PRINCIPLES AND STEPS- CLINICAL RESEARCH

RESEARCH

- SYSTEMATIC INVESTIGATION TO ESTABLISH FACTS
- IMPORTANT TOOL TO HELP DEVELOP SOLUTION TO BENEFIT PEOPLE ALL OVER THE WORLD

- IDENTIFICATION OF BETTER WAYS TO PREVENT,DIAGNOSE,TREAT AND UNDERSTAND HUMAN DISEASES

- TREATMENT– CARE PROVIDED TO IMPROVE A SITUATION OR DISEASE

CLINICAL TRIAL

- RESEARCH STUDY THAT TESTS HOW WELL AN INTERVENTION WORKS IN A GROUP OF PEOPLE

- TESTS NEW METHODS OF SCREENING,PREVENTTION DIAGNOSIS OR THERAPY

- CONDUCTED IN PHASES
- ANSWERS SCIENTIFIC QUESTIONS
- ETHICAL

ELEMENTS AND PRINCIPLES

- PROTOCOL
- PROTOCOL REVIEW
- SPONSORS
- ELIGIBILITY CRITERIA
- INFORMED CONSENT
- TYPES OF CLINICAL TRIALS
- PHASES OF CLINICAL TRIALS

- WHO CAN PARTICIPATE IN CLINICAL TRIALS – INCLUSION AND EXCLUSION CRITERIA

- IMPORTANCE OF ETHICS IN CLINICAL TRIALS

PROTOCOL

- PLAN OR ACTION PLAN
- WHO IS ELIGIBLE
- DETAILS ABOUT TEST,PROCEDURES
- LENGTH OF STUDY
- WHAT INFORMATION WILL BE GATHERED
- LED BY PRINCIPAL INVESTIGATOR

PROTOCOL REVIEW

- APPROVAL BY INSTITUITIONAL REVIEW BOARD OR IRB,ETHICAL COMMITTEE
- SURGEONS,STATISTICIANS,OTHER MEMBERS
- ENSURES ETHICS AND RIGHTS OF ALL PARTICIPANTS

SPONSOR

- FOUNDATIONS
- MEDICAL INSTITUIIONS
- SURGEON
- VOLUNTARY GROUPS
- PHARMA COMPANIES
- OTHER FEDERAL AGENCIES

ELIGIBILITY CRITERIA

- GUIDELINES WHO CAN OR CAN'T PARTICIPATE
- CHARACTERISTICS THAT MUST BE MINIMALLY SHARED BY ALL PARTICIPANTS

  AGE

  GENDER

  MEDICAL HISTORY

  CURRENT HEALTH STATUS,LAB VALUES

INFORMED CONSENT

- PROCESS OF PROVIDING POTENTIAL PARTICIPANTS WITH IMPORTANT FACTS ABOUT A CLINICAL TRIAL BEFORE THEY DECIDE TO PARTICIPATE
- NOT A CONTRACT OR PIECE OF PAPER
- PROCESS

- IN PARTICIPANTS NATIVE LANGUAGE

- AT AN APPROPRIATE EDUCATIONAL LEVEL

- RESEARCH TEAM PROVIDES AN INFORMED CONSENT DOCUMENT THAT INCLUDES DETAILS LIKE

  PURPOSE OF STUDY

  DURATION

  REQUIRED PROCEDURE

  EXPLANATION OF RISK,BENEFIT

  WHO TO CONTACT

- PARTCIPANT DECIDES WHETHER TO SIGN OR NOT
- AFTER SIGNING,NOT BOUND

- IF UNCOMFORTABLE AT ANY POINT,CAN WITHDRAW

TYPES OF CLINICAL TRIALS

- TREATMENT—NEW APPROCH TO SURGERY
- PREVENTION
- DIAGNOSTIC
- SCREENING
- QUALITY OF LIFE—EXPLORE WAYS TO IMPROVE COMFORT AND QOL WITH CHRONIC ILLNESS

WHAT HAPPENS IN A TRIAL?

- CLINICAL TRIAL COMPARE A NEW MANAGEMENT STRATEGY OR SURGICAL TECHNIQUE WITH ANOTHER THAT ALREADY EXISTS.

- THIS DETERMINES IF NEW ONE IS AS SUCCESSFUL OR BETTER THAN EXISTING ONE.

- RANDOMIZATION IS DONE WHEN TWO OR MORE ALTERNATIVE TREATMENTS ARE ASSIGNED TO VOLUNTEERS BY CHANCE INSTEAD OF CHOICE.

- SINGLE BLIND

- DOUBLE BLIND STUDY

WHO CAN PARTICIPATE?

- INCLUSION CRITERIA– FACTORS THAT ALLOW TO PARTICIPATE.

- EXCLUSION CRITERIA--- FACTORS THAT DO NOT ALLOW PARTICIPATION

- AGE
- GENDER
- TYPE AND STAGE OF DISEASE
- SPECIFIC LAB VALUES
- OTHER MEDICAL CONDITIONS

- NOT PERSONAL
- IDENTIFY APPROPRIATE PARTICIPANTS
- KEEP THEM SAFE
- APPROPRIATE ANSWER TO QUESTION/HYPOTHESIS

ETHICS

- RESPECT FOR PERSONS
- BENEFICENCE—TO DO GOOD,TO DO NO HARM
- JUSTICE OR FAIRNESS

RESPECT

- RIGHT TO MAKE THEM OWN CHOICES
- FACTS PRESENTED PROPERLY
- NO PRESSURE
- COMMUNITY RESPECTED
- CAB—COMMUNITY ADVISORY BOARD

BENEFICENCE

- RESEARCH SHOULD NOT HARM PARTICIPANTS
- LOW RISK
- MORE BENEFITS

JUSTICE

- FAIRLY RECRUITED AS RESEARCH PARTICIPANTS
- NO FAVOUR TO PARTICULAR,ALL EQUAL

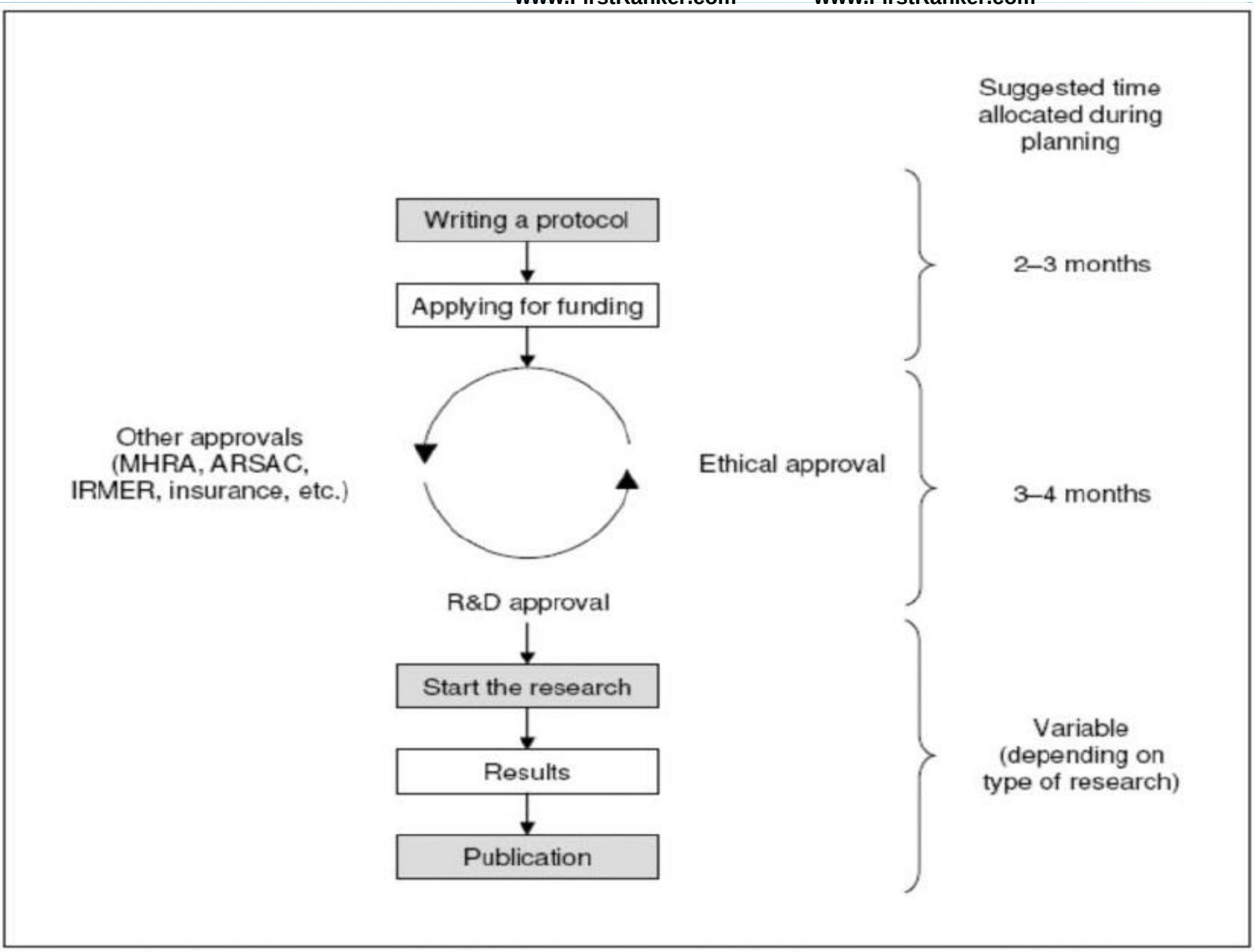
WHO IS RESPONSIBLE?

- ETHICAL COMMITTEE OR INSTITUITIONAL REVIEW BODY
- REVIEW PROTOCOL
- ASK TO CHANGE PROTOCOL WHEN NEEDED
- SUPERVISE- BEGINNING TO END
- OVERSEE SCIENTIFIC DESIGN
- REVIEW COMMUNITY INTEREST

- ENFORCE INFORMED CONSENT
- ENFORCE CONFIDENTIALITY

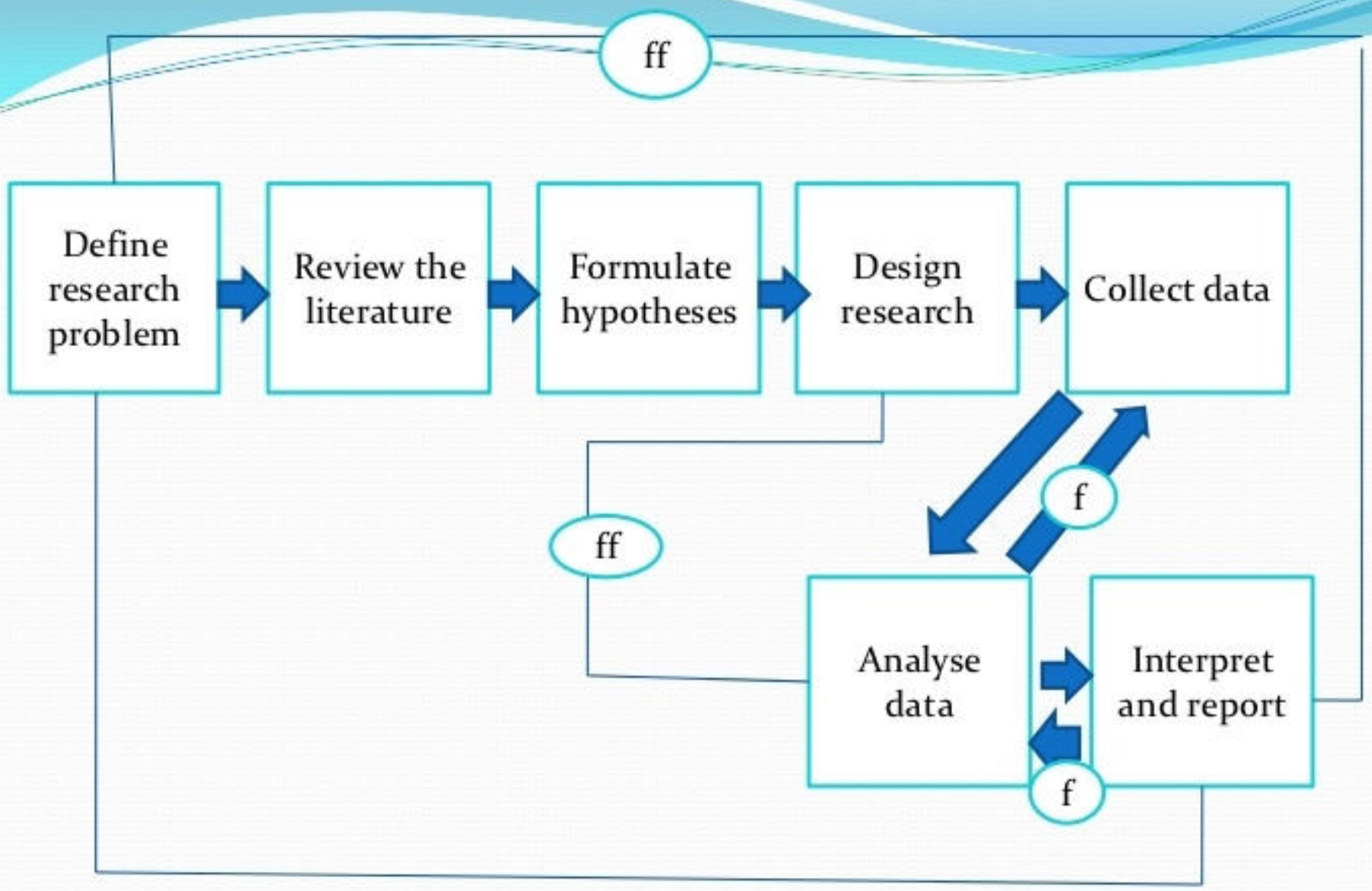
ETHICAL COMMITTEE

- MEMBERS WITH SCIENCE BACKGROUND
- MEMBERS WITHOUT SCIENCE BACKGROUND
- RELIGION OR COMMUNITY LEADERS
- PEOPLE WHO PARTICIPATED EARLIER
- CLEAR UNDERSTANDING WHEN TO TAKE SECOND OPINION



7 STEPS OF RESEARCH PROCESS

- Step One: Define research problem
- Step Two: Review of literature
- Step Three: Formulate hypotheses
- Step Four: Preparing the research design
- Step Five: Data collection
- Step Six: Data analysis
- Step Seven: Interpretation and report writing



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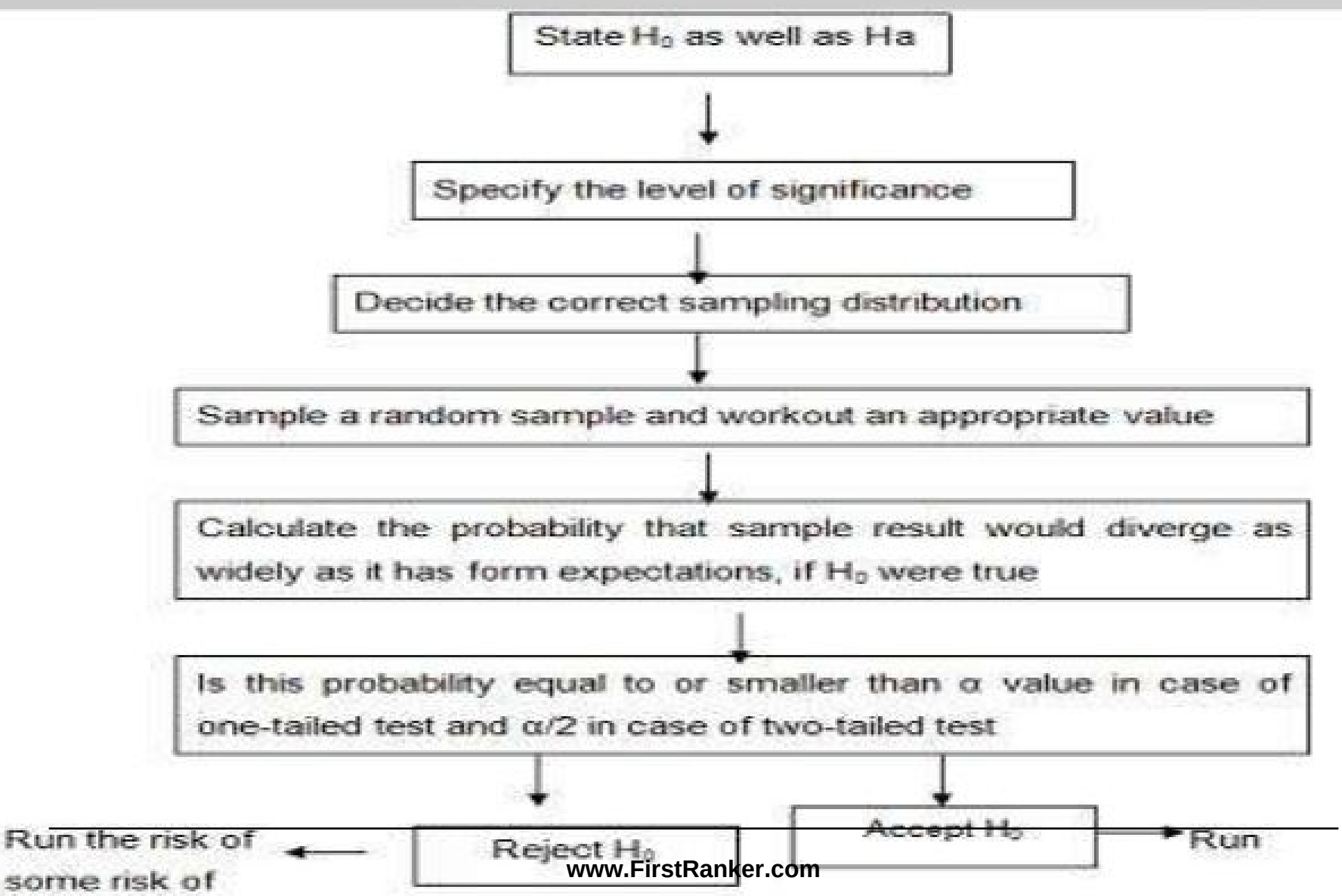
Steps in Hypothesis Testing



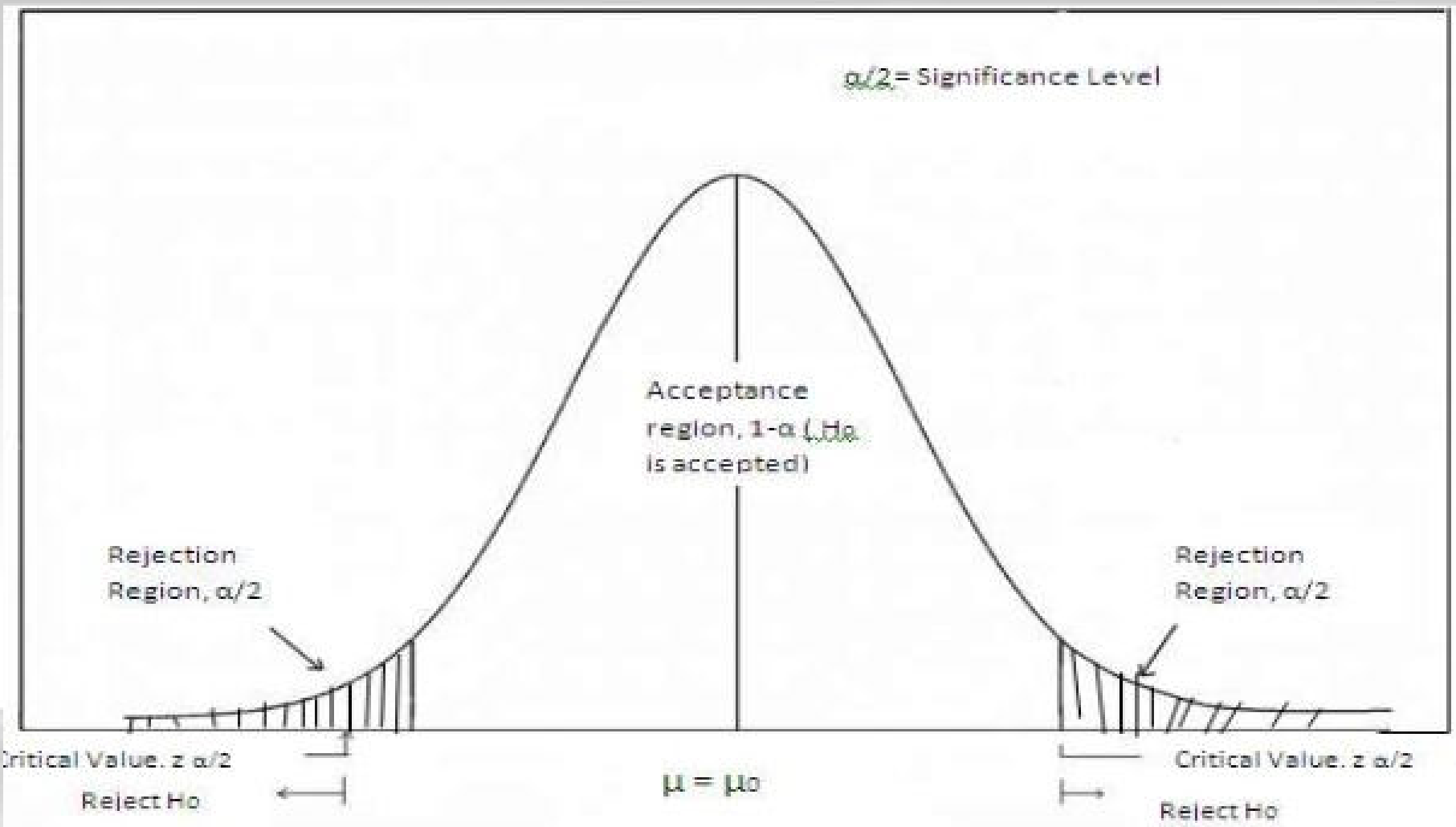
Types of Hypothesis

- **Null Hypothesis (H_0)**
- **Alternative Hypothesis (H_a or H_1)**

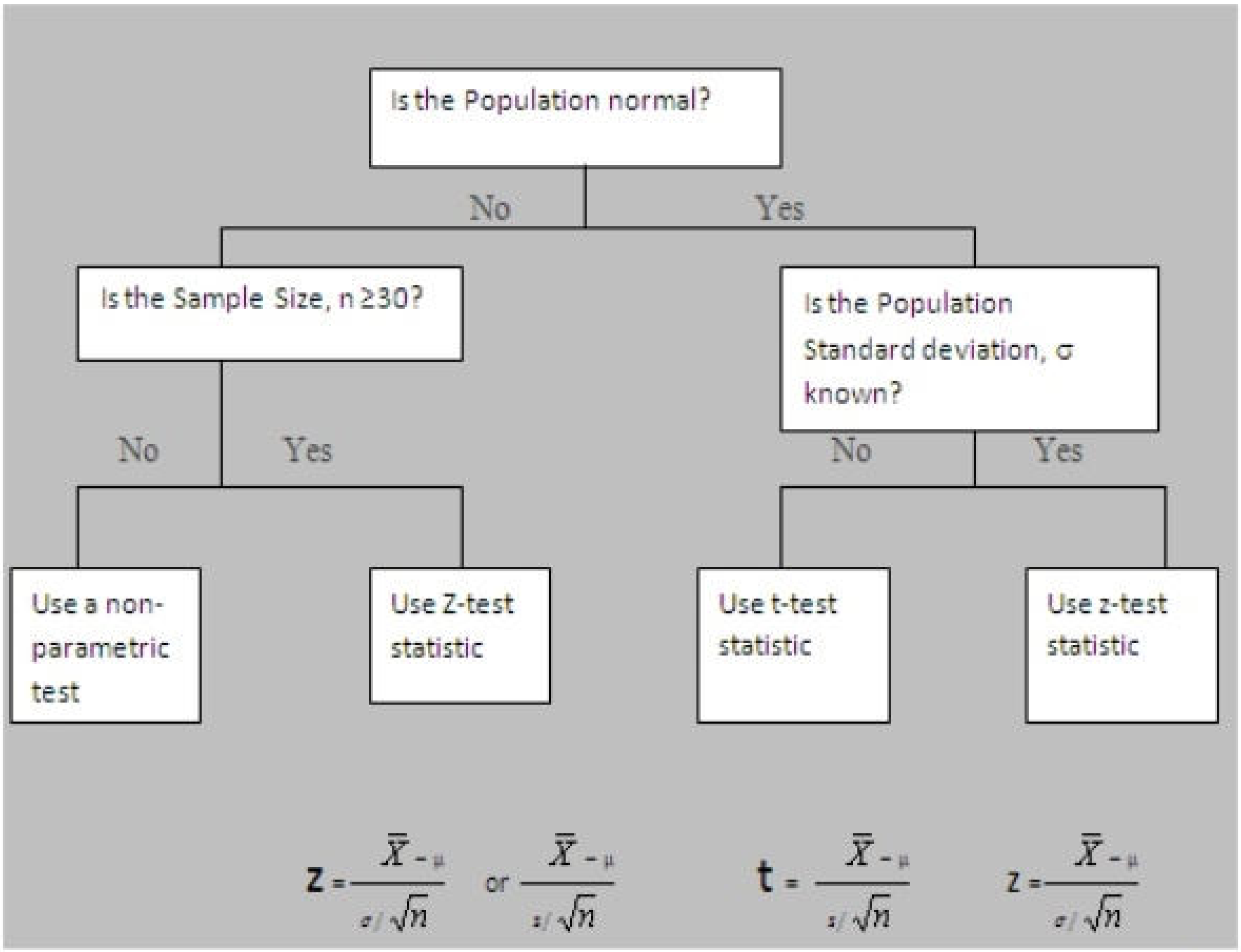
Each of the following statements is an example of a null hypothesis and alternative hypothesis.

$H_0 : \mu = \mu_0$	$H_a : \mu \neq \mu_0$
$H_0 : \mu \leq \mu_0$	$H_a : \mu > \mu_0$
$H_0 : \mu \geq \mu_0$	$H_a : \mu < \mu_0$

Establish Critical or Rejection region



Areas of Accepted and Rejection of H_0 (Two –Tailed test)



Formulate a Decision Rule to Accept Null Hypothesis

- Accept H_0 if the test statistic value falls within the area of acceptance.
- Reject otherwise.

ERRORS IN HYPOTHESIS TESTING

Types of error		
Type of decision	**H_0 true**	**H_0 false**
Reject H_0	Type I error (α)	Correct decision ($1-\beta$)
Accept H_0	Correct decision ($1-\alpha$)	Type II error (β)