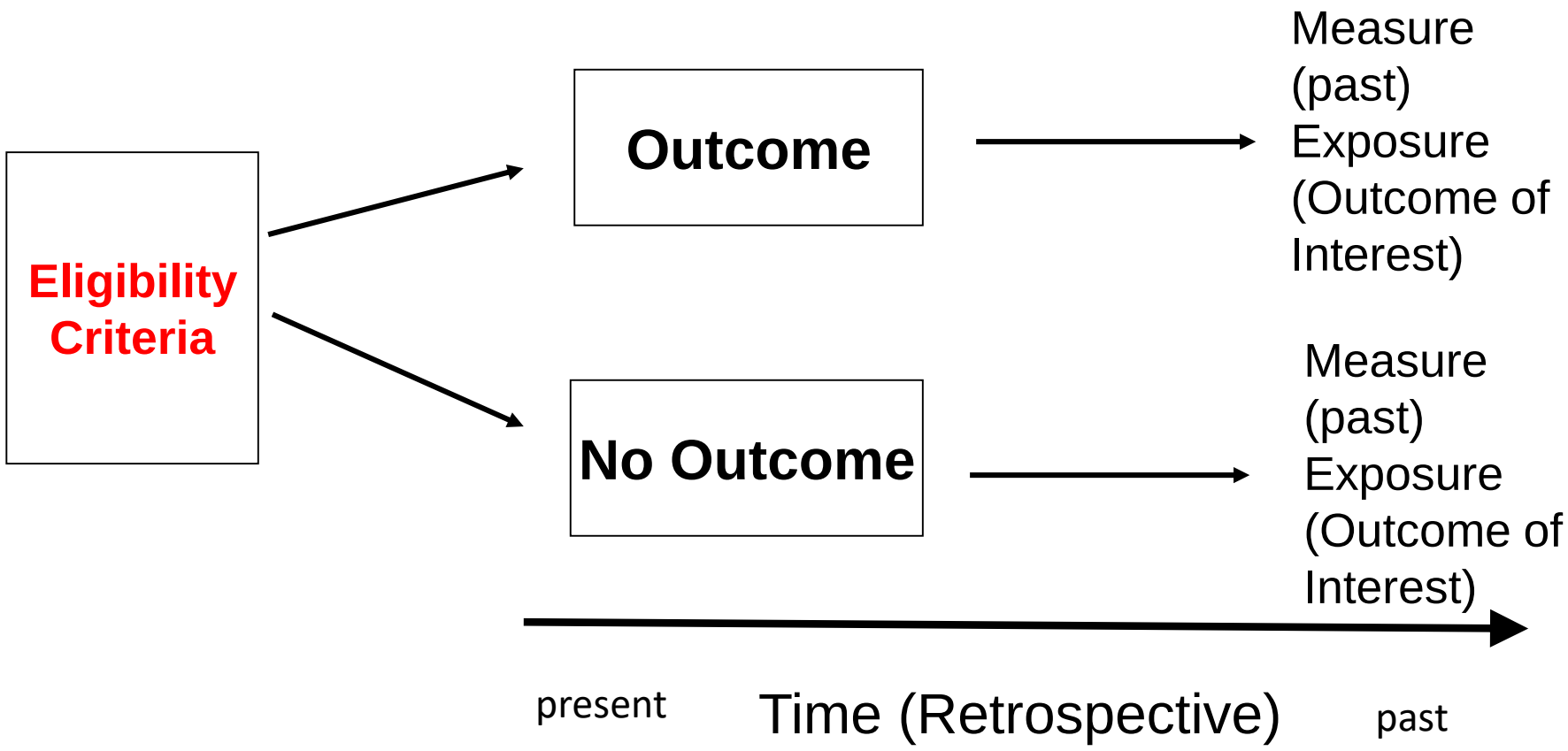


Image adapted from: CEBM (2020)

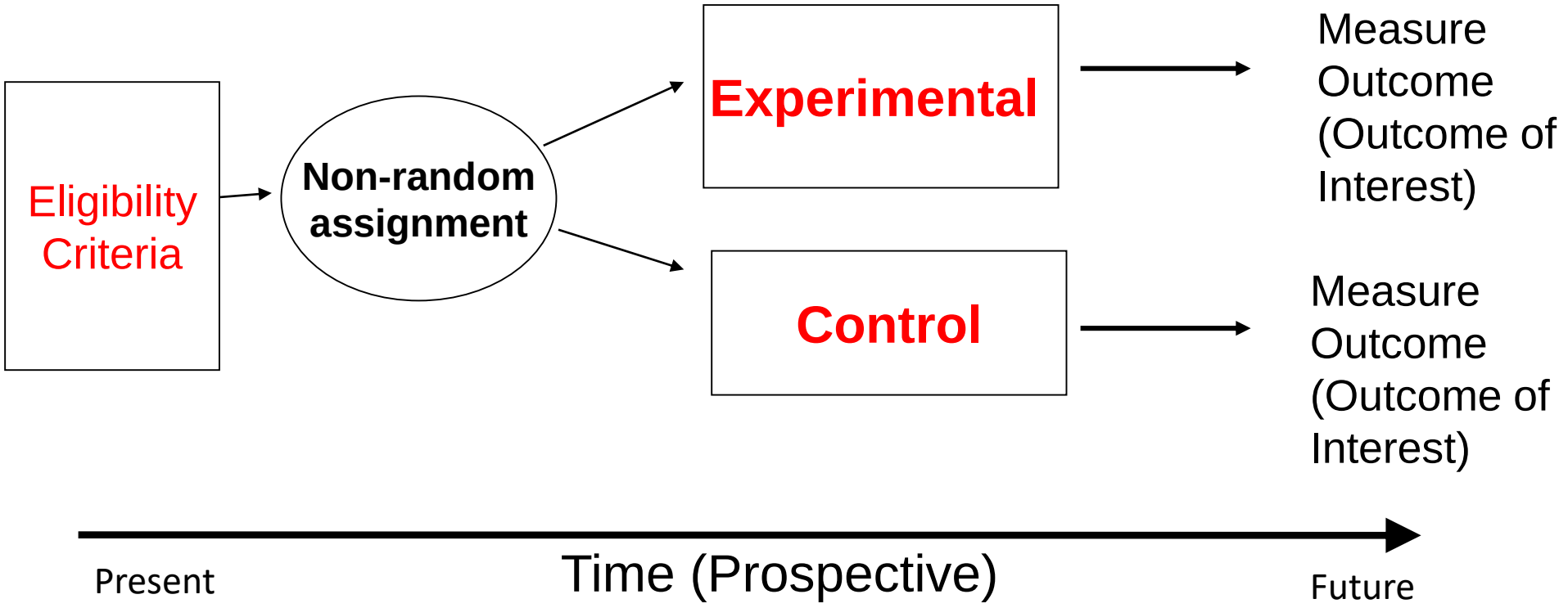
Non-Interventional: Cross-Sectional



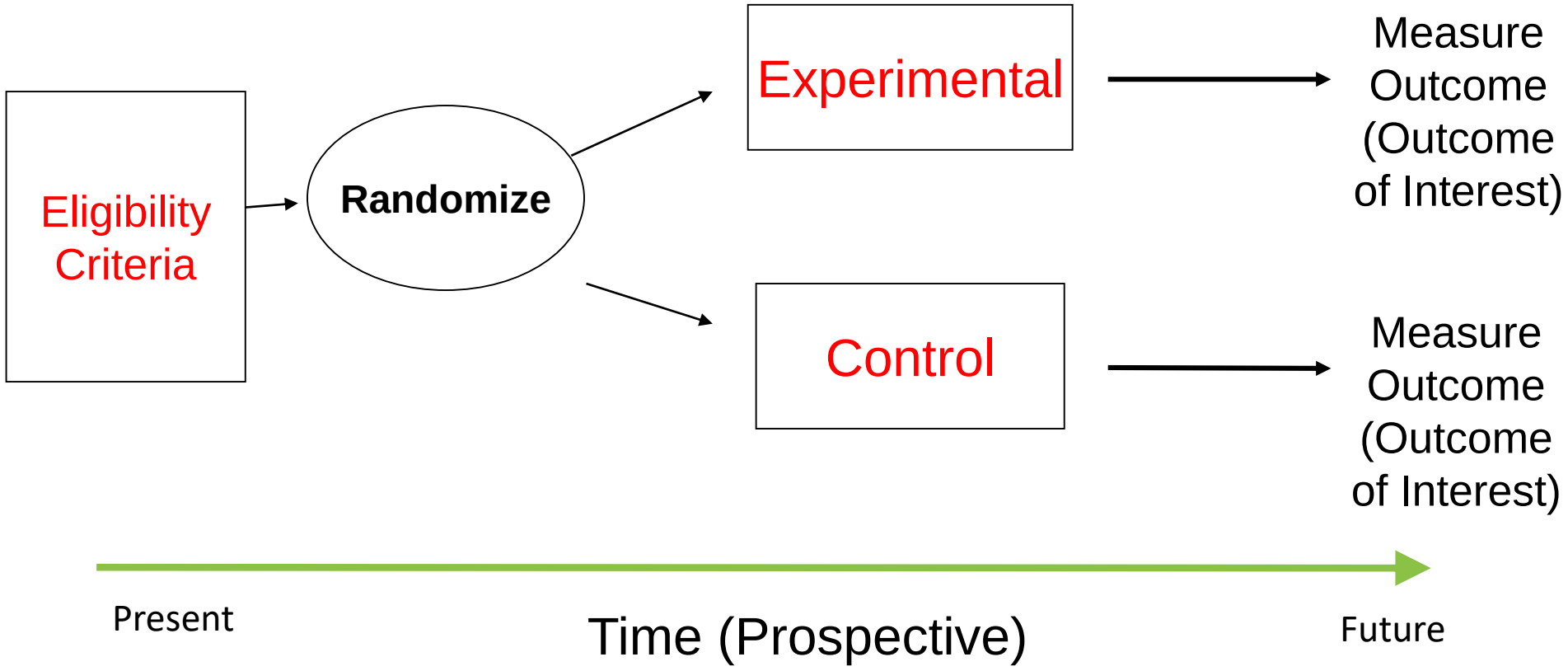
Non-Interventional: Case- Control



Interventional: Quasi-Experimental



Interventional: Randomized Clinical (Control) Trial



Question

What is the main difference between a quasi-experimental and randomized clinical (control) trial?

A. Randomization process
B. Selection Criteria
C. Data collection procedures
D. Data analysis procedures

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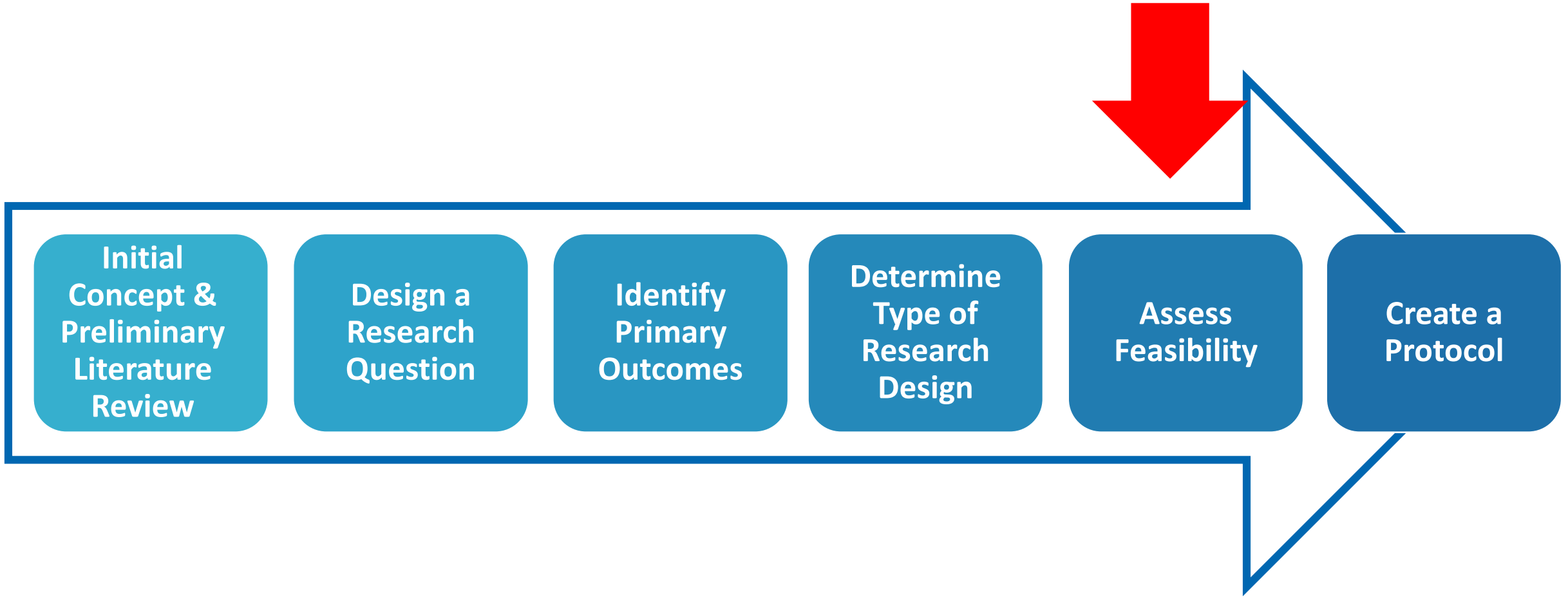

Practical considerations when planning clinical research studies

Safety events

Ensuring there is enough money & personnel to address safety events should they occur

Time spent recruiting

Often longer & disruptive to other study work!

Local vs. out of town study participants

Travel time & costs for travel need to be considered

Study design – timing of procedures

Scheduling participant visits to multiple departments (imaging, DPLM etc.)

Assessing Feasibility

An interesting research question does not necessarily equal an answerable question.

SCIENCE	FEASIBILITY	OPERATIONS
• Is the study population appropriate? • Is the hypothesis reasonable?	• Is the current clinical population adequate?	• Do all aspects of the protocol make sense? • Is the study budget appropriate to carry out the protocol?

The review is completed by clinicians/scientists that are **NOT** a part of the study team

- Usually done at departmental meetings (HINT: check when these are scheduled to plan your SFO review!)
- Should avoid conflict of interest (i.e. collaborator) and ensure appropriate expertise

Clinical Research vs. Quality Improvement Projects / Initiatives

Research vs. Quality Improvement

	Quality Improvement	Research
Purpose	To **implement knowledge**, assess a process or program as judged by established or accepted standards	To develop or contribute to generalizable knowledge
Rationale	Knowledge-seeking integral to the ongoing process of health care delivery	Knowledge-seeking independent routine care and intended to answer a question or test a hypothesis
Design	**Adaptive, iterative design**; flexible and responsive to change throughout project lifecycle	Follows a rigid protocol that will remain unchanged throughout the study
Benefits	**Directly benefits** a process, system or program; might or might not benefit patients	Might or might not benefit current subjects; intended to benefit future patients
Risks	**Does not increase risk** or cause excessive burden to patients or staff	May put subjects at risk
Participant Obligation	**Participation typically occurs as component of care or work**	No obligation of individuals to participate
Endpoint	**Improve a program, process or system**	Answer a research question and contributes to generalizable knowledge
Analysis	**Compare program, process or system to an already established or accepted standard**	Statistically prove or disprove hypothesis
Adoption of Results	Results **rapidly adopted** into local setting	Little urgency to disseminate results

Is it Research or Quality Improvement?

In the example, would you consider it to be a research study or quality improvement project?

This project aims to increase the proportion of children undergoing orchidopexy surgery by the Division of Urology at SickKids before they are 18 months old from 49% to 75%, by the end of November 2020. This intervention applies specifically to children diagnosed with UDT before their 5th birthday. In Canada, the recommendation is that orchidopexy be performed between 6 and 18 months of age. The focus of this project will be on reducing the time between referral and surgery, which currently stands at a mean of 10 months by:

- Prioritization of orchidopexy surgery and review organization of orchidopexy wait-list
- Referring doctor education

What criteria are you using to make this decision?

Research vs. QI Reflective Checklist

Is the aim of the project to improve care for the next patient, local operations or efficiency?
Is there a precedent for this intervention or practice change?
Are the proposed methods incorporating rapid evaluation, feedback and incremental changes?
Do the methods include control groups, randomization or a fixed protocol?
Is there a known intervention or practice change included as part of this project?
Is the risk related to the project minimal and no more than usual care?
Does the project involve use of a pharmaceutical device, drug or natural health product under Health Canada Food and Drug Act regulations or guidelines?
Will this project only involve participants (patients, parents, or staff) who are already seen, cared for, or work in the project setting?
Will this project require participants to be involved outside of a hospital visit or work hours?
Is the project externally funded?

Is it Research or Quality Improvement?

1. Is the aim of the project to improve care for the next patient, local operations or efficiency?

YES

2. Is there a precedent for this intervention or practice change?

YES

3. Are the proposed methods incorporating rapid evaluation, feedback and incremental changes?

YES, changes

4. Do the methods include control groups, randomization or a fixed protocol?

NO

5. Is there a known intervention or practice change included as part of this project?

No intervention

6. Does the project involve use of a pharmaceutical device, drug or natural health product under Health Canada Food and Drug Act regulations or guidelines?

NO

7. Will this project only involve participants (patients, parents, or staff) who are already seen, cared for, or work in the project setting?

Yes, current patients

8. Will this project require participants to be involved outside of a hospital visit or work hours?

NO

9. Is the project externally funded?

NO

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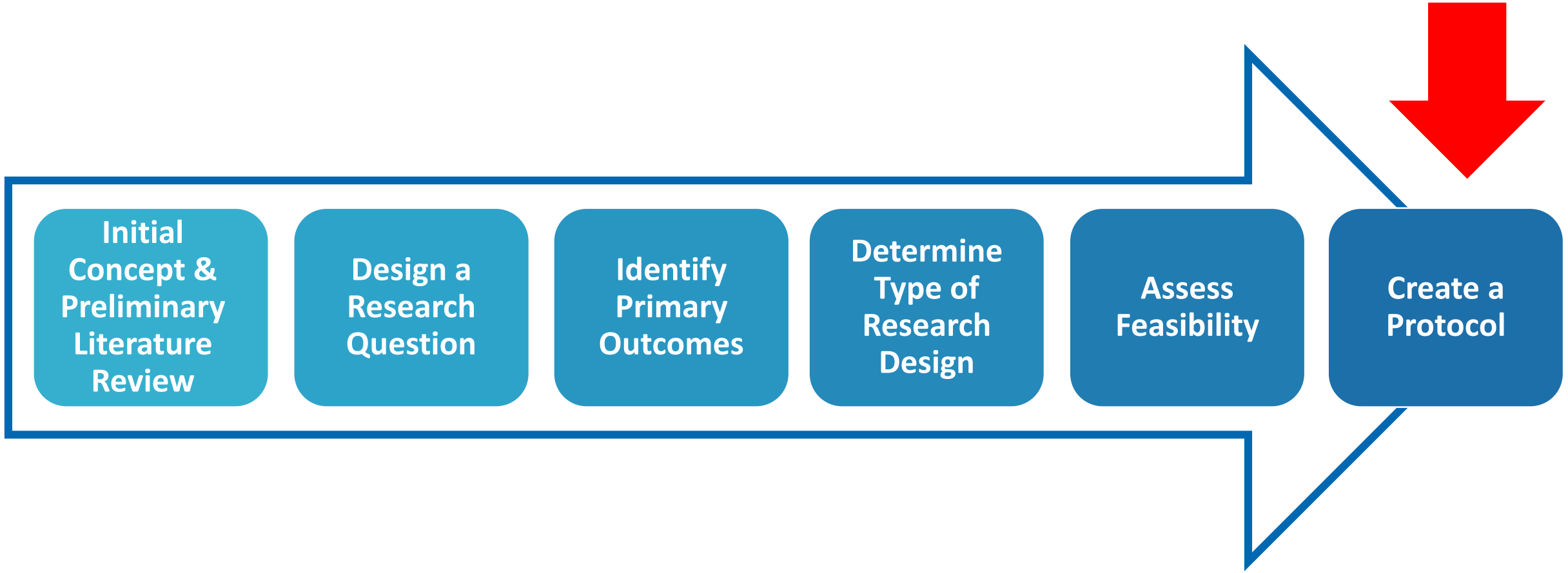


What is the difference between a proposal and a protocol?

"Here's why you should give me $$ to study this!"

Research Proposal

- What you plan to achieve
- Why you want to achieve it
- How you are going to do it
- What resources are available

Research Protocol

- Describes a research study in detail
- A protocol includes:
  - Study objectives
  - Design
  - Statistical considerations
  - Procedures to be carried out

"Here's how I'm going to conduct this study!"

Components of a Research Protocol

Introduction (Background)

Study Aims & Objectives

Research questions & hypothesis

Methods & Materials

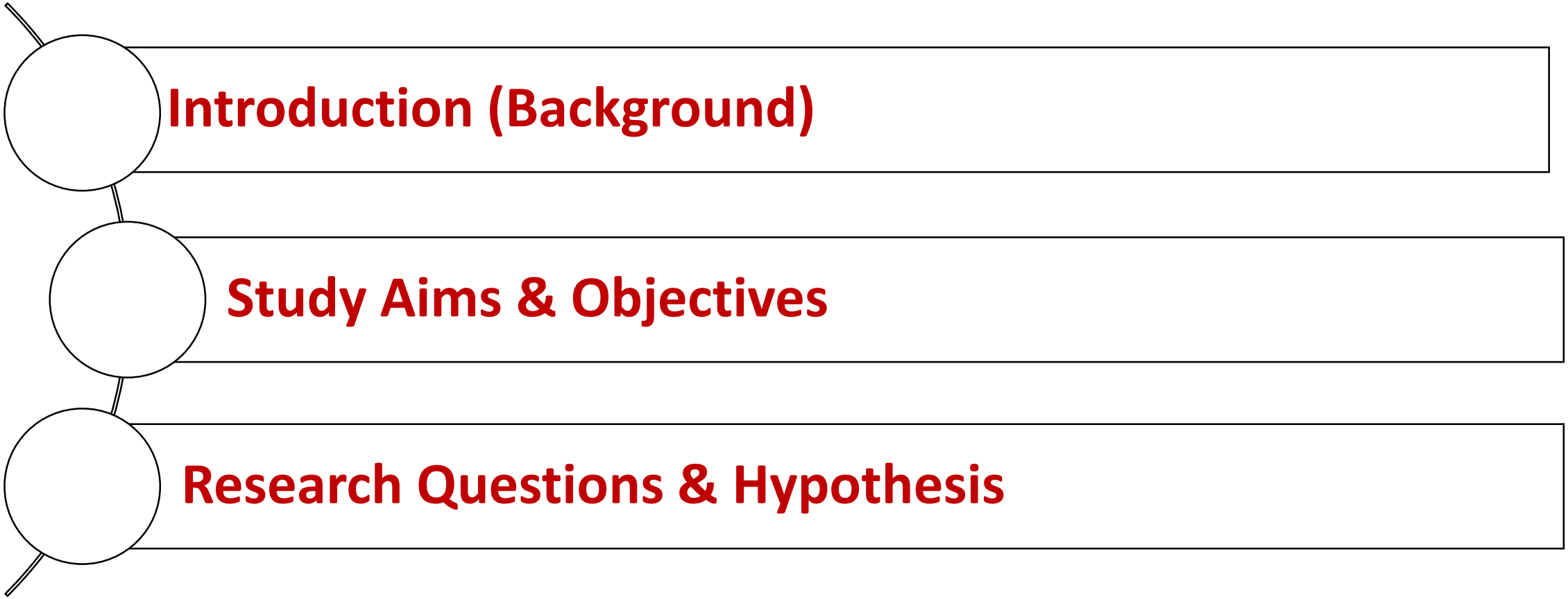
Ethical Considerations

Data Monitoring Plan

Knowledge Translation Plan

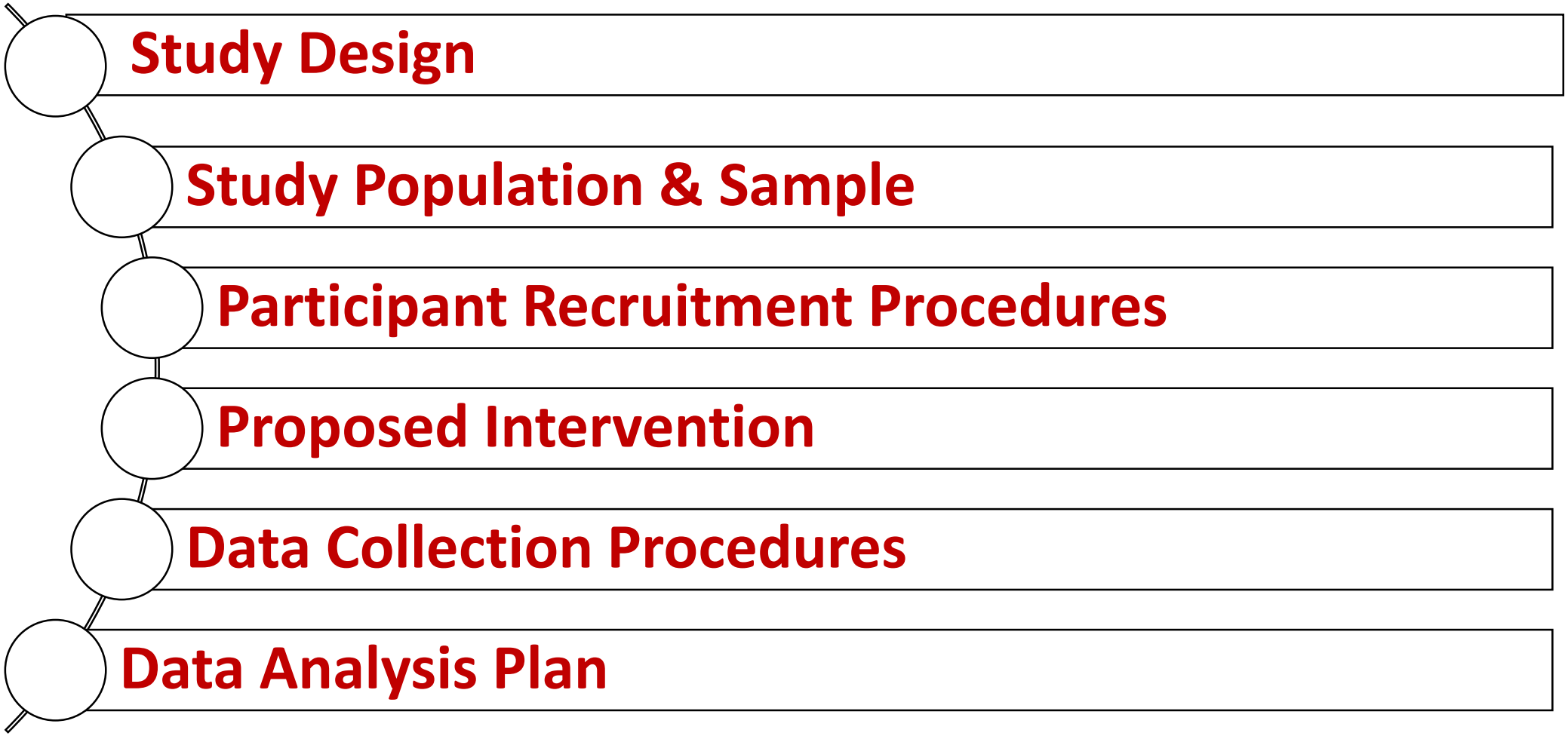
References

Components of a Research Protocol



Components of a Research Protocol

Methods & Materials



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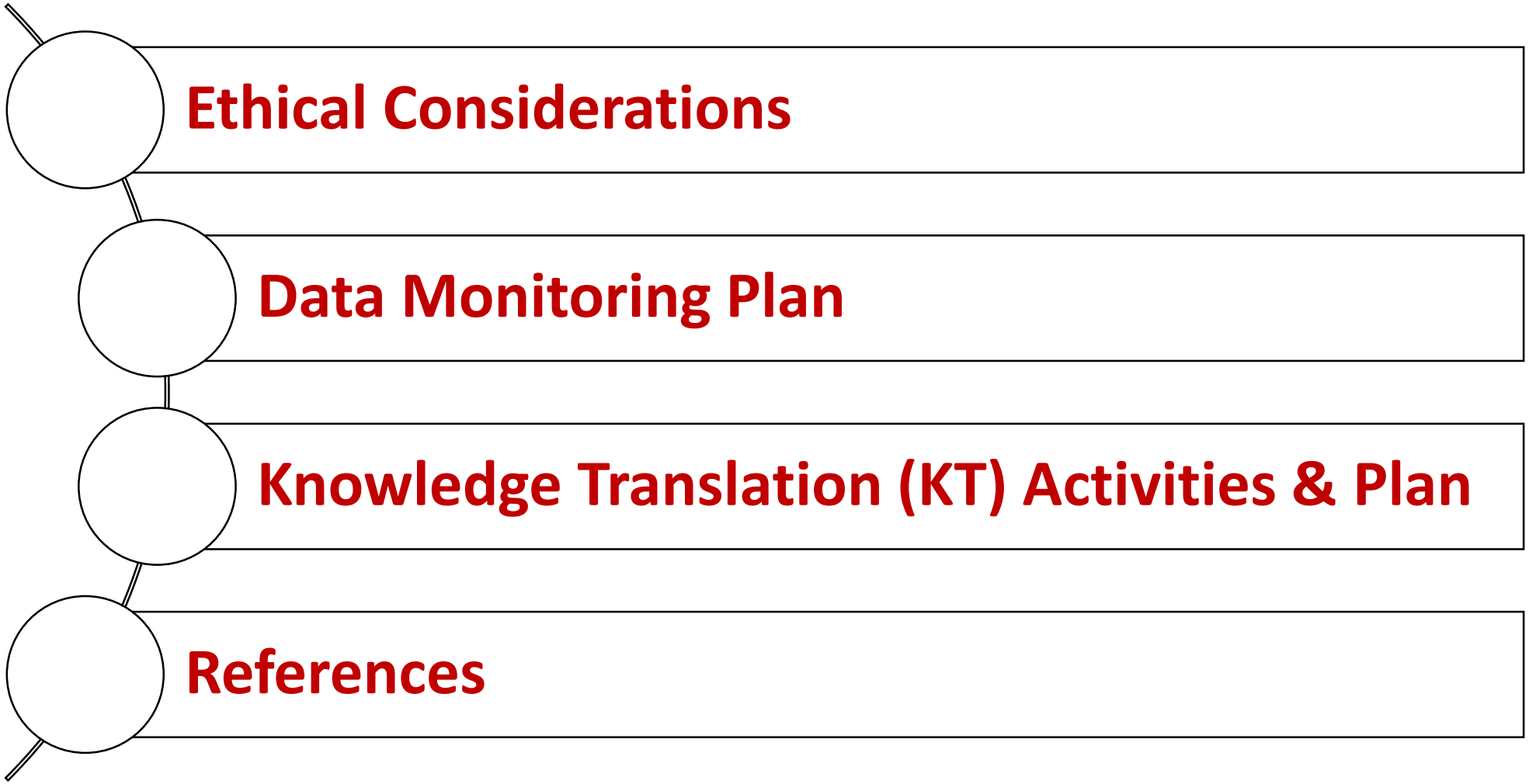

Question

When submitting one's research plan to a funding agency (i.e., CIHR), are you submitting a proposal or a protocol?

a) Proposal

a) Protocol

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When submitting one's research plan to a funding agency (i.e., CIHR), are you submitting a proposal or a protocol?

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Resources to Develop a Protocol

CONSORT statement - Consolidated Standards of Reporting Trials
https://www.strobe-statement.org/?id=available-checklists

PRISMA statement - Preferred Reporting Items for Systematic Reviews and Meta-Analyses
http://prisma-statement.org/documents/PRISMA%202009%20checklist.pdf

STROBE Statement - Strengthening the Reporting of Observational studies in Epidemiology
https://www.strobe-statement.org/index.php?id=strobe-home

CARE Guidelines - Case Reports
http://data.care-statement.org/wp-content/uploads/2016/08/CAREchecklist-English-2016.pdf

AGREE reporting checklist - Appraisal of Guidelines for Research & Evaluation
https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf

CHEERS - Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement
http://www.equator-network.org/wp-content/uploads/2013/04/Revised-CHEERS-Checklist-Oct13.pdf

ARRIVE - Animal Research: Reporting of In Vivo Experiments
https://www.nc3rs.org.uk/arrive-guidelines

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The Centre for Evidence-Based Medicine (CEBM). (2020). Study Designs. Retrieved from: https://www.cebm.net/2014/04/study-designs/

Stillwell, S., Fineout-Overholt, E., Melnyk, B., & Williamson, K. (2010). Asking the clinical question: A key step in evidence-based practice. *American Journal of Nursing, 110*(3), 58-61.