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RESEARCH METHODOLOGY

Dr. E. Kamatchi Mahalakshmi
Dr. S Sriranjani Mokshagundam
Dr.J.Thirumagal
Dr.S.Sheeba
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They have sufficient teaching and research experience with expertise in Research Methodology. They have written this book for the benefits of undergraduate and postgraduate students.

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PREFACE

The first edition of “Textbook of Research Methodology “this book was written to help students to learn about the scientific method is the process of objectively establishing facts through testing and experimentation. The basic process involves making an observation, forming a hypothesis, making a prediction, conducting an experiment and finally analyzing the results.

We welcome comments by readers of Textbook of Scientific Research Methodology for ways to improve the book and to increase its value. Such suggestions will be seriously considered in the preparation of subsequent editions.

CHAPTER–I

Importance and Need for Research, Ethics in Scientific research, designing a Research work, Formulation of Hypothesis, Scientific Writing−Research and Review article. Logical format for Dissertation–Title, Certificate, Declaration, Acknowledgement, Contents, Abstract, Introduction, Review of Literature, Materials and Methods, Results, Discussion, Summary, Conclusion, Appendix and References–Harvard and Vancouver systems.

INTRODUCTION TO RESEARCH

Introduction

The ultimate goal of any national health-development process is to enable its people to reach a level of health that enables them to make meaningful participation in the social and economic life of the community in which they live. To attain this objective, countries should decide on the best approaches to adopt. However, this requires detailed and accurate information on the existing health systems of these countries. Unfortunately, such information is often lacking, inadequate, or unreliable. As a result, decisions are based on assumptions and unjustified conclusions and often result in inappropriate policy choices. In this regard, the search for scientific knowledge and information should be strongly supported. Research in the context of public health thus aims to provide all aspects of information necessary for planning and the effective implementation of a health system. For all communities, whether affluent or poor, health research is the top priority. The research questions are formidable: how to join with policy makers and communities in assessing priority needs, planning, financing and implementing programs, and

evaluating them in terms of coverage, efficiency and effectiveness.

Definition and characteristics of research Definition: Research is a scientific inquiry aimed at learning new facts, testing ideas, etc. It is the systematic collection, analysis and interpretation of data to generate new knowledge and answer a certain question or solve a problem.

Characteristics of research

- It demands a clear statement of the problem
- It requires a plan (it is not aimlessly "looking" for something in the hope that you will come across a solution)
- It builds on existing data, using both positive and negative findings
- New data should be collected as required and be organized in such a way that they answer the research question(s)

The significance of research cannot be understated. It is integral to succeeding in school as well as in many professions, such as law, writing, and finance. The main purposes of research are to inform action, gather evidence for

theories, and contribute to developing knowledge in a field of study. This article discusses the significance of research and the many reasons why it is important for everyone—not just students and scientists.Understanding that research is important might seem like a no-brainer, but many people avoid it like the plague. Yet, for those who like to learn, whether they are members of a research institution or not, conducting research is not just important—it's imperative.

Why Research Is Necessary and Valuable

1. It's a tool for building knowledge and facilitating learning.
2. It's a means to understand issues and increase public awareness.
3. It helps us succeed in business.
4. It allows us to disprove lies and support truths.
5. It is a means to find, gauge, and seize opportunities.
6. It promotes a love of and confidence in reading, writing, analysing, and sharing valuable information.
7. It provides nourishment and exercise for the mind.

1. Research expands your knowledge base

The most obvious reason to do research is that you'll learn more. There's always more to learn about a topic, even if you

are already well-versed in it. If you aren't, research allows you to build on any personal experience you have with the subject. The process of research opens up new opportunities for learning and growth.

2. Research gives you the latest information

Research encourages you to find the most recent information available. In certain fields, especially scientific ones, there's always new information and discoveries being made. Staying updated prevents you from falling behind and giving info that's inaccurate or doesn't paint the whole picture. With the latest info, you'll be better equipped to talk about a subject and build on ideas.

3. Research helps you know what you're up against

In business, you'll have competition. Researching your competitors and what they're up to helps you formulate your plans and strategies. You can figure out what sets you apart. In other types of research, like medicine, your research might identify diseases, classify symptoms, and come up with ways to tackle them. Even if your "enemy" isn't an actual person or competitor, there's always some kind of antagonist force or problem that research can help you deal with.

4. Research builds your credibility

People will take what you have to say more seriously when they can tell you're informed. Doing research gives you a solid foundation on which you can build your ideas and opinions. You can speak with confidence about what you know is accurate. When you've done the research, it's much harder for someone to poke holes in what you're saying. Your research should be focused on the best sources. If your "research" consists of opinions from non-experts, you won't be very credible. When your research is good, though, people are more likely to pay attention.

5. Research helps you narrow your scope

When you're circling a topic for the first time, you might not be exactly sure where to start. Most of the time, the amount of work ahead of you is overwhelming. Whether you're writing a paper or formulating a business plan, it's important to narrow the scope at some point. Research helps you identify the most unique and/or important themes. You can choose the themes that fit best with the project and its goals.

6. Research teaches you better discernment

Doing a lot of research helps you sift through low-quality and high-quality information. The more research you do on a

topic, the better you'll get at discerning what's accurate and what's not. You'll also get better at discerning the gray areas where information may be technically correct but used to draw questionable conclusions.

7. Research introduces you to new ideas

You may already have opinions and ideas about a topic when you start researching. The more you research, the more viewpoints you'll come across. This encourages you to entertain new ideas and perhaps take a closer look at yours. You might change your mind about something or, at least, figure out how to position your ideas as the best ones.

8. Research helps with problem-solving

Whether it's a personal or professional problem, it helps to look outside yourself for help. Depending on what the issue is, your research can focus on what others have done before. You might just need more information, so you can make an informed plan of attack and an informed decision. When you know you've collected good information, you'll feel much more confident in your solution.

9. Research helps you reach people

Research is used to help raise awareness of issues like climate change, racial discrimination, gender inequality, and more.

Without hard facts, it's very difficult to prove that climate change is getting worse or that gender inequality isn't progressing as quickly as it should. The public needs to know what the facts are, so they have a clear idea of what "getting worse" or "not progressing" actually means. Research also entails going beyond the raw data and sharing real-life stories that have a more personal impact on people.

10. Research encourages curiosity

Having curiosity and a love of learning take you far in life. Research opens you up to different opinions and new ideas. It also builds discerning and analytical skills. The research process rewards curiosity. When you're committed to learning, you're always in a place of growth. Curiosity is also good for your health. Studies show curiosity is associated with higher levels of positivity, better satisfaction with life, and lower anxiety.

Codes and Policies for Research Ethics

Given the importance of ethics for the conduct of research, it should come as no surprise that many different professional associations, government agencies, and universities have adopted specific codes, rules, and policies relating to research

ethics. Many government agencies have ethics rules for funded researchers.

Ethical Principles

The following is a rough and general summary of some ethical principles that various codes address:

Honesty

Strive for honesty in all scientific communications. Honestly report data, results, methods and procedures, and publication status. Do not fabricate, falsify, or misrepresent data. Do not deceive colleagues, research sponsors, or the public.

Objectivity

Strive to avoid bias in experimental design, data analysis, data interpretation, peer review, personnel decisions, grant writing, expert testimony, and other aspects of research where objectivity is expected or required. Avoid or minimize bias or self-deception. Disclose personal or financial interests that may affect research.

Integrity

Keep your promises and agreements; act with sincerity; strive for consistency of thought and action.

Carefulness

Avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers. Keep good records of research activities, such as data collection, research design, and correspondence with agencies or journals.

Openness

Share data, results, ideas, tools, resources. Be open to criticism and new ideas.

Transparency

Disclose methods, materials, assumptions, analyses, and other information needed to evaluate your research.

Accountability

Take responsibility for your part in research and be prepared to give an account (i.e. an explanation or justification) of what you did on a research project and why.

Intellectual Property

Honor patents, copyrights, and other forms of intellectual property. Do not use unpublished data, methods, or results without permission. Give proper acknowledgement or credit for all contributions to research. Never plagiarize.

Confidentiality

Protect confidential communications, such as papers or grants submitted for publication, personnel records, trade or military secrets, and patient records.

Responsible Publication

Publish in order to advance research and scholarship, not to advance just your own career. Avoid wasteful and duplicative publication.

Responsible Mentoring

Help to educate, mentor, and advise students. Promote their welfare and allow them to make their own decisions.

Respect for Colleagues

Respect your colleagues and treat them fairly.

Social Responsibility

Strive to promote social good and prevent or mitigate social harms through research, public education, and advocacy.

Non-Discrimination

Avoid discrimination against colleagues or students on the basis of sex, race, ethnicity, or other factors not related to scientific competence and integrity.

Competence

Maintain and improve your own professional competence and expertise through lifelong education and learning; take steps to promote competence in science as a whole.

Legality

Know and obey relevant laws and institutional and governmental policies.

Animal Care

Show proper respect and care for animals when using them in research. Do not conduct unnecessary or poorly designed animal experiments.

Human Subjects protection

When conducting research on human subjects, minimize harms and risks and maximize benefits; respect human dignity, privacy, and autonomy; take special precautions with vulnerable populations; and strive to distribute the benefits and burdens of research fairly.

Types of study designs

A study design is the process that guides researchers on how to collect, analyse and interpret observations. It is a logical model that guides the investigator in the various stages of the

research. Several classifications of study types are possible, depending on what research strategies are used.

1. Non-intervention (**Observational) studies** in which the researcher just observes and analyses researchable objects or situations but does not intervene;

2. Intervention studies in which the researcher manipulates objects or situations and measures the outcome of his manipulations (e.g., by implementing intensive health education and measuring the improvement in immunisation rates.) Study designs could be exploratory, descriptive or analytical

a. Exploratory studies An exploratory study is a small-scale study of relatively short duration, which is carried out when little is known about a situation or a problem. It may include description as well as comparison.

For example: A national AIDS Control Programme wishes to establish counselling services for HIV positive and AIDS patients, but lacks information on specific needs patients have for support. To explore these needs, a number of in-depth interviews are held with various categories of patients (males, females, married and single) and with some counsellors working on a programme that is already under way. When

doing exploratory studies we describe the needs of various categories of patients and the possibilities for action. We may want to go further and try to explain the differences we observe (e.g., in the needs of male and female AIDS patients) or to identify causes of problems. Then we will need to compare groups. If the problem and its contributing factors are not well defined it is always advisable to do an exploratory study before embarking on a large-scale descriptive or comparative study.

b. Descriptive studies: Descriptive studies may be defined as studies that describe the patterns of disease occurrence and other health-related conditions by person place and time.

Personal variables include basic demographic factors, such as age, sex marital status or occupation, as well as the consumption of various types of food or medication use. Characteristics of place refer to the geographic distribution of disease, including variation among countries or within countries, such as between urban and rural areas. With regard to time, descriptive studies may examine seasonal patterns in disease onset, etc.

Uses of descriptive studies

- They can be done fairly quickly and easily.

- Allow planners and administrators to allocate resources
- Provide the first important clues about possible determinants of a disease (useful for the formulation of hypotheses)

a) Case reports and case series Case report: a careful, detailed report by one or more clinicians of the profile of a single patient. The individual case report can be expanded to a case series, which describes characteristics of a number of patients with a given disease.

Uses :

- Important link between clinical medicine and epidemiology
- One of the first steps in outbreak investigation
- Often useful for hypothesis generating and examining new diseases, but conclusions about etiology cannot be made.

b) Ecological studies: data from entire populations are used to compare disease frequencies between different groups during the same period of time or in the same population at different points in time.

Example: Countries with low cigarette consumption have lower lung cancer rates than those countries with high cigarette consumption.

- Ecological studies are usually quick and easy to do and can be done with already available information.
- Since ecological studies refer to whole populations rather than to individuals, it is not possible to link an exposure to occurrence of disease in the same person.

c) Cross-sectional studies: A cross-sectional (prevalence) study provides information concerning the situation at a given time. In this type of study, the status of an individual with respect to the presence or absence of both exposure and disease is assessed at the same point in time.

- Usually involve collection of new data.
- In general, measure prevalence rather than incidence
- Not good for studying rare diseases or diseases with short duration; also not ideal for studying rare exposures. For factors that remain unaltered over time, such as sex, blood group, etc., the crosssectional survey can provide evidence of a valid statistical

association. As can be noted from the above explanation, a cross-sectional study can be either analytical or descriptive, according to its purpose. If data are collected both on exposures and outcomes of interest, and if the data are analysed so as to demonstrate differences either between exposed and non-exposed groups, with respect to the outcome, or between those with the outcome and those without the outcome, with respect to the exposure, then this is an analytical cross-sectional study. If the information collected is purely of a descriptive nature, not involving the comparison of groups formed on the basis of exposure or outcome status, then this is a descriptive cross-sectional study. Often a cross-sectional study may have both descriptive and analytical components. Nowadays, there is an increasing emphasis on the value of longitudinal studies in which observations are repeated in the same community over a prolonged period (i.e., longitudinal studies provide the required data at more than one point in time unlike cross- sectional surveys).

II. Analytic studies Analytic studies may be defined as studies used to test hypotheses concerning the relationship between a suspected risk factor and an outcome and to measure the magnitude of the association and its statistical significance.

Analytic study designs can be divided into two broad design strategies: Observational and intervention.

Observational studies:

- No human intervention involved in assigning study groups; simply observe the relationship between exposure and disease.
- Subject to many potential biases, but by careful design and analysis, many of these biases can be minimized.
- Examples of observational studies: comparative cross-sectional, cohort and casecontrol studies.

a) Comparative cross-sectional studies: Depending on the purpose of a given study, a cross-sectional survey could have an analytical component.

b) Cohort studies: Study groups identified by exposure status prior to ascertainment of their disease status and both exposed and unexposed groups followed in identical manner until they develop the disease under study, they die, the study ends, or they are lost to follow-up.

c) Case-control studies: Group of subjects with the disease (cases) and group of subjects without the disease (controls) are identified. Information, about previous exposures are obtained for cases and controls, and frequency of exposure compared for the two groups.

Intervention studies In intervention studies, the researcher manipulates a situation and measures the effects of this manipulation. Usually (but not always) two groups are compared, one group in which the intervention takes place (e.g. treatment with a certain drug) and another group that remains 'untouched' (e.g. treatment with a placebo).

The two categories of intervention studies are: • experimental studies and • quasi-experimental studies

1. Experimental studies An experimental design is a study design that gives the most reliable proof for causation. In an experimental study, individuals are randomly allocated to at least two groups. One group is subject to an intervention, or experiment, while the other group(s) is not. The outcome of the intervention (effect of the intervention on the dependent variable/problem) is obtained by comparing the two groups. A number of experimental study designs have been developed. These are widely used in laboratory settings and

in clinical settings. For ethical reasons, the opportunities for experiments involving human subjects are restricted. However, randomised control trials of new drugs are common. At community level, where health research is frequently undertaken, we experience not only ethical but also practical problems in carrying out experimental studies. In real life settings, it is often impossible to assign persons at random to two groups, or to maintain a control group. Therefore, experimental research designs may have to be replaced by quasi-experimental designs.

2. Quasi-experimental studies In a quasi-experimental study, one characteristic of a true experiment is missing, either randomisation or the use of a separate control group. A quasi-experimental study, however, always includes the manipulation of an independent variable which is the intervention.

One of the most common quasi-experimental designs uses two (or more) groups, one of which serves as a control group in which no intervention takes place. Both groups are observed before as well as after the intervention, to test if the intervention has made any difference. (This quasi-experimental design is called the ‘non-equivalent control

group design' because the subjects in the two groups (study and control groups) have not been randomly assigned.) Another type of design that is often chosen because it is quite easy to set up uses only one group in which an intervention is carried out. The situation is analysed before and after the intervention to test if there is any difference in the observed problem. This is called a 'BEFORE-AFTER' study. This design is considered a 'pre-experimental' design rather than a 'quasi-experimental' design because it involves neither randomisation nor the use of a control group.

Formulation of a Hypothesis in research is an essential task in the entire Research Process that comes in the third step. A hypothesis is a tentative solution to a research problem or question. Here, we will cover a functional definition of a hypothesis & basic Steps in the formulation of hypotheses for your research.

Research works, in fact, are designed to verify the hypothesis. Therefore, a researcher, of course, would understand the meaning and nature of the hypothesis in order to formulate a hypothesis and then test the hypothesis.

What is Hypothesis in Research?

A hypothesis is a tentative statement of a proposition that the researcher seeks to prove. It's basically a concrete generalization. Of course, this generalization requires essential characteristics that pertain to an entire class of phenomena.

When a theory is stated as a testable proposition formally and subjects to empirical verification we can define it as a hypothesis. Researchers make a hypothesis on the basis of some earlier theories and some rationale that is generally accepted as true. The hypothesis test finally will decide whether it is true or rejected.

So, to clarify a hypothesis is a statement about the relationship between two or more variables. The researcher set out the variables to prove or disprove. Hypothesis essentially includes three elements. For example-

1. Variables
2. Population
3. Relationship between variables.

Example of Hypothesis

1. Rewards increase reading achievements
2. Rewards decrease reading achievements

3. Or rewards have no effect on reading achievements

In the above examples- variables are- Rewards & Achievements.

Logical format for Dissertation

Steps in Formulation of Hypothesis

A hypothesis is a tentative assumption drawn from practical knowledge or theory. A hypothesis is used as a guide in the inquiry of other facts or theories that a researcher does not know. However, the formulation of the hypothesis is one of the most difficult steps in the entire scientific research process.

Therefore, in this regard, we intend to point out the basic steps in the formulation of a hypothesis. We are pretty sure that this guideline will be helpful in your research work.

1. Define Variables

At first, with a view to formulating a hypothesis, you must define your variables. What do you want to test? Will you test that rewards increase reading achievement? Or do rewards decrease reading achievement? Whatever your goals are, they need to be clearly defined, quantifiable, and measurable. This will provide you with a clear idea of what to follow to achieve results.

2. Study In-Depth the Variables

If we do think that your variables are Rewards & Achievements, then you need to intense study how rewards increase reading achievements? An in-depth study, rigorous questions, and data of rewards increase reading achievements will make you able to confirm your hypothesis. Specify dependent and independent variables.

3. Specify the Nature of the Relationship

Then, identify what relationship there exists between the variables. What variable influences the other? That is what the dependent variable is and what is the independent variable? How do Rewards impact achievements? If reward plays a key role in reading achievements, then reward is the independent variable.

4. Identify Study Population

The population in research means the entire group of individuals is going to study. If you want to test how rewards increase reading achievements in the United Kingdom, you need not study the whole population of the United Kingdom. Because the total population does not involve in reading achievements. Therefore, the researcher must identify the study population.

5. Make Sure Variables are Testable

Variables in your hypothesis must be testable. Otherwise, the hypothesis would be worthless. Because your research study must accept or reject a variable. So, variables you must need to test. Testable variables can only be accepted or rejected. Moreover, the sole aim of a research hypothesis is to test variables in the long run.

Scientific writing−Research and Review article:

Scientific writing is a technical form of writing that communicates scientific information to other scientists in a document, book or presentation in written form. It requires a lot of research and exact wording and can include grant requests, peer reviews and summarized findings. While there are many documents that fall under the category of scientific writing, typically anything written in a research environment is scientific writing. While there are many documents that fall under the category of scientific writing, typically anything written in a research environment is scientific writing.

When preparing the dissertation for submission, students must follow strict formatting requirements. Any deviation from these requirements may lead to rejection of the dissertation and delay in the conferral of the degree.

Language of the Dissertation

The language of the dissertation is ordinarily English, although some departments whose subject matter involves foreign languages may accept a dissertation written in a language other than English.

Length

Most dissertations are 100 to 300 pages in length. All dissertations should be divided into appropriate sections, and long dissertations may need chapters, main divisions, and subdivisions.

Page and Text Requirements

PAGE SIZE

- 8½ x 11 inches, unless a musical score is included

MARGINS

- At least 1 inch for all margins

SPACING

- Body of text: double spacing

- Block quotations, footnotes, and bibliographies: single spacing *within* each entry but double spacing *between* each entry
- Table of contents, list of tables, list of figures or illustrations, and lengthy tables: single spacing may be used

FONTS AND POINT SIZE

Use 10-12 point size. Fonts must be embedded in the PDF file to ensure all characters display correctly.

Recommended Fonts

If fonts are not embedded, non-English characters may not appear as intended. Fonts embedded improperly will be published to DASH as-is. It is the student's responsibility to make sure that fonts are embedded properly prior to submission.

Instructions for Embedding Fonts

Body of Text, Tables, Figures, and Captions

The **font** used in the body of the text must also be used in headers, page numbers, and footnotes. Exceptions are made only for tables and figures created with different software and inserted into the document.

Tables and figures must be placed as close as possible to their first mention in the text. They may be placed on a page with no text above or below, or they may be placed directly into the text. If a table or a figure is alone on a page (with no narrative), it should be centered within the margins on the page. Tables may take up more than one page as long as they obey all rules about margins. Tables and figures referred to in the text may not be placed at the end of the chapter or at the end of the dissertation.

- Given the standards of the discipline, dissertations in the Department of History of Art and Architecture and the Department of Architecture, Landscape Architecture, and Urban Planning often place illustrations at the end of the dissertation.

Figure and table numbering must be continuous throughout the dissertation or by chapter (e.g., 1.1, 1.2, 2.1, 2.2, etc.). Two figures or tables cannot be designated with the same

number. If you have repeating images that you need to cite more than once, label them with their number and A, B, etc.

Headings should be placed at the top of tables. While no specific rules for the format of table headings and figure captions are required, a consistent format must be used throughout the dissertation (contact your department for style manuals appropriate to the field).

Captions should appear at the bottom of any figures. If the figure takes up the entire page, the caption should be placed alone on the preceding page, centered vertically and horizontally within the margins.

Each page receives a separate page number. When a figure or table title is on a preceding page, the second and subsequent pages of the figure or table should say, for example, “Figure 5 (Continued).” In such an instance, the list of figures or tables will list the page number containing the title. The word “figure” should be written in full (not abbreviated), and the “F” should be capitalized (e.g., Figure 5). In instances where the caption continues on a second page, the “(Continued)” notation should appear on the second and any subsequent page. The figure/table and the caption are viewed as one

entity and the numbering should show correlation between all pages. Each page must include a header.

Landscape orientation figures and tables must be positioned correctly and bound at the top so that the top of the figure or table will be at the left margin. Figure and table headings/captions are placed with the same orientation as the figure or table when on the same page. When on a separate page, headings/captions are always placed in portrait orientation, regardless of the orientation of the figure or table. Page numbers are always placed as if the figure were vertical on the page.

If a graphic artist does the figures, GSAS will accept lettering done by the artist only within the figure. Figures done with software are acceptable if the figures are clear and legible. Legends and titles done by the same process as the figures will be accepted if they too are clear, legible, and run at least 10 or 12 characters per inch. Otherwise, legends and captions should be printed with the same font used in the text.

Original illustrations, photographs, and fine arts prints may be scanned and included, centered between the margins on a page with no text above or below.

Use of Third-Party Content

In addition to the student's own writing, dissertations often contain third-party content or in-copyright content owned by parties other than you, the student who authored the dissertation. The **Office for Scholarly Communication** recommends consulting the information below about fair use, which allows individuals to use in-copyright content, on a limited basis and for specific purposes, without seeking permission from copyright holders.

Because your dissertation will be made available for online distribution through **DASH**, Harvard's open-access repository, it is important that any third-party content in it may be made available in this way.

Fair Use and Copyright

Pagination

Pages should be assigned a number except for the **Dissertation Acceptance Certificate**. Preliminary pages (abstract, table of contents, list of tables, graphs, illustrations, and preface) should use small Roman numerals (i, ii, iii, iv, v, etc.). **All pages must contain text or images.**

Count the title page as page i and the copyright page as page ii, but **do not print page numbers on either page**.

For the body of text, use Arabic numbers (1, 2, 3, 4, 5, etc.) starting with page 1 on the first page of text. Page numbers must be centered throughout the manuscript at the top or bottom. Every numbered page must be consecutively ordered, including tables, graphs, illustrations, and bibliography/index (if included); letter suffixes (such as 10a, 10b, etc.) are not allowed. It is customary not to have a page number on the page containing a chapter heading.

- Check pagination carefully. Account for all pages.

Dissertation Acceptance Certificate

A copy of the **Dissertation Acceptance Certificate** (DAC) should appear as the first page. This page should not be counted or numbered. The DAC will appear in the online version of the published dissertation.

Title Page

The dissertation begins with the title page; the title should be as concise as possible and should provide an accurate description of the dissertation.

- Do not print a page number on the title page: It is understood to be page *i* for counting purposes only.

Copyright Statement

A copyright notice should appear on a separate page immediately following the title page and include the copyright symbol ©, the year of first publication of the work, and the name of the author:

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Alternatively, students may choose to license their work openly under a **Creative Commons** license. The author remains the copyright holder while at the same time granting up-front permission to others to read, share, and (depending on the license) adapt the work, so long as proper attribution is given. (By default, under copyright law, the author reserves all rights; under a Creative Commons license, the author reserves some rights.)

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Abstract

An abstract, numbered as page *iii*, should immediately follow the copyright page and should state the problem, describe the

methods and procedures used, and give the main results or conclusions of the research. The abstract will appear in the online and bound versions of the dissertation and will be published by ProQuest. There is no maximum word count for the abstract.

- The abstract text should be:
  - double-spaced
  - left-justified
  - indented on the first line of each paragraph
- The top of the abstract page should include:
  - The author's name, right justified
  - The words "Dissertation Advisor:" followed by the advisor's name, left-justified (a maximum of two advisors is allowed)
  - Title of the dissertation, centered, several lines below author and advisor

Table of Contents

Dissertations divided into sections must contain a table of contents that lists, at minimum, the major headings in the following order:

1. Title page
2. Copyright

3. Abstract
4. Table of Contents
5. Front Matter
6. Body of Text
7. Back Matter

Front and Back Matter

Front matter includes (if applicable):

- acknowledgements of help or encouragement from individuals or institutions
- a dedication
- a list of illustrations or tables
- a glossary of terms
- one or more epigraphs.

Back matter includes (if applicable):

- appendices
- bibliography
- supplemental materials, including figures and tables
- an index (in rare instances).

Supplemental Material

Supplemental figures and tables must be placed at the end of the dissertation in an appendix, not within or at the end of a

chapter. If additional digital information (including audio, video, image, or datasets) will accompany the main body of the dissertation, it should be uploaded as a supplemental file through **ProQuest ETD**. Supplemental material will be available in DASH and ProQuest and preserved digitally in the Harvard University Archives.

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1. **Missing Dissertation Acceptance Certificate.** The first page of the PDF dissertation file should be a scanned copy of the **Dissertation Acceptance Certificate** (DAC). This page should not be counted or numbered as a part of the dissertation pagination.
2. **Conflicts Between the DAC and the Title Page.** The DAC and the dissertation title page must match **exactly,** meaning that the author name and the title on the title page must match that on the DAC. If you use your full middle name or just an initial on one document, it must be the same on the other document.

3. **Abstract Formatting Errors.** The advisor name should be left-justified, and the author's name should be right-justified. Up to two advisor names are allowed. The Abstract should be double spaced and include the page title “Abstract,” as well as the page number “iii.” There is no maximum word count for the abstract.
4. **Pagination**
    1. The front matter should be numbered using Roman numerals (iii, iv, v, …). The title page and the copyright page should be counted but not numbered. The first printed page number should appear on the Abstract page (iii).
    2. The body of the dissertation should be numbered using Arabic numbers (1, 2, 3, …). The first page of the body of the text should begin with page 1. Pagination may not continue from the front matter.
    3. All page numbers should be centered either at the top or the bottom of the page.
5. **Figures and tables** Figures and tables must be placed within the text, as close to their first mention as possible. Figures and tables that span more than one page must be labeled on each page. Any second and subsequent page

of the figure/table must include the "(Continued)" notation. This applies to figure captions as well as images. Each page of a figure/table must be accounted for and appropriately labeled. All figures/tables must have a unique number. They may not repeat within the dissertation.

6. **Horizontal Figures and Tables**
    1. Any figures/tables placed in a horizontal orientation must be placed with the top of the figure/ table on the left-hand side. The top of the figure/table should be aligned with the spine of the dissertation when it is bound.
    2. Page numbers must be placed in the same location on all pages of the dissertation, centered, at the bottom or top of the page. Page numbers may not appear under the table/ figure.
7. **Supplemental Figures and Tables.** Supplemental figures and tables must be placed at the back of the dissertation in an appendix. They should not be placed at the back of the chapter.
8. **Permission Letters Copyright.** permission letters must be uploaded as a supplemental file, titled

‘do_not_publish_permission_letters,” within the dissertation submission tool.

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10. **Overall Formatting.** The entire document should be checked after all revisions, and before submitting online, to spot any inconsistencies or PDF conversion glitches.

8.3 Writing a research report

Writing a good report may take much time and effort. The most difficult task is usually the preparation of the first draft. The report should be easily intelligible. This requires clarity of language, a logical presentation of facts and inferences, the use of easily understood tables and charts, and an orderly arrangement of the report as a whole. It should be no longer than is necessary. Conventionally, a report usually contains the following major components.

- Title and cover page

  The cover page should contain the title, the names of the authors with their titles and positions, the institution that is publishing the report, (e.g., Gondar College of Medicine and Health Sciences) and the month and year of publication. The title could consist of a challenging statement or question, followed by an informative subtitle covering the content of the study and indicating the area where the study was implemented.

  Abstract (Summary) The summary should be brief and informative. A reader who has been attracted by the title will usually look at the summary to decide whether the report is worth reading. The summary should be written only after the first or even the second draft of the report has been completed. It should contain: — a very brief description of the problem (WHY this study was needed) — the main objectives (WHAT has been studied) — the place of study (WHERE) — the type of study and methods used (HOW) — major findings and conclusions, followed by — the major (or all) recommendations. The summary will be the first (and for busy health decision makers most likely the only)

part of your study that will be read. Therefore, its writing demands thorough reflection and is time consuming. Several drafts may have to be made, each discussed by the research team as a whole Acknowledgements It is good practice to thank those who supported you technically or financially in the design and implementation of your study. Also your employer who has allowed you to invest time in the study and the respondents may be acknowledged. Acknowledgements are usually placed right after the title page or at the end of the report, before the references.

Table of contents A table of contents is essential. It provides the reader a quick overview of the major sections of your report, with page references, so that (s)he can go through the report in a different order or skip certain sections. List of tables, figures If you have many tables or figures it is helpful to list these also, in a ‘table of contents’ type of format with page numbers. List of abbreviations (optional) If abbreviations or acronyms are used in the report, these should be stated in full in the text the first time they are mentioned. If there are many, they should be listed in alphabetical order as

well. The list can be placed before the first chapter of the report. The table of contents and lists of tables, figures, abbreviations should be prepared last, as only then can you include the page numbers of all chapters and sub-sections in the table of contents. Then you can also finalise the numbering of figures and tables and include all abbreviations.

- **Introduction** The introduction is a relatively easy part of the report that can best be written after a first draft of the findings has been made. It should certainly contain some relevant (environmental/ administrative/ economic/ social) background data about the country, the health status of the population, and health service data which are related to the problem that has been studied. You may slightly comprise or make additions to the corresponding section in your research proposal, including additional literature, and use it for your report. Then the statement of the problem should follow, again revised from your research proposal with additional comments and relevant literature collected during the implementation of the study. It

should contain a paragraph on what you hope(d) to achieve with the results of the study. Global literature can be reviewed in the introduction to the statement of the problem if you have selected a problem of global interest. Otherwise, relevant literature from individual countries may follow as a separate literature review after the statement of the problem. You can also introduce theoretical concepts or models that you have used in the analysis of your data in a separate section after the statement of the problem.

- **Objectives** The general and specific objectives should be included as stated in the proposal. If necessary, you can adjust them slightly for style and sequence. However, you should not change their basic nature. If you have not been able to meet some of the objectives this should be stated in the methodology section and in the discussion of the findings. The objectives form the HEART of your study. They determined the methodology you chose and will determine how you structure the reporting of your findings.

- **Methods** The methodology you followed for the collection of your data should be described in detail. The methodology section should include a description of:

  • the study type;

  • major study themes or variables (a more detailed list of variables on which data were collected may be annexed);

  • the study population(s), sampling method(s) and the size of the sample(s);

  • data-collection techniques used for the different study populations; • how the data were collected and by whom;

  • procedures used for data analysis, including statistical tests (if applicable). If you have deviated from the original study design presented in your research proposal, you should explain to what extent you did so and why. The consequences of this deviation for meeting certain objectives of your study should be indicated. If the quality of some of the data is weak, resulting in possible biases, this should be

described as well under the heading 'limitations of the study'.

- Results: Findings should be presented
- Tables and graphs could be used (should be well titled and captioned)
- The tables should be well constructed, and without anomalies such as percentages which do not add up to 100 percent
- Avoid too many decimal places
- Graphs should clarify and not complicate, and care should be taken that they do not mislead
- If appropriate statistical tests are used, the results should be included. P-values alone are not very helpful. Confidence intervals and the type of tests used should be indicated.

V) Discussion The findings can now be discussed by objective or by cluster of related variables or themes, which should lead to conclusions and possible recommendations. The author interprets the findings. Care should be taken not to introduce new findings, i.e., findings not mentioned in the result section. The discussion may include findings from

other related studies that support or contradict your own. Limitation of the study and generalizability of the finding should also be mentioned.

VI) Conclusions and recommendations The conclusions and recommendations should follow logically from the discussion of the findings. Conclusions can be short, as they have already been elaborately discussed in chapter 5. As the discussion will follow the sequence in which the findings have been presented (which in turn depends on your objectives) the conclusions should logically follow the same order. It makes easy reading for an outsider if the recommendations are again placed in roughly the same sequence as the conclusions. However, the recommendations may at the same time be summarised according to the groups towards which they are directed, for example:

• policy-makers,

• health and health-related managers at district or lower level,

• health and health-related staff who could implement the activities,

• potential clients, and
• the community at large.

Remember that action-oriented groups are most interested in this section. In making recommendations, use not only the findings of your study, but also supportive information from other sources. The recommendations should take into consideration the local characteristics of the health system, constraints, feasibility and usefulness of the proposed solutions. They should be discussed with all concerned before they are finalised. VII) References The references in your text can be numbered in the sequence in which they appear in the report and then listed in this order in the list of references (Vancouver system). Another possibility is the Harvard system of listing in brackets the author's name(s) in the text followed by the date of the publication and page number, for example: (Shan 2000: 84). In the list of references, the publications are then arranged in alphabetical order by the principal author's last name. You can choose

either system as long as you use it consistently throughout the report.

VIII) Annexes or appendices: The annexes should contain any additional information needed to enable professionals to follow your research procedures and data analysis.

Information that would be useful to special categories of readers but is not of interest to the average reader can be included in annexes as well.

Examples of information that can be presented in annexes are:

• tables referred to in the text but not included in order to keep the report short; • lists of hospitals, districts, villages etc. that participated in the study; • questionnaires or checklists used for data collection.

CHAPTER–II

Collection and Classification of Data−Diagrammatic and Graphic representation of data−Measurement of Central Tendency−Standard Deviation-Normal distribution-test of significance based on large samples and small samples, Student ‘t’ test, Correlation and Regression.

In this chapter, we will be looking into the aspects of data collection and data analysis as a part of research. Once the problem is defined and the research design is completed, data collection is carried out. It is essential to collect data regarding the research problem and the variables that are involved in the research in order to better understand the problem and it is even more essential to analyse the data using the appropriate techniques for better reliability and validity. We will discuss the data types, data collection methods and techniques and tools used for analysis of the gathered data.

Collection and Classification of Data

Data is the processed form of information.To carry out any research, data of one or the other form is required and this data has to be collected from various sources.

Based on method of data collection: The data is classified as primary data and secondary data.

- Primary data is the first-hand data that collected directly from the respondents for the first time by the researcher himself/herself. This is the data that is collected expressly for the purpose of research being carried out. Primary data can be collected by using various methods:

- Observation method: In this method, the data is collected by the researcher through direct observation of the respondents under certain conditions rather than questioning the respondents.
- Interview method: In this method, the researcher or the interviewer directly or directly collects data through verbally questioning the respondent. This could either be direct interview or indirect interview.
- Questionnaire: This method consists of distributing a set of printed questions related to the research topic, known as questionnaire, to the respondents who then diligently write the answers to the questions in the questionnaire and return it to the researcher. This is a written form of data collection.
- Other methods of primary data collection are surveys, schedules, audits, panel interviews, depth interviews, projection techniques such as word association test, thematic appreciation test etc.

- Secondary data is the data that is not collected by the researcher directly. It is adopted from other sources of data which is already collected for reasons other than that of the researcher's purpose. The sources of secondary data are
  - Newspapers
  - Magazines
  - Trade Journals
  - Government records
  - Reports prepared by Government
  - Reports prepared and published by private entities
  - Reports prepared by universities, schools of research and research scholars.
  - Internet and websites of companies

Diagrammatic and Graphic representation of data

Once the data is collected, it is then organized in a tabular form, and is sometimes coded into analysis tools and software such as SPSS, MS-Excel etc. This process is called data cleaning and helps in making the analysis of data easier.

Analysis of data can be as simple as studying a single variable to as complex as studying the relationships among multiple variables which are inter-related and providing insights based on the analysis of data.

The simplest and the first method of data analysis is data visualization. Data visualization is the process of presenting the collected data in a visual format in the form of either diagrams or graphs. The advantages of data visualization are:

- It helps in making comparisons easier.
- It is easier to understand as compared to blocks of numbers.
- It converts complex numerical data to easy to understand and attractive charts and graphs.

The data can be presented in two forms:

a) Diagrammatic representation of data: The data collected can be represents as diagrams and charts. Generally, this type of data visualization is used when studying the changes of a single variable over a period of time or when comparing two or more variables over a period of time. For this purpose, bar charts, histograms, line charts are used. Pie charts can be used to study the contribution of various entities to a single factor.

b) Graphical representation of data: The data is represented as graphs if the relationship between two or more variables needs to be studied. In this case, time series analysis and correlation between variables are presented in the form of graphs.

Measurement of Central tendency

Apart from data visualization, the data can be processed and analyzed further. One of the basic analysis techniques used to derive a solution is the measurement of central tendency. Measures of Central Tendency are used to study the data collected as a whole and aims to represent the whole range of data with a single value like average of marks, CGPA, Average monthly sales etc. There are three measures of central tendency. They are:

- Mean: This measure of central tendency calculated the average of all the data pertaining to a single variable or aspect of data. For example, the performance of a class in a test is calculated using the average of the marks scored by all the students in that class.

$$\bar{x} = \frac{\sum x}{N}$$

Where $\bar{x}$ is the mean

$\sum x$ is the sum of all the values of observations

N is the total number of observations

- Median: It is the middlemost term in the data when it is arranged in either ascending or descending order. In case, of even number of terms, then the median is calculated as the average of the two middlemost terms when arrange in either ascending or descending order.
- Mode: This is the term that repeats most in the data collected. It denotes the frequency of a repetition of the value for a particular variable.

In addition to the measures of central tendency, measures of dispersion are also used for analysis. The measures of variance denote the variation over the data collected with respect to a single variable. They include range, mean deviation and standard deviation.

Standard Deviation

It is one of the most commonly used tests for measuring the dispersion of data. It denotes how the data varies with respect to the average of the data. It can be defined as the square root of the average of the squares of deviations when the deviations are calculated with respected to the average value of the data.

Standard deviation is the square root of variance.

Population Standard Deviation is given by:

$$\sigma = \sqrt{\frac{\sum(x - \mu)^2}{n}}$$

where σ = population standard deviation

x = the values of observations

μ = population mean

n = number of observations

Sample Standard Deviation is given by:

$$s = \sqrt{\frac{\sum(x - \bar{x})^2}{n - 1}}$$

where s = sample standard deviation

x = the values of observations

$\bar{x}$ = sample mean

n = number of observations

Normal distribution

It is a probability distribution that is symmetric and centred around the average value of the data collected. It is a bell curve, in which the arithmetic mean or the average is the

highest point and the graph is symmetric on either side of the average. It describes how the values are distributed and the probability of such values appearing in the data. It is to be noted that the values of data cluster around the mean and probabilities of values taper off equally on either side of mean as the value is further away from the mean. The distance of values from the mean is given by the standard deviation. The below figure shows the probability of values when the data is normally distributed.

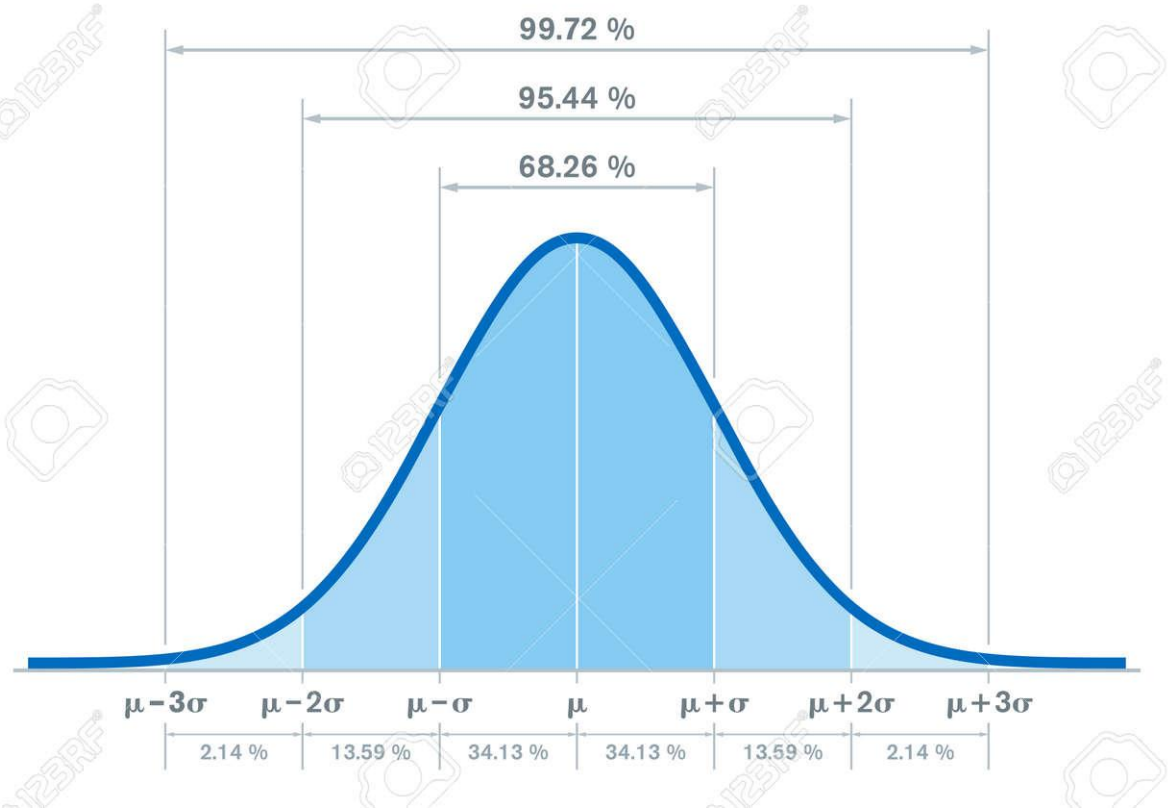

fig: Normal distribution curve

test of significance based on large samples and small samples

Test of significance is used to either accept or reject claims made with regards to the sample data. These claims are called as hypothesis. Initially, a null hypothesis, denoted by H_0 is framed. This is an unbiased, neutral claim regarding the data collected. In other words, it is an assumption made with the help of the data. Then the test of significance is performed to either accept the null hypothesis, if the results of the test of significance supports the claim or to reject the null hypothesis, if the test of significance proves otherwise.

The null hypothesis can be accepted or rejected with the help of p-value. It denotes the significance of the data and is the probability of obtaining the test results as extreme as the sample data or the observed results of the statistical test assuming that the null hypothesis is correct. If the p-value is very less, then it suggests the null hypothesis is wrong and test results will be different from the observed results of the statistical test. If p-value is < 0.05, then it is considered to be significant variation and the null hypothesis is rejected.

Various tests of significance are used based on the type of data collected and the purpose of the research being carried. One of the common tests of significance is the comparison of means of two groups of sample data. Large sample is any

sample that consists of more than 30 observations. In this case, Z test is carried out. If the number of observations is less than 30, then t-test can be carried out.

Few of them are t-test, correlation, regression analysis, chi-square test and anova.

Student 't' test

Student 't' test, or simply known as 't' test, is a test of significance carried out to compare the means to two small samples i.e., the number of observations is less than 30. In this test, two groups of sample data are considered. For example, let us consider the height of boys and girls in the class. T-test is used to compare the average height of boys and average height of girls in the class and determine if they are equal in value. 't'-test provides the p-value, with the help of which the null hypothesis can either be accepted or rejected.

t = variance between groups

variance within groups

$$t = \frac{(\bar{x}_1 - \bar{x}_2)}{\sqrt{\frac{s_1^2}{n_1} - \frac{s_2^2}{n_2}}}$$

where t = student t-value

$\bar{x}_1$ = mean of sample 1

$\bar{x}_2$= mean of sample 2

s_1 = standard deviation of sample 1

s_2 = standard deviation of sample 2

n_1 = number of observations in sample 1

n_2 = number of observations in sample 2

Correlation and Regression

Correlation is the measure of relationship between two sets of variables. The measure of correlation is given by the correlation co-efficient denoted by 'r'. The value of 'r' is between -1 and 1. There is no relationship between the variables if the 'r' value is zero and there is increasing relationship between the variables as the value of 'r' increases on either side of zero. While positive 'r' value represents a strong positive correlation, negative 'r' value denotes a strong negative correlation i.e., if the 'r' value is positive, then if one variable increases in value, the other variable also increases in value and vice-versa and if the 'r' value is negative, then if one variable increases in value, then the other variable decreases in value and vice-versa.

$$\gamma = \frac{n(\sum xy) - (\sum x)(\sum y)}{\sqrt{[n\Sigma x^2 - (\sum x)^2][n\Sigma y^2 - (\sum y)]^2}}$$

where γ = correlation co-efficient

n = Quantity of Information

Σx = Total of the First Variable Value

Σy = Total of the Second Variable Value

Σxy = Sum of the Product of first & Second Value

Σx^2 = Sum of the Squares of the First Value

Σy^2 = Sum of the Squares of the Second Value

Regression test is the significance test carried out to find out the impact independent variables have on a dependent variable. The dependent variable is the variable that is being studied. It is the variable that is influenced by or is dependent on other variables. Independent variables are those variables that do not depend on any other variable and their values are independent of other variables. At the same time, some of the independent variable might influence the values of the dependent variable. Regression test helps in determining which independent variable impact the dependent variable and to what extent is the impact. Regression analysis is used for prediction and forecasting of dependent variable and also is used to infer causal relationships between the independent and dependent variables.

Regression equation is in the form of

$$y = a + bx$$

$$\text{where } b = \frac{n\Sigma xy - (\sum x)(\sum y)}{n\Sigma x^2 - (\sum x)^2}$$

$$a = \frac{\sum y - b(\sum x)}{n}$$

b = Slope of the line.

a = Y-intercept of the line.

X = Values of the first data set.

Y = Values of the second data set.

Correlation analysis determines if there is a relationship between two variables whereas regression analysis determines the cause-effect relationship between independent and dependent variables.

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CHAPTER-III

Introduction and Scope of Bioinformatics, Role of Computers in Biology. Useful search engines−Boolean searching, Search engine algorithms. Finding scientific articles in Google scholar, Science Direct, Scopus, Web of Science and UGC-CARE.

DEFINITION

Bioinformatics is the combination of biology and information technology. It is defined as the application of computer technology to get the information that's stored in biological data. This helps the scientists to submit, search and analyse data. It provides tools for modelling, visualizing, exploring and interpreting data. It converts complex data into useful information and knowledge.

SCOPE OF BIOINFORMATICS:

- To understand the cell organizations, regulations and functions of cell.
- To understand the function of genes.
- To analyse and interpret biological data like amino acid sequences, protein domains, protein structures and three-dimensional shapes of proteins.
- To develop evolutionary relationships.
- To develop new algorithms and statistics.
- To develop and implement tools.

- To efficiently access and management of databases and integrated mapping information.
- To sequence human genomes.
- To research and future applications in biology, chemistry, health care industries, pharmaceuticals, medicine, agriculture and biomedical research.
- To analyse the drug targets.
- To design the drug with relation to diseases.
- To diagnose genetic diseases and application in medical genomics.
- To examine the characteristics of various diseases.
- To integrate and develop various tools for the management of biological databases.
- To analyze microbes and computing.
- To provide tools for modelling, visualising, exploring and interpreting data.

ROLE OF COMPUTERS IN BIOLOGY:

In Business:

A computer has high speed of calculation, diligence, accuracy, reliability and versatility. Hence, it has more application in business organizations.

Computer is mainly used in business for:

• Payment calculations

• Budgeting

• Sales – Profit and loss analysis

• Maintenance of employee database

• Maintenance of stocks, etc.

In Banking:

Banking solely depends on computers.

• **Online account**–To check current balance, deposits, overdrafts, checking interest charges, sharesetc.

• **ATM machines**- completely automated and easy for customers.

In Insurance:

Insurance companies maintain all the records up-to-date with the help of computers.

Insurance companies, finance companies and stock broking firms are widely using computers.

Insurance companies will maintainthe database of all clients with informationslike:

- Procedure for policies
- Starting date of the policies
- Next due installment of a policy
- Maturity date
- Interests due
- Survival benefits
- Bonus

In Education:

The computer provides many facilities in the education system.

• The computer provides a tool in the education system known as CBE (Computer Based Education).

• CBE involves control, delivery, and evaluation of learning.

• It is used to prepare a database regarding the performance of a student.

In Marketing:

In marketing, computer has several roles like:

• Advertising − With computers, the professionals create art and graphics, write and revise copy, print and disseminate ads for selling the products.

• Home Shopping − provide access to product information and permit direct entry of orders to be filled by the customers.

In Healthcare:

Computers have become an important part in hospitals, laboratories, and dispensaries.

They are used in hospitals to maintain the record of patients and medicines.

It is also used in scanning and diagnosing different diseases.

ECG, EEG, ultrasounds and CT scans, etc. are also done by computerized machines.

Some major fields involves:

• **Diagnostic System** − Computers are used to collect data and identify the cause of illness.

• **Lab-diagnostic System** − All diagnostics can be done and the reports are prepared by computer.

• **Patient Monitoring System** − Used to check the patient's signs and symptoms for abnormalities like Cardiac Arrest, ECG, etc.

• **Pharma Information System** − Computer is used to check drug labels, expiry dates, harmful side effects etc.

• **Surgery** − Nowadays, computers are also used while performing surgery.

In Engineering Design:

Computers are widely used for engineering purpose.

One of the major areas is CAD (Computer Aided Design), that provides creation and modification of images.

Some of the important fields are:

• **Structural Engineering** − Requires stress and strain analysis for the design of ships, buildings, budgets, airplanes, etc.

- **Industrial Engineering** − Computers deal with design, implementation, and improvement of integrated systems of people, materials, and equipment.
- **Architectural Engineering** − Computers help in planning towns, designing buildings, determining a range of buildings on a site using both 2D and 3D drawings.

In Military:

Computers are largely used in defense like modern tanks, missiles, weapons, etc.

Military also employs computerized control systems. Some military areas where a computer has been used are:

- Missile Control
- Military Communication
- Military Operation and Planning
- Smart Weapons

In Communication :

Communication is a way to convey a message, an idea or speech, that is received and understood clearly by the person for whom it is meant.

Some main areas in this category are:

- E-mail
- Chatting
- File Transfer Protocol
- Telnet
- Video-conferencing

In Government:

Computers play an important role in government services.

Some major fields in this category are:

- Budgets
- Sales tax department
- Income tax department
- Computation of male/female ratio
- Computerization of voters lists
- Computerization of PAN card
- Weather forecasting

SEARCH ENGINES

Definition:

Search Engine is defined as a database of internet resources such as web pages, newsgroups, programs, images etc. This helps to locate information on World Wide Web.

User can search for any information by passing query in form of keywords or phrase. It then searches the relevant information in its database and return to the user.

Components of Search Engine:

Generally there are three basic components of a search engine:

1. Web Crawler
2. Database
3. Search Interfaces

Web crawler

It is also known as **spider** or **bots.** It is a software component that traverses the web to gather information.

Database

All the information on the web is stored in database. It consists of huge web resources.

Search Interfaces

This component is an interface between user and the database. It helps the user to search through the database.

Working Mechanism of Search Engine:

Web crawler, database and the search interface are the major component of a search engine that actually makes search engine to work. Usually, search engines use Boolean expression AND, OR, NOT to restrict and also widen the search results.

Steps Involved:

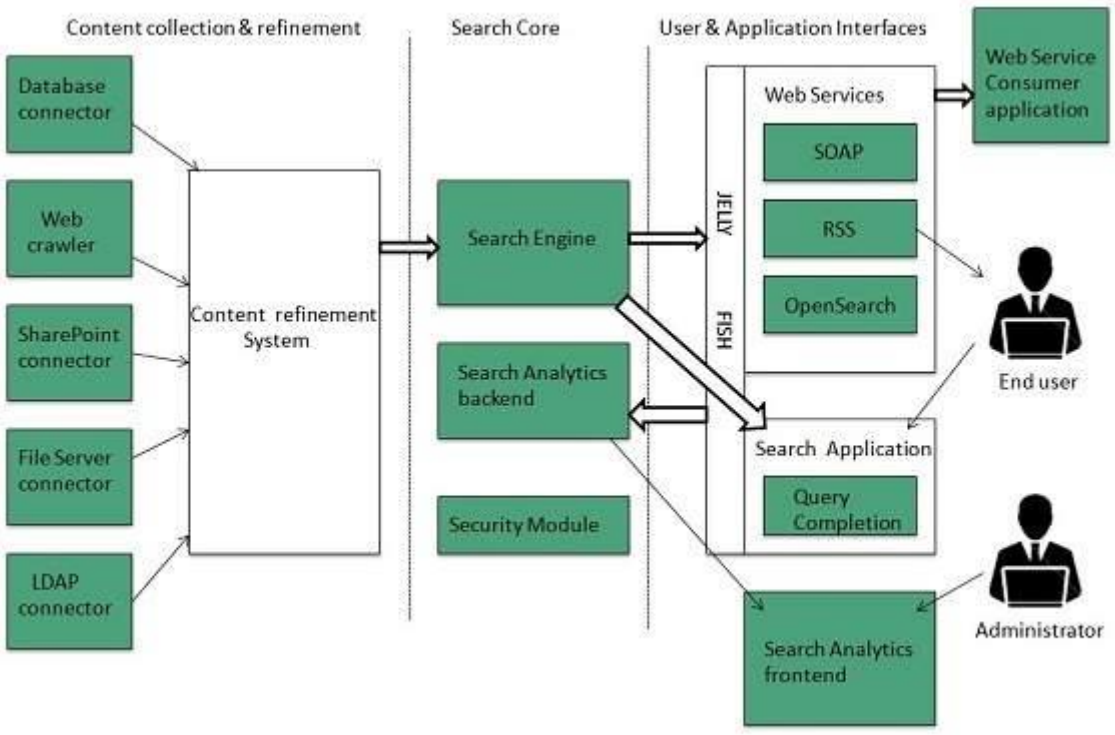
- The search engine will search for the keyword in the index for predefined database. It will not go to web for searching the keyword.
- Later, it uses software to search for the information. This software component is known as web crawler.

- Once web crawler finds the pages, the search engine shows the relevant web pages as a result.
- These retrieved web pages include title of the page, size of text portion, starting sentences etc.
- The retrieved information is ranked as frequency of keywords, relevancy of information, relevant links etc.
- Now, the user can click on any of the search results to open it.

Architecture:

There are three basic layers:

- Content collection and refinement.
- Search core
- User and application interfaces



BOOLEAN SEARCH

Boolean search is the advanced type of search that allows users to combine the keywords with operators or modifiers, such as AND, NOT and OR to get relevant results.

Eg: “school” AND “Delhi”. This will limit the search results to only those documents with two keywords.

BOOLEAN SEARCH OPERATORS:

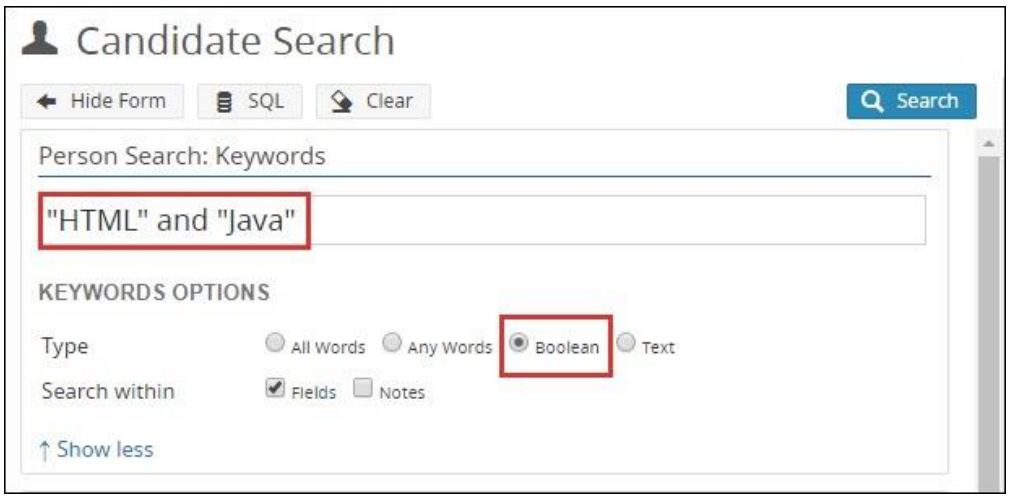
The search operator AND, NOT and OR should be in capital letters.

- **Quotes** - Use quotes to search for an exact phrase. *Example: "database management"*

  - **Parenthesis** - Combine modifiers to create complex s
  - earch. *Example: computer AND (keywords OR phrases)*
  - **AND** - Includes two search items. *Example network AND data*
  - **OR** - Broaden thesearch with multiple words. *Example: "network director" OR "network manager"*
  - **NOT** - Used to exclude a specific word. *Example: director NOT manager*

Requirements for Boolean search:

- Enter the desired keywords within the quotation marks.
- Use appropriate Boolean search word from the list below, but between the keywords.
- Select **Boolean** as the Keyword Option type.
- When all desired parameters are achieved, click **Search** .
- Results acquired.

- 

Boolean Search Symbols

- **Or:** The **OR** keyword tells the search to look for instances with either of the phrases entered. For example, searching for candidates who have "Java" OR "HTML" in their profile.
- **And:** The **AND** keyword tells the search to look for instances with both phrases entered. For example, searching for candidates who have "Java" AND "HTML" in their profile.
- **Near:** The **NEAR** keyword is similar to the AND keyword in that it will only return instances where it finds both phrases entered. However, the NEAR keyword will also return results in order of proximity;

the closer together the words are on the candidate's resume, the higher that candidate's profile will be ranked.

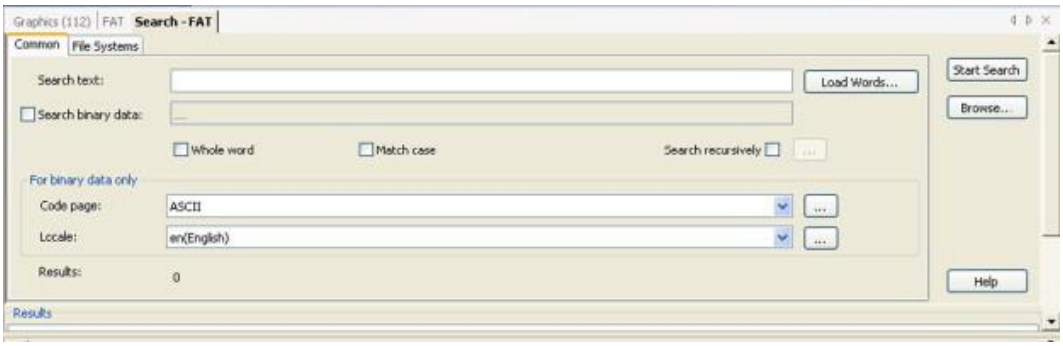
- **And Not:** The **AND NOT** keywords tell the search to exclude certain text from the search. For example, searching for candidates who have "Java" AND NOT "JavaScript" in their profile.
- **Quotation Marks:** Use quotation marks to enclose phrases. For example, typing *system manager* into a Boolean search will return an error because the search phrases (*system* and *manager*) are not recognized as having been connected. Typing *"system manager"* will return all instances where the search finds the phrase *system manager*.
- **Parentheses:** Use parentheses to combine parts of a complex search equation. For example, searching for candidates who have "HTML" OR ("Java" AND NOT "JavaScript") in their profile. As in mathematics, items enclosed within parentheses are searched for first.
- **Asterisk:** The asterisk (*****) serves as a wild card character. Use it to search for words with a common prefix or suffix. For example, typing in *"link******"* will return all instances of *link*, *linking*, *linked*, etc.

- **Double Asterisks:** Double asterisks (**) allow searching for all forms of a word. For example, typing in *"sell***"* will return all instances of *sell*, *sold*, *selling*, etc.

Searching Data Using Boolean Search :

1. Click on the Search button, or select Tools Search.

2. The search pane opens.



3. Click on the “Browse” button to specify the subfolders of the selected folder. Here,search will be performed.

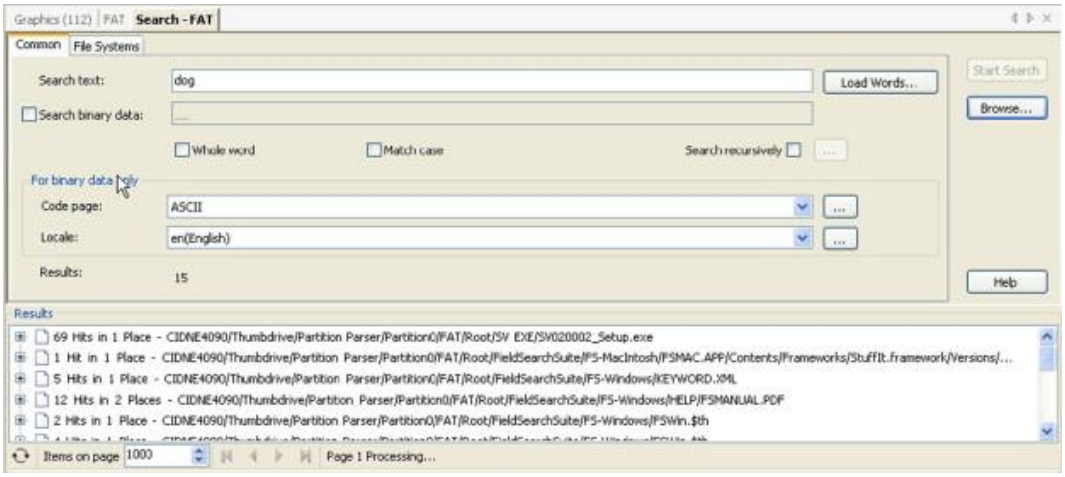
4. Enter the keywords to search for in the block for keywords. This will search throughout the sorted files.

5. Search parameters can be added, by clicking on the radio buttons.

6. Click the “Run Query” button. To find all sorted files, leave all fields empty and click on the “Run Query” button.

7. The search starts. The status shown in the Tasks pane can be stopped, paused, and started from there. The results of the finished searches are saved. They will be stored until the task is removed from the Task Pool.

8. Search results are shown in the bottom part of the search pane.



9. After double clicking on the search result, it will be opened in the data viewer pane and can be viewed.

10. The results area of the search pane has the right-click context menu, which contains the following commands:

- **Copy URL:** copies the selected result URL to the clipboard.
- **Add bookmark:** adds a bookmark pointing to the selected result.
- **Bookmark search results:** adds a bookmark to the results of the currently finished search.
- **Navigate to URL:** navigates to the selected results in the "Data View" pane and "Case Explorer" pane.
- **Save to XML:** saves the results of the search to XML.

USES:

- Boolean searching is used to help find search results faster.
- This gives more precision.
- Boolean searching uses operators words like AND, OR, and NOT. These are logic-based words, will help search engines narrow down or broaden search results.

SEARCH ENGINE ALGORITHMS:

- A search engine algorithm is a collection of formula that determines the quality and relevance of a particular ad or web page to the user's query.

- Searching Algorithms are designed to check or retrieve an element from any data structure where it is being stored.
- They search for a target key in the search space.

CLASSIFICATION:

Search engine algorithms are mainly classified into *2* categories. They are:

1. **Sequential Search:** In this, the list or array is traversed sequentially and every element is checked. For example: Linear Search
2. **Interval Search**: These algorithms are specifically designed for searching in sorted data-structures. These type of searching algorithms are more efficient than Linear Search method, as they repeatedly target the center of the search structure and divide the search space in *2* half. For Example: Binary Search.

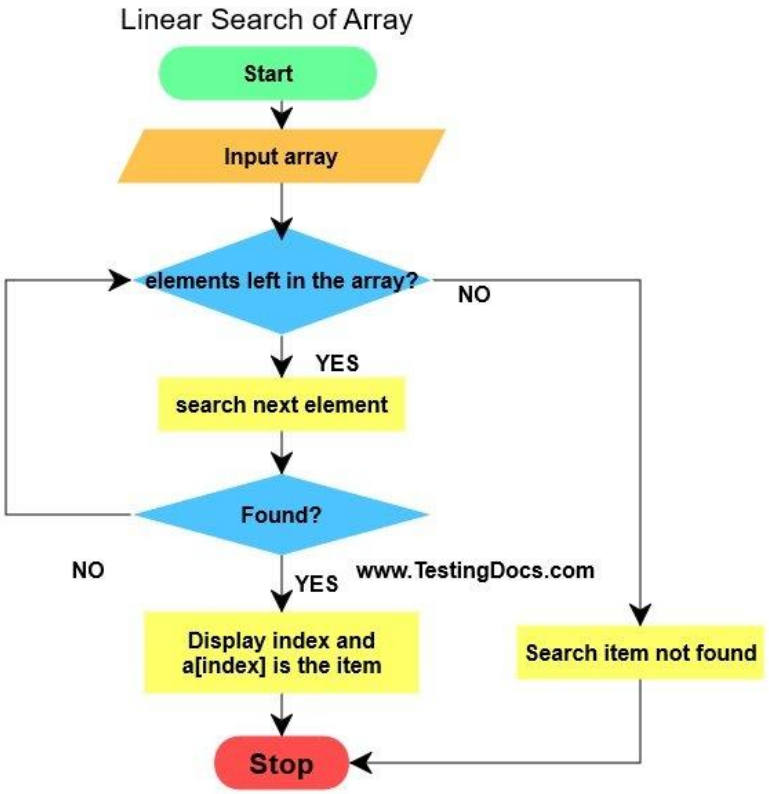
TYPES OF SEARCHING ALGORITHMS:

- Linear Search
- Binary Search

- Jump Search
- Interpolation Search
- Exponential Search
- Sublist Search (Search a linked list in another list)
- Fibonacci Search

Linear Search:

- A linear search or sequential search is a method for finding an element within a list.
- This type of searching algorithms sequentially checks each element of the list, until a match is found.
- A linear search runs in at worst linear time and makes at most *n* comparisons, where *n* is the length of the list.
- If each element is equally likely to be searched, then linear search has an average case of $n+1/2$ comparisons.
- Linear search is rarely practical because other search algorithms, allow significantly faster searching for all but short lists.



Binary Search:

- A binary search is also known as a half-interval search or logarithmic search.
- This type of searching algorithms is used to find the position of a specific value contained in a sorted array.
- Binary search algorithm works on the principle of divide and conquer. It is considered as the best searching algorithms, because of its faster speed to search.
- It starts by searching in the middle of the array and going down the first lower or upper half of the sequence.

- If the median value is lower than the target value, the search needs to go higher.
- If not, then look on the descending portion of the array.

Properties of binary search tree:

- The left subtree of a node contains only nodes with keys lesser than the node's key.
- The right subtree of a node contains only nodes with keys greater than the node's key.
- The left and right subtree each must also be a binary search tree.
- There must be no duplicate nodes.

A binary search is a quick and efficient method of finding a specific target value from a set of ordered items. By starting in the middle of the sorted list, it can effectively cut the search space in half by determining whether to ascend or descend the list based on the median value compared to the target value.

Jump Search:

- *Jump Search* is one of the **searching algorithms** for sorted arrays.

- This will check fewer elements by jumping ahead, by fixed steps.
- Sometimes, it may skip some elements in place of searching all elements.

Interpolation Search:

- It was first described by W. W. Peterson in 1957.
- This method is an improved variant of binary search.
- This search algorithm works on the probing position of the required value.
- Here, the data collection should be in a sorted form and equally distributed.
- It is used for searching for a key in an array that has been ordered by numerical values assigned to the keys.

Exponential Search:

- **Exponential search** is also known as doubling or galloping search.
- This mechanism is used to find the range, where the search key may present.
- If L and U are the upper and lower bound of the list, then L and U both are the power of 2.

- For the last section, the U is the last position of the list. For that reason, it is known as exponential.
- After finding the specific range, it uses the binary search technique to find the exact location of the search key.

Applications of Exponential Search:

1. It is particularly useful for unbounded searches, where size of array is infinite.
2. It works better than Binary Search for bounded arrays, and also when the element to be searched is closer to the first element.

Sublist Search:

- **Sublist search** is used to detect a presence of one list in another list.
- Suppose, if we have a single-node list (first list), and have to ensure that the list is present in another list (second list), then perform the **sublist search** to find it.

Fibonacci Search:

- Fibonacci search is a method, where a sorted array uses a divide and conquer algorithm that narrows down possible locations with the aid of Fibonacci numbers.

- Here, the sorted array is divided into two equal-sized parts, one of which is examined further.
- Fibonacci search divides the array into two parts, that have sizes that are consecutive Fibonacci numbers.

GOOGLE SCHOLAR

Google Scholar is an interface of Google, that makes it easier to do academic research than the standard Google interface.

It is designed to search for scholarly articles and case law, though it can also uncover books through Google Books.

The Google Scholar Searches:

- Journal publisher websites
- Open Access repositories (university, discipline-based, and government)
- Preprint services
- Academic social networks
- Google Books
- Anything else Google thinks is hosting scholarly research

Features of Google Scholar:

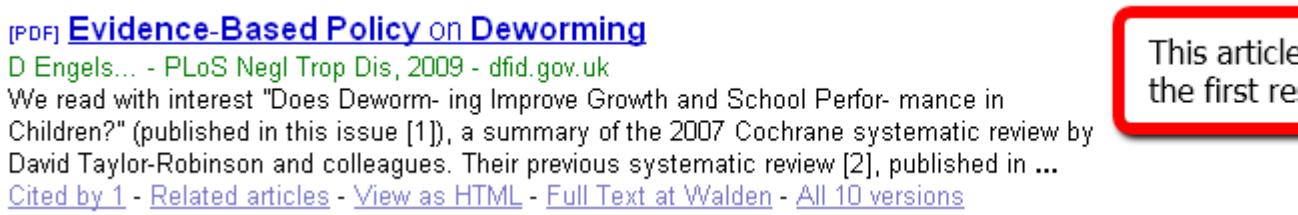
- Search all scholarly literature from one convenient place

- Explore related works, citations, authors, and publications
- Locate the complete document through library or on the web
- Keep up with recent developments in any area of research
- Check the person citing your publications, create a public author profile

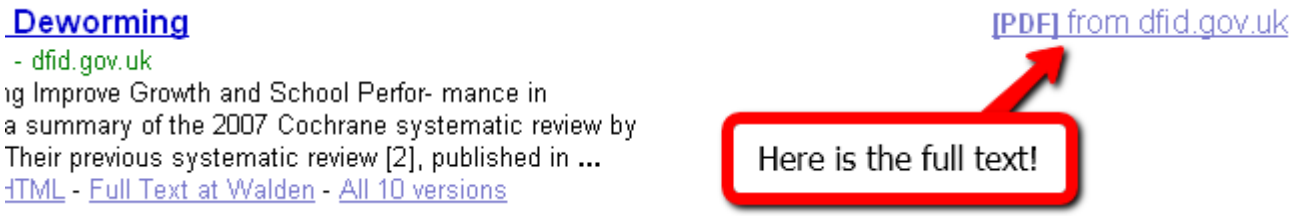
Steps Involved In Finding Article:

1. Go to Google Scholar, enter the article title, and click Search. For best results, put quote marks around the title.

2. If available, your article should appear as one of the first few results:



3. If you click an article's title, you may be taken to a publisher's site that will ask you to pay for full text. Instead, look for a **PDF** or **HTML** link to the right of the article. This is a free, full-text copy.



If there is no link on the right:

- Click the article title. Though rare, you may get it free from the publisher.
- Try searching regular Google.
- Buy the article.
- Use the Document Delivery Service. Usually, it can takes 7-10 business days to get an article from DDS.

CREATING A PROFILE ON GOOGLE SCHOLAR:

- If the author wishing to submit their researchwork and articles to Google Scholar, they must have their own profile.
- For creating the profile, visit scholar.google.com website.
- Then select ‘My Citations’ option, which is visible on top of the web page.
- Click this option.
- Immediately you can find out, whether you have a profile on Google Scholar or not.
  - In case if there is no profile, we have to create it by:
    - specifying your affiliations
    - areas of expertise and interest
    - entering the link to the website
    - adding a profile image
    - making ther profile public so that it is visible to all
  - After entering the information, move on to adding the research articles and papers.

METHODS TO ENTER RESEARCH ARTICLES:

- There are two ways in which one can add their research work to their profile.

Manual Entry:

For adding articles manually:

- Firstly, choose the document type:
  - a patent,
  - a thesis,
  - a book,
  - chapter of a book,
  - an issue of a journal,
  - a conference article,
  - a court case, etc.
- Secondly, provide specifics about the article:
  - its title,
  - the name(s) of the author(s),
  - the date of publication,
  - the volume or issue number of the journal it was originally published in,
  - the name of the publisher,
  - the affiliated institution or organization which sponsored the research, etc.

- Lastly, click the ‘Save’ option.
- The user is notified that their article was successfully added to their Google Scholar profile.

Submit An Entire Website:

- This method is more suitable for career academics and researchers.
- To add a website to their Google Scholar profile:
- First, pick the sort of website that they wish to submit, which may be a personal publication or other.
- Second, check all the boxes that are applicable to them, which might include the option ‘My Inclusion Request Is For My Personal Publications’;
- Third, enter in all the necessary details about the webpage that is being added
- Lastly, include a couple of example articles the sort of which may be found on the website. This includes one or more PDF documents.
- Then click ‘Submit’ option.
- A message stating that the website was submitted for consideration pops up.

- This message states that the submitted website will be scrutinized by Google's crawl team. It will check:
    - its originality,
    - the significance of the findings
    - the ingenuity of the research methods employed
    - the profoundness of the conclusions
- If it meets all the above criteria, the website and the articles will appear on Google Scholar's search results within 4 to 6 weeks.
- User will receive emails about the updation of their articles.

Advantages of using Google Scholar:

1. Google Scholar is familiar and relatively simple to use.
2. Google Scholar allows users to search wide variety of articles, books, conference proceedings etc.
3. Google Scholar allows to see articles related to the one that might interest, how many times an article has been cited and by whom, and provides citations for articles in a number of styles.
4. Google Scholar can display links to articles and books.

5. Google Scholar allows to save both citations and articles to read later.

Disadvantages of using Google Scholar:

1. Google Scholar's coverage is wide-ranging but not comprehensive.
2. Google Scholar does not provide the criteria for what makes its results "scholarly".
3. Results often vary in quality and it is upto the researcher to determine, which of the results are suitable for their purposes.
4. Google Scholar does not allow users to limit results to either peer reviewed or full text materials or by discipline.
5. Google Scholar does not provide notice about the updation.
6. Google Scholar's citation tracker can be difficult to use and inaccurate.

SCOPUS

Scopus is an abstract and indexing database with full-text links that is produced by the Elsevier Co. The name, Scopus, was inspired by the bird, Hammerkop (*Scopus umbretta*),

which reportedly has excellent navigation skills. The database was developed working with 21 research institutions and more than 300 researchers and librarians.

Diversity of Source Types:

There are two different types namely – Serial and Non-serial source type.

SERIAL SOURCE TYPE:

Book Series:

- Book series is a book with an overall title, an ISBN (International Standard Book Number), and an ISSN (International Standard Serial Number).
- Usually, they are published inconsistently.
- Each book is a monographic publication, with a title separate from the series title and a different editor.

Journals:

- Most of the content in Scopus is made up of Journals.
- They have many physical formats like print, electronic and more.

- Content coverage policy plays a huge role in the selection of titles.
- Any serial publication with an ISSN can be suggested for a Scopus review, newsletters, secondary sources, or patent publications.

Trade Journals:

- Trade journals are serial publications.
- They are dedicated to a particular industry, trade, or type of business.
- Publications such as magazines with topical articles, news items, and advertisements are there.

NON – SERIAL SOURCE TYPE:

- A non-serial source is also known as a monograph or composed work.
- It is a publication with an ISBN.
- It may be a report, part of a book series, or patent. It can have different physical formats (e.g., print, electronic).
- It also now includes edited volumes, monologues, major reference books etc.

OTHER SOURCE TYPES:

Secondary documents:

- Approximately 210 million records are non-core or secondary documents. These are citations that appear in Scopus core records but are not themselves indexed in Scopus. Books and older journal articles are the most highly cited of these non-core items.

Patents:

- More than 43.7 million patent records have been procured from five patent offices that are a part of Scopus:

1. World Intellectual Property Organization (WIPO)
2. European Patent Office (EPO)
3. US Patent Office (USPTO)
4. Japanese Patent Office (JPO)
5. UK Intellectual Property Office (IPO.GOV.UK)

IMPORTANT DATAS:

1. Keywords and Index Terms: 80% of the index terms added are acquired from thesauri, that Elsevier owns or licenses and are added by Scopus's manual efforts. The controlled vocabularies are:

- MeSH (life sciences, health sciences)
- Ei Thesaurus (engineering, technology, physical sciences)
- Emtree medical terms (life sciences, health sciences)

2. Affiliation Data: There is a tool available in Scopus, wherein the Scopus Affiliation Identifier identifies and compliments an organization with all of its research output. This tool will search, based on affiliation data available on Scopus, making it extremely relevant for researchers, project leaders, faculty heads, etc., to complete a task in minutes.

3. Document Types: Some documents go as far back as 1960. The main focus of Scopus lies in primary documents, and it does not include secondary documents. Documents like articles, books, data papers, etc., are included and other types like letters, reviews, notes etc are not included.

FEATURES OF SCOPUS:

• Links to both citing and cited documents, allowing the user to go both forwards and backwards in time.

• Open access titles are included in the index

• Indexes web pages and patents, with a claim to over 167 million relevant web pages.

• Open URL compliant and works with any link resolver, using image-based linking.

• Runs an entitlement check prior to returning a full-text image if the article if available to the user.

• Can link to the publisher's web site to view the document.

• Developers claim that "citation accuracy is achieved by using state-of-the-art technology, with 99% of citing references and citing articles matched exactly."

• For statistics on usage, Scopus delivers customer-specific usage reports which will be COUNTER compliant.

• Offers both on- and off-site training as well as web-based training and online tutorials. The database website offers quick reference guides, tips, etc. (in English and other languages) and offers online technical support.

• Works equally well with Internet Explorer, Netscape and Foxfire.

SEARCH MODES FOR SCOPUS:

There are two search modes for Scopus – Basic and Advanced

Basic Search:

- The Basic Search uses fill-in and drop-down boxes to search different fields.
- The search gives information about date, document type, subject area or recent updates.
- Once the citations are retrieved, results can be excluded according to set criteria.
- A particular author can be searched by name.
- After searching, the user will get a list of possible matches.

- One or more names can be selected from this list.

- The user can search for variants of a name and for parts of a name.

Advanced Search:

The user can use Boolean operators and nesting using field labels.

Article Search Algorithm:

- First, select the Search section,then documents and select the Article Title field to enter the name of the document.
- Scopus Preview provides more number of documents.
- The service offers many filters: keywords; additional terms; year of publication; type of document, etc.
- If the title contains brackets, replace them with spaces.
- After that, a certain number of articles will be displayed, from that identify the specified work.
- We can also save the search query and turn for next time.
- If some articles are missing from the list, search using the keywords in the title or abstract.
- Author Search enables search for all documents that link to a specific article.

- There is a sorting by the number of references to the document.
- After finding the article, we can go to the page on which there is a full description of the article.

Journal search

In search of the journal, we can go to the publication that interests and see the main data, including the articles published.

STARTING A DOCUMENT SEARCH:

Document Search:

This tab is the main search window of the homepage. To begin, enter the search terms in the space provided.

Author Search:

Choose the Author search tab to search for a specific author by name or by ORCID (Open Research and Contributor Identifier) ID.

Affiliation Search:

Choose the Affiliation search to search for a specific affiliation.

Browse Sources:

Browse an alphabetical list of all journals, book series, trade publications, and conference proceedings available in Scopus.

Compare Journals:

This option opens up compare journals to get the details.

Boolean Operators:

Select from AND, OR, AND NOT to combine search terms.

Search Items:

Select the specified fields to search.

Add Search Field:

To search using multiple keywords and search items, click Add search field button.

Limit to Section:

Control search by limiting to: published years, recently added, document type and subject areas.

Search History:

After carrying out a search, the search history will be displayed at the bottom. The search history will be cleared for each new search.

Combine Queries:

In the Combine queries bar in Search history, we can enter the list number of each search for combining, using the # symbol and the AND, OR, and AND NOT operators.

Set Alerts or RSS Feeds:

Many options like Set alert (to receive email alerts), Set feed (to receive RSS updates), Save query, Edit query, or Delete query are used.

OPTIONS FOR SORTING:

Set Alert:

This alert will notifies when a new article matches the search conditions by email.

Analyze Search Results:

Click to see an analysis of the results, showing the number of documents broken down by various criteria, including year, source, author, affiliation, and so on.

Number of Search Results:

This option displays the number of documents results.

Search within Results:

Add additional terms to the search by directly entering them here.

Results:

Use the Refine Results pane to limit the results list to certain categories of documents.

Display Document Details Page:

Click the article title to view the document of the article. The search result will show the following links: • View at Publisher • Show abstract • Related documents

Link to Full Text:

By clicking View at Publisher, we can link to the full text on each publisher's website if authorized.

Sort Options:

By default, search results are listed by date. Sort on Cited by, relevance, author name and source title are options.

View references:

Displays all documents referenced by the article.

Add to my list:

This option will add the articles to a temporary list. Later, they can be checked from My List menu or save the list under a new name.

Create bibliography:

Change the output to typical reference list format.

Email:

This option helps to send the articles as an email.

Print:

Displays the articles in a format suited for printing.

Advantages of SCOPUS:

- **Helps to spread the word about the research outcomes**
- **Gain a reputation in the scientific community**
- **Paves the way for collaborative opportunities**
- **Bolstering the integrity of firm**
- **Helps in acquiring financing / funding**

WEB OF SCIENCE

Web of Science is a database providing access to billions of cited references, dating back to 1900 in the areas of life sciences, social sciences, arts, and humanities. Reference materials include journals, books, reports, and conference papers. The Web of Science is published by Thomson Reuters and is an interdisciplinary database with records from

several bibliographic databases, among them Science Citation Index Expanded (SCI-EXPANDED) and Social Sciences Citation Index (SSCI). It is used for searching of a subject and cited references. It retrieves the articles that are cited by a reference article. It helps in viewing of the references that are already cited in a relevant article. It shows 10–15 results per page, with details like name of authors and source. The articles can be searched by using entries like author name, country, title, and source. This can retrieve number of articles from various disciplines and hence saves time.

BASIC SEARCH:

1.Choose a search option

- Basic search
- Author search
- Cited reference search
- Advanced search
- Structure Search

2.Limit your search

- Change your timespan limit in your search.
- Click “More settings” to see the list of all indexes in the Web of science core subscription

3.Tools

- Use Tools and searches and alerts to move to your saved searches

4.Search

- Combine words and phrases to search across the source records in Web of Science collection

5.Select a database

- Use a dropdown to select another content set

6.Add another search field

- In case of necessity, we can add another field to search

7.Select the search field

- Use a dropdown to select search field

SEARCH OPERATORS:

- Use AND to find records containing all search items
- Use OR to find records containing any of the search items
- Use NOT to exclude records containing certain words of the search items
- Use NEAR to find records containing all terms within certain number of words
- Use SAME to find terms in same line

Phrase Searching:

- It is used to search exact phrases in topic or title searches.
- The phrase should be included in quotation marks.

Author Searching:

- Enter the last name first, followed by space and upto five initials.
- Use truncation and search alternative spelling to find name variants.

SCIENCE DIRECT

Science Direct is an authoritative, full-text scientific, technical and health publications with intuitive functionality.

With high-quality books and reference content and journals, the Science Direct platform uniquely supports an uninterrupted workflow.

It helps the researchers in academia, government and corporate organizations to make smarter and faster decisions.

The users can work more effectively and efficiently.

Steps Involved:

1. Go to library home page at www.esc.edu/library
2. Click Article databases
3. Scroll down the alphabetical list
4. Click on Science direct
5. Enter the login and password
6. Science Direct main page appears
7. Now search by keywords or browse by topic.

In case of first login into Science Direct,

- Basic search box will appear at the top of the screen
- Type your search into the box.
- Click the search button.

While searching:

1. Put quotation marks around the search keywords

- Use AND between any two keywords
- Use OR between keywords to search for articles

2. Browse publications by subject area using the expandable list right below the search box, on the left side.

3. If the title of journal is known, use browse publications by title menu, which is below the search boxes, on the right.

Advanced Search:

Click Advanced Search Link for advanced search.

First decide the type of search

- All sources, journals, books, reference works or images, using the tabs up at the top of the search box.
- Books, reference works or images – Choose journal tab

1. Each search box has pull- down menu to the right of it. Some fields are:

- All Fields – keyword search
- Authors – the author of the article
- Source title – title of the article
- Keywords – important words
- Full text – words in text

2. A pull down menus between the two search boxes are added with AND, OR or NOT.
3. Select a particular subject area to search in.

Search Result List:

1. The search results page will display 25 search results per page.
2. If more than 1 page of search results are there, page numbers will be seen at the top and bottom right.
3. The title of the article is a link to the Article Information Page.
4. Beneath each search result the PDF icon and related articles are seen.
5. On the left side of search results page is the search within results menu. Use it to narrow the search.
6. Below that, on the left side of search results page is the Refine results menu.

Article Information:

1. Click on the title of the article to get the article information page. It shows:
2. Authors, journal name, volume, issue, page numbers, publication date.
3. Abstract, is the summary of articles content.
4. An outline, use to click HTML full text.
5. Download PDF and Export citation
6. Related Articles – the way to find articles on the same topic.

Finding full article:

Science Direct always has the full text. Articles are available in HTML full text. They are also available as downloadable PDF files.

UGC – CARE

UGC Approved Journals are the medium for publishing the research articles. University Grant Commission will consider the research article as valid only when we submit it in the UGC Approved Journals.The UGC-CARE List of Quality

journal is now divided into 2 groups. These are not hierarchic or ranked groups.

- **UGC-CARE List Group I:** Journals found qualified through UGC-CARE protocols
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- UGC-CARE List is updated quarterly i.e. on first of January, April, July, and October every year.
- Journals found to be involved in unethical practices are immediately removed.

Essential Features of UGC-CARE list:

- To promote quality research, academic integrity, and publication.
- To prevent publications in dubious/predatory/sub-standard journals.
- To maintain the Reference UGC CARE List of Quality Journals.
- To develop a methodology and approach for good quality journal identification.

Steps Involved:

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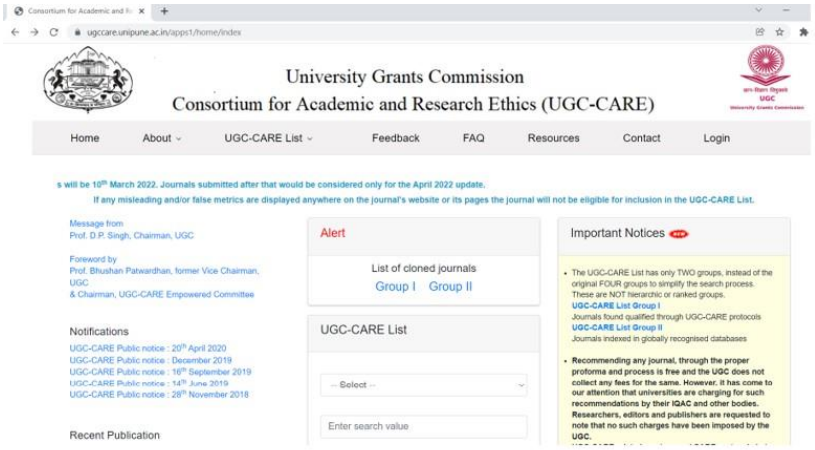
- Click the website link



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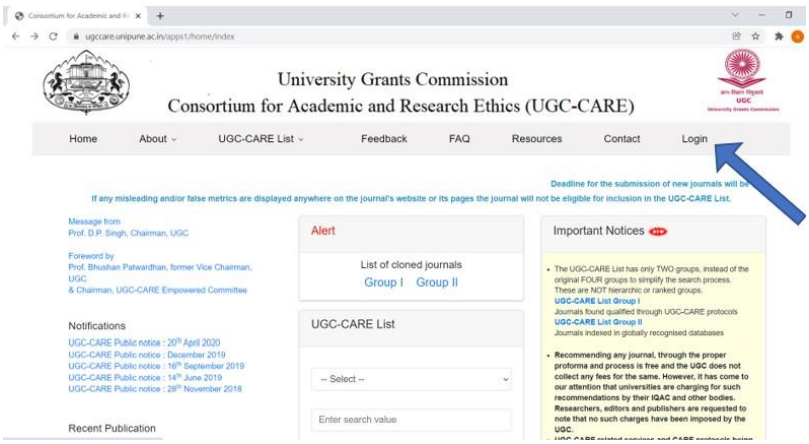

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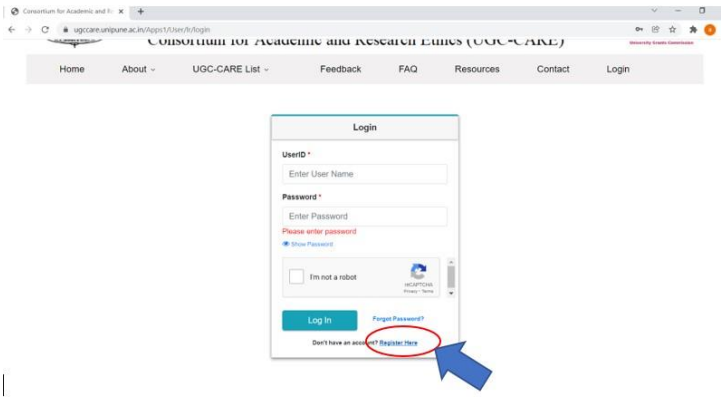

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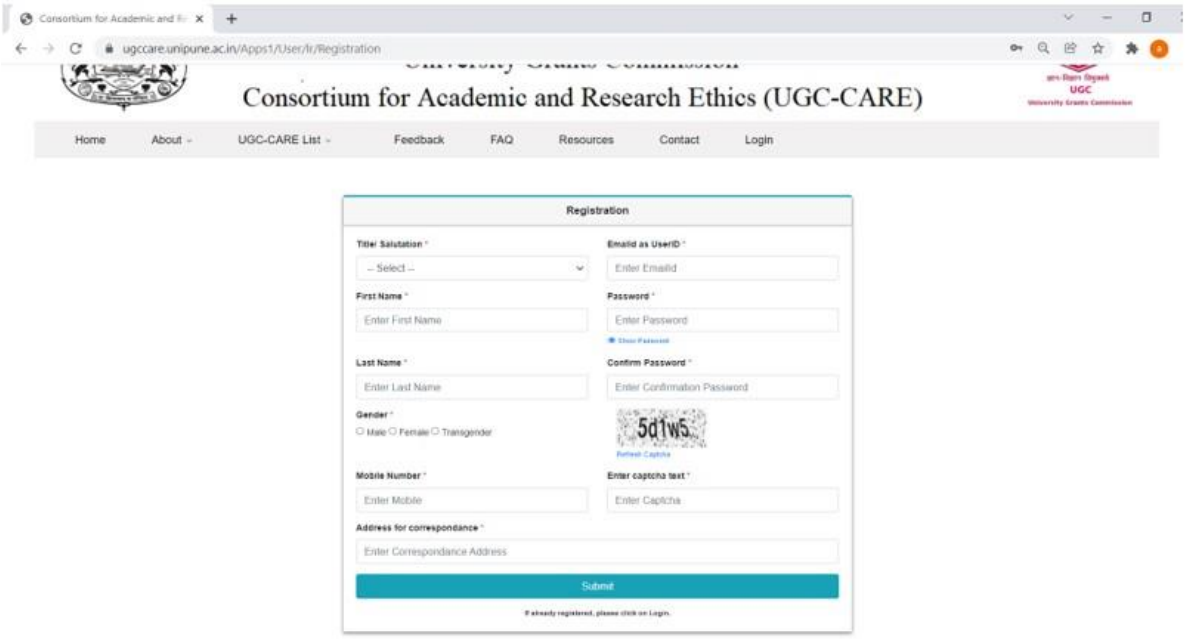

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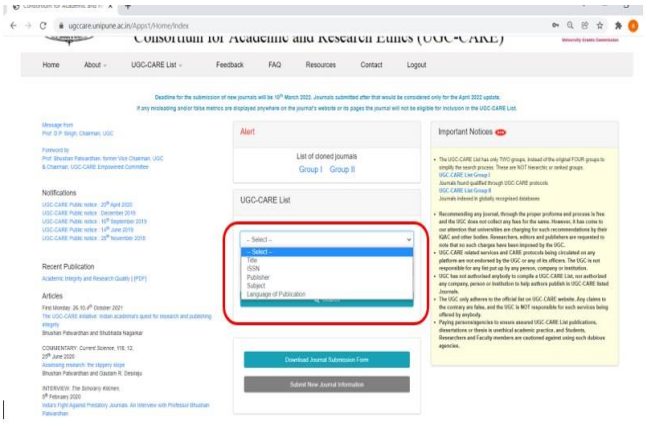

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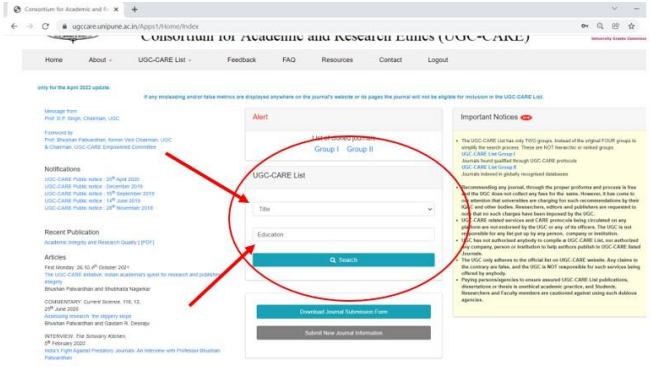

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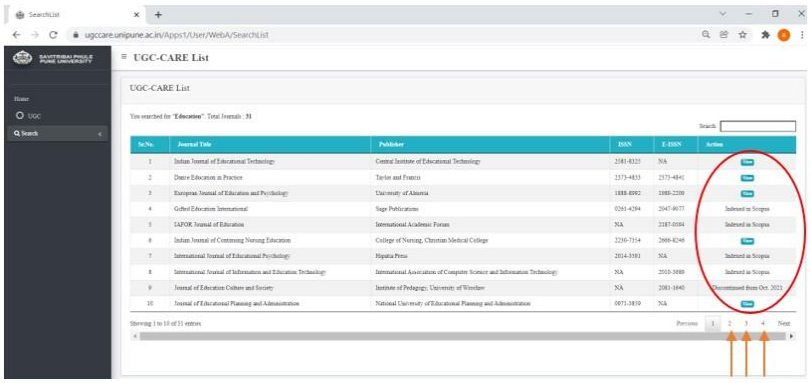

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CHAPTER-IV

Laboratory animals used for Life science research. Ethics in animal experimentation. CPCSEA guidelines−Animal care and technical personnel environment, animal husbandry, feed, bedding, water, sanitation and cleanliness, waste disposal, anaesthesia and euthanasia.

INTRTODUCTION

Choosing the correct animal model is an essential component to the success of biomedical research. Each species used in biomedical research must be provided with adequate housing and care to ensure the well-being of the animals. Because good science and good animal care go hand in hand, it is important to understand and address the biological and behavioural needs of the animals being studied.

MICE

Mice and rats make up approximately 95% of all laboratory animals, with mice the most commonly used animal in biomedical research. Mice (Fig.1) are a commonly selected animal model for a variety of reasons, including small size (facilitating housing and maintenance); short reproductive cycle and lifespan; generally mild-tempered and docile; wealth of information regarding their anatomy, genetics, biology, and physiology; and the possibility for breeding genetically manipulated mice and it have spontaneous mutations. They are used to model human diseases for the purpose of finding treatments or cures. Some of the diseases they model include: hypertension, diabetes,

cataracts, obesity, seizures, respiratory problems, deafness, Parkinson's disease, Alzheimer's disease, various cancers, cystic fibrosis, and acquired immunodeficiency syndrome (AIDS), heart disease, muscular dystrophy, and spinal cord injuries. Mice are also used in behavioural, sensory, aging, nutrition, and genetic studies. This list is in no way complete as geneticists, biologists, and other scientists are rapidly finding new uses for the domestic mouse in research.

Mice are mammals and their organ systems are very similar to organ systems in humans in terms of shape, structure, and physiology. Mice have only two types of teeth, incisors and molars. The incisors are open-rooted and erupt (i.e., grow) continuously throughout their lives. This predisposes mice to malocclusion if not given feeds or objects such as nylon bones to help wear down the teeth during mastication. The molars are rooted and, thus, do not continuously erupt. The stomach has two compartments with the proximal portion completely keratinized and the distal portion entirely glandular. Their intestines are simple, but the rectum is very short (1–2 mm) and hence is prone to prolapse, especially if the animal has colitis. The gastrointestinal flora

consists of more than 100 species of bacteria that form a complex ecosystem that aids digestion and health of the mouse.

Mice have no sweat glands but have a relatively large surface area per gram of body weight. In addition to the lack of sweat glands, they cannot pant or produce large amounts of saliva to aid in cooling their body temperature. The thermo neutral zone, the range of ambient temperatures at which the mouse does not have to perform regulatory changes in metabolic heat production or evaporative heat loss to maintain its core temperature, is about 29.6°C–30.5°C. The female reproductive system is comprised of paired ovaries and oviducts, uterus, cervix, vagina, clitoris, and paired clitoral glands. Pregnant female mice have hemochorial placentation, similar to humans. The female mouse also has five pairs of mammary glands. The male reproductive system consists of paired testes, penis, and associated sexual ducts and glands. Both sexes have well-developed preputial glands, which can become infected. Mice breed continuously throughout the year unless conditions are very unfavourable to them (e.g., lack of food). Their reproductive potential can be affected by

a number of external influences such as noise, diet, light cycles, population density, or cage environment.

RATS

Rats (Fig.2) and humans have a long history of coexistence. The origins of the laboratory rat, also known as the Norway rat, stretch back centuries to the areas of modern day China and Mongolia. The dispersal of the Norway rat has occurred across the centuries and its natural habitat stretches from the Mediterranean across Southeast Asia and down into Australia and New Guinea. Over the centuries, rats have also been used for food (e.g., in Imperial China), companionship, and sport. Ratting, a vicious blood sport where people laid bets on the dog that could kill the most rats in a given period of time was especially popular in both the Victorian England and American Underworld.

The first recorded use of rats as research subjects occurred in 1828, and the first known rat breeding experiments occurred in the late 1800s. The first major effort to perform research in the United States using laboratory rats occurred at the Wistar Institute of Philadelphia, the oldest

independent research institute in the United States, in 1894. *Rattus norvegicus* constitutes one of the most commonly used laboratory species, second only to the laboratory mouse.

RABBIT

The ancestral home of the European rabbit (Fig 3) (*Oryctolagus cuniculus*) is the Iberian Peninsula. European rabbits have been used in research since the middle of the 19th century. Early work with the species was concentrated on the comparative anatomy of the rabbit with other species, such as the frog, and the unique features of the rabbit's heart and circulatory system. Louis Pasteur used rabbits in a series of experiments that led to the development of the world's first rabies vaccine.

While there are numerous so-called “fancy” breeds of rabbits available in the pet trade, the list of breeds routinely used in research is much shorter. The New Zealand White (NZW) rabbit is the most frequent breed of used in research. The California and Dutch-belted rabbit breeds are also occasionally used. Researchers have developed genetically inbred rabbit strains for particular research applications. For example, the Watanabe heritable hyperlipidemic (WHHL) and the myocardial infarction-prone WHHL rabbit (WHHLMI),

both developed by researchers in Japan, are used to explore diseases associated with dyslipidemia such as atherosclerosis.

ZEBRAFISH

The zebrafish (Fig 4), *Danio rerio* of the Cyprinidae family, is a small, dark blue and yellow striped, shoaling, teleost fish, popular among aquarium enthusiasts, and increasingly among the research community. The adult fish are 4–5 cm in length, with an incomplete lateral line and two pairs of barbels. Males have larger anal fins and more yellow coloration; females have a small genital papilla just rostral to the anal fin.

Zebrafish are hardy, fresh water fish originating from a tropical region with an annual monsoon season. The fish are generally found among slow moving waters of rivers, streams, and wetlands, across the South Asia region of India, Bangladesh, and Nepal. The waters tend to be shallow, relatively clear with substrates of clay, silt, or stone of varying size. The fish feed mostly on insects and plankton, with evidence of feeding along the water column as well as water surface. The small size of zebrafish, the ease of keeping large numbers, frequent spawning, large egg clutches, translucent nonadherent eggs, rapid development and complex

sequencing of the zebrafish genome are all key components that make the zebrafish an attractive research model. Interestingly, approximately 70% of zebrafish genes have at least one orthologous human gene. Developmental biology was the initial focus of zebrafish research use. However, in recent years, use of the zebrafish in research related to biochemistry and molecular biology, cell biology, neurological sciences, and genetics has been rapidly increasing.

GUINEA PIGS

Guinea pigs (Fig 5) (*Cavia porcellus*) are rodents, related to porcupines and chinchillas in the suborder Hystricomorpha. They originate from the mountain and grassland regions along the mid-range of the Andes Mountains in South America. They are small, stocky, non burrowing, crepuscular herbivores with short legs and little to no tail, ranging from 700 to 1200 g, females being smaller than males. Guinea pigs have a long-standing historical role in research stretching as far back as the 1600s, when they were first used in anatomical studies. Further, they were used by Louis Pasteur and Robert Koch in their investigations of infectious disease, and have contributed to the work of several Nobel Prize worthy studies.

Specifically, the guinea pig has been used as a model for infectious diseases such as tuberculosis, Legionnaires disease, sexually transmitted diseases such as chlamydia and syphilis, and one of the more common causes of nosocomial infections in people, *Staphylococcus aureus* . Guinea pigs have also been useful tools in researching cholesterol metabolism, asthma, fetus and placental development and aspects of childbirth, as well as Alzheimer's disease.

Guinea pigs have many similarities to humans hormonally, immunologically, and physiologically. Unlike other rodents, and more like primates (including people), guinea pigs are prone to scurvy if they do not receive adequate vitamin C, typically in their diet. Guinea pigs are housed similarly to other rodents, although they require more room than the smaller rodents.

HAMSTERS

Hamsters (Fig6)are of the *Rodentia* order, suborder *Myo morpha* along with the mouse and the rat. There are over 24 species of hamsters described in the literature, with the most common hamster used in research being the Golden or Syrian

hamster, *Mesocricetus auratus* . Originating from the northwest region of Syria, Golden hamsters are thought to be descendants of only three or four littermates collected from Syria in 1930. As their name implies, the typical wild-type coat is reddish gold along their dorsum, with a gray underside. They are granivores and insectivores, weighing 85–150 g, females weighing more than males, with short legs and short tail, and large cheek pouches.

ETHICS AND EXPERIMENTS ON ANIMALS

The ethical assessments related to the use of animals in research are wide-ranging. It is generally thought that it may be necessary to use laboratory animals in some cases in order to create improvements for people, animals or the environment. At the same time, the general opinion is that animals have a moral status, and that our treatment of them should be subject to ethical considerations. Such views are reflected in the following positions: (i) Animals have an intrinsic value which must be respected, (ii) Animals are sentient creatures with the capacity to feel pain, and the interests of animals must therefore be taken into consideration, (iii) Our treatment of animals, including the use

of animals in research, is an expression of our attitudes and influences us as moral actors.

The guidelines reflect all these positions, and stipulate principles and considerations that can be used as tools when balancing between harm and benefit. The three Rs (Replace, Reduce, and Refine) are established principles that are also enshrined in legislation. These principles can establish absolute limits for experiments on animals, even when there are great benefits. These principles also state what can reasonably be considered harm and benefit, and the principles thus facilitate good assessments. Assessments of harm and benefit associated with experiments on animals are particularly demanding, because experiments may result in researchers intentionally causing actual harm to animals, while the future benefits are often uncertain.

The guidelines are dynamic and must be reviewed in line with technological developments and the appearance of new ethical issues. New gene technology methods create new opportunities for the use of genetically modified animals in research, which is a growing trend. Genetically modifying laboratory animals, i.e. changing the genetic material of

laboratory animals using gene technology, gives rise to a special responsibility in that this method entails a double intervention: first, intervention in the animal's genetic material and second, use of the animal as a research object. This practice has the potential to change our view of humans and our attitudes towards generating or eliminating genetic characteristics in ourselves.

RESPECT FOR ANIMALS' DIGNITY

Researchers must have respect for animals' worth, regardless of their utility value, and for animals' interests as living, sentient creatures. Researchers must be respectful when choosing their topic and methods, and when disseminating their research. Researchers must provide care that is adapted to the needs of each laboratory animal.

RESPONSIBILITY FOR CONSIDERING OPTIONS (*REPLACE*)

Researchers are responsible for studying whether there are alternatives to experiments on animals. Alternative options must be prioritised if the same knowledge can be acquired without using laboratory animals. If no good options are available, researchers should consider whether the research

can be postponed until alternative methods have been developed. When justifying experiments on animals, researchers therefore must be able to account for the absence of options and the need to acquire knowledge immediately.

THE PRINCIPLE OF PROPORTIONALITY: RESPONSIBILITY FOR CONSIDERING AND BALANCING SUFFERING AND BENEFIT

Researchers must consider the risk that laboratory animals experience pain and other suffering (see guideline 5) and assess them in relation to the value of the research for animals, people or the environment. Researchers are responsible for considering whether the experiment may result in improvements for animals, people or the environment. The possible benefits of the study must be considered, substantiated and specified in both the short and the long term. The responsibility also entails an obligation to consider the scientific quality of the experiments and whether the experiments will have relevant scientific benefits. Suffering can only be caused to animals if this is counterbalanced by a substantial and probable benefit for animals, people or the environment. There are many different methods for analysing

harm and benefit. Research institutions should provide training on suitable models, and researchers are responsible for using such methods of analysis when planning experiments on animals.

RESPONSIBILITY FOR CONSIDERING REDUCING THE NUMBER OF ANIMALS (*REDUCE*)

Researchers are responsible for considering whether it is possible to reduce the number of animals the experiment plans to use and must only include the number necessary to maintain the scientific quality of the experiments and the relevance of the results. This means, among other things, that researchers must conduct literature studies, consider alternative experiment designs and perform design calculations before beginning experiments.

RESPONSIBILITY FOR MINIMISING THE RISK OF SUFFERING AND IMPROVING ANIMAL WELFARE (*REFINE*)

Researchers are responsible for assessing the expected effect on laboratory animals. Researchers must minimise the risk of suffering and provide good animal welfare. Suffering includes pain, hunger, thirst, malnutrition, abnormal cold or

heat, fear, stress, injury, illness and restrictions on the ability to behave normally/naturally. A researcher's assessment of what is considered acceptable suffering should be based on the animals that suffer the most. If there are any doubts regarding perceived suffering, consideration of the animals must be the deciding factor. Researchers must not only consider the direct suffering that may be endured during the experiment itself, but also the risk of suffering before and after the experiment, including trapping, labelling, anaesthetising, breeding, transportation, stabling and euthanising. This means that researchers must also take account of the need for periods of adaptation before and after the experiment.

RESPONSIBILITY FOR MAINTAINING BIOLOGICAL DIVERSITY

Researchers are responsible for ensuring that the use of laboratory animals does not endanger biological diversity. This means that researchers must consider the consequences to the stock and to the ecosystem as a whole. The use of endangered and vulnerable species must be reduced to an absolute minimum. When there is credible, but uncertain,

knowledge that the inclusion of animals in research or the use of certain methods may have ethically unacceptable consequences for the stock and the ecosystem as a whole, researchers must observe the precautionary principle.

RESPONSIBILITY WHEN INTERVENING IN A HABITAT

Researchers are responsible for reducing disruption and any impact on the natural behaviour of individual animals, including those that are not direct subjects of research, as well as of populations and their surroundings. Certain research and technology-related projects, like those regarding environmental technology and environmental surveillance, may impact on animals and their living conditions, for example as a result of installing radar masts, antennas or other measurement instruments. In such cases, researchers must seek to observe the principle of proportionality (see guideline 3) and minimise the possible negative impact.

RESPONSIBILITY FOR OPENNESS AND SHARING OF DATA AND MATERIAL

Researchers are responsible for ensuring that there is transparency about research findings and facilitating the

sharing of data and material from experiments on animals. Such transparency and sharing are important in order to avoid unnecessary repetition of experiments. Transparency is also important in order to ensure that the public are informed and is part of researchers' responsibility for dissemination. In general, the negative results of experiments on animals should be public knowledge. Disclosing negative results may give other researchers information about which experiments are not worth pursuing, shine a light on unfortunate research design, and help reduce the use of animals in research.

REQUIREMENT OF EXPERTISE ON ANIMALS

Researchers and other parties who handle live animals must have adequately updated and documented expertise on animals. This includes specific knowledge about the biology of the animal species in question, and a willingness and ability to take care of animals properly.

REQUIREMENT OF DUE CARE

There are national laws and rules and international conventions and agreements regarding the use of laboratory animals, and both researchers and research managers must

comply with these. Any person who plans to use animals in experiments must familiarise themselves with the current rules.

COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION ON EXPERIMENTS ON ANIMALS (CPCSEA): GUIDELINES

Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) it Includes various guidelines and sub committees¬Head quarters at Chennai Revived in 1998, under the committed chairpersonship of Meneka Gandhi Formed in 1964 Statutory body formed by the Act of the Indian Parliament under the Prevention of Cruelty to Animals Act, 1960. In 2004 CPCSEA officially accepts the concept of the 4th R "investigators have a moral responsibility to take care of laboratory animals after use" Introduced the credo of 3R principles Introduced a national "Good Laboratory Practice" document National level expert committee to scrutinize and approve the research projects conducted using animals. The committee has 10 experts and 3 official members⎪Animal activists. Regulatory authority's members of the scientific community this committee is

composed of Ministry of Environment and Forests (Animal welfare). For large animals- make its recommendation to SCLA (Sub-Committee on Large Animals) for small animals- give the final approval IAEC scrutinize all project proposals for experimentation on animals. CPCSEA Nominee important link between CPCSEA and IAEC is to monitor animal experiments through ethics committees set up in institutions IAEC. The validity of IAEC is for 3 years. other members: Main nominee, Link Nominee, scientist from outside and socially aware nominee. The Chairman (preferably Head of the Institution / Department) and Member Secretary need to be nominated from the above five members. Scientist in-Charge of animal house facility. a veterinarian involved in care of animals. Two scientists from different biological disciplines, Effective functioning of Institutional animal ethical committee to provide specifications that will enhance animals well being and quality of research.

Permission of Committee for Conducting Experiments approval of animal house facilities for breeding of animals for experiments on animals, registration of establishments main activities Physical separation of animals by species to prevent anxiety and behavioural change Physiologic, psychological

and nutritional stabilization required Quarantine period for small lab animals: one week to one month, large lab animals : up to 6 weeks daily observation of animals adopted quarantine, stabilization and separation: Provided by a veterinarian Permissible number of animals accommodated in each container use of transport containers (cages or crates) of appropriate size during transport, stress avoided by: procurement of animals done from established commercial animal vendors.

Good Laboratory Practices (GLP) for animal facilities is intended to assure quality maintenance and safety of animals used in laboratory studies while conducting biomedical and behavioural research and testing of products. The goal of these Guidelines is to promote the humane care of animals used in biomedical and behavioural research and testing with the basic objective of providing specifications that will enhance animal well being, quality in the pursuit of advancement of biological knowledge that is relevant to humans and animals.

Adequate veterinary care must be provided and is the responsibility of a veterinarian or a person who has training or experience in laboratory animal sciences and medicine. Daily

observation of animals can be accomplished by someone other than a veterinarian; however, a mechanism of direct and frequent communication should be adopted so that timely and accurate information on problems in animal health, behaviour, and well being is conveyed to the attending veterinarian. The veterinarian can also contribute to the establishment of appropriate policies and procedures for ancillary aspects of veterinary care, such as reviewing protocols and proposals, animal husbandry and animal welfare; monitoring occupational health hazards containment, and zoonosis control programs; and supervising animal nutrition and sanitation. Institutional requirements will determine the need for full-time or part-time or consultative veterinary services.

All animals must be acquired lawfully as per the CPCSEA guidelines. A health surveillance program for screening incoming animals should be carried out to assess animal quality. Methods of transportation should also be taken into account (Annexure 4). Each consignment of animals should be inspected for compliance with procurement specifications, and the animals should be quarantined and stabilized according to procedures appropriate for the species and circumstances.

Quarantine is the separation of newly received animals from those already in the facility until the health and possibly the microbial status of the newly received animals have been determined. An effective quarantine minimizes the chance for introduction of pathogens into an established colony. A minimum duration of quarantine for small lab animals is one week and larger animals are 6 weeks (cat, dog, monkey, etc.) Effective quarantine procedures should be used for non-human primates to help limit exposure of humans to zoonotic infections. Regardless of the duration of quarantine, newly received animals should be given a period for physiologic, psychologic and nutritional stabilization before their use. The length of time stabilization will depend on the type and duration of animal transportation, the species involved and the intended use of the animals. Physical separation of animals by species is recommended to prevent interspecies disease transmission and to eliminate anxiety and possible physiological and behavioural changes due to interspecies conflict. Such separation is usually accomplished by housing different species in separate rooms; however, cubicles, laminar-flow units, cages that have filtered air or separate ventilation, and isolators shall be suitable alternatives. In

some instances, it shall be acceptable to house different species in the same room, for example, if two species have a similar pathogen status and are behaviourally compatible.

SURVEILLANCE, DIAGNOSIS, TREATMENT AND CONTROL OF DISEASE

All animals should be observed for signs of illness, injury, or abnormal behaviour by animal house staff. As a rule, this should occur daily, but more-frequent observations might be warranted, such as during postoperative recovery or when animals are ill or have a physical deficit. It is imperative that appropriate methods be in place for disease surveillance and diagnosis (Annexure 1 & 2). Unexpected deaths and signs of illness, distress, or other deviations from normal health condition in animals should be reported promptly to ensure appropriate and timely delivery of veterinary medical care. Animals that show signs of a contagious disease should be isolated from healthy animals in the colony. If an entire room of animals is known or believed to be exposed to an infectious agent (e.g. Mycobacterium tuberculosis in non-human primates), the group should be kept intact and isolated during the process of diagnosis, treatment, and control. Diagnostic clinical laboratory may be made available.

ANIMAL CARE AND TECHNICAL PERSONNEL ENVIRONMENT

Animal care programs require technical and husbandry support. Institutions should employ people trained in laboratory animal science or provide for both formal and on-the-job training to ensure effective implementation of the program.

Personal Hygiene is essential that the animal care staff maintain a high standard of personal cleanliness. Facilities and supplies for meeting this obligation should be provided e.g. showers, change of uniforms, footwear etc. Clothing suitable for use in the animal facility should be supplied and laundered by the institution. A commercial laundering service is acceptable in many situations; however, institutional facilities should be used to decontaminate clothing exposed to potentially hazardous microbial agents or toxic substances. In some circumstances, it is acceptable to use disposable gear such as gloves, masks, head covers, coats, coveralls and shoe covers. Personal should change clothing as often as is necessary to maintain personal hygiene. Outer garments worn in the animal rooms should not be worn outside the animal

facility. Washing and showering facilities appropriate to the program should be available. Personnel should not be permitted to eat, drink, smoke or apply cosmetics in animal rooms. A separate area or room should be made available for these purposes.

Institutions should have policies governing experimentation with hazardous agents. Institutional Biosafety Committee whose members are knowledgeable about hazardous agents are in place in most of the higher-level education, research institutes and in many pharmaceutical industries for safety issues. Since the use of animals in such studies requires special consideration, the procedures and the facilities to be used must be reviewed by both the Institutional Biosafety committee and Institutional Animal Ethics Committee (**IAEC**).

ANIMAL HUSBANDRY

Building materials should be selected to facilitate efficient and hygienic operation of animal facilities. Durable, moisture-proof, fire-resistant, seamless materials are most desirable for interior surfaces including vermin and pest resistance. Corridor(s) should be wide enough to facilitate the movement of personnel as well as equipments and should be

kept clean. Utilities such as water lines drain pipes, and electrical connections should preferably be accessible through service panels or shafts in corridors outside the animal rooms. Animal room doors should be rust, vermin and dust proof. They should fit properly within their frames and provided with an observation window. Door closures may also be provided. Rodent barriers can be provided in the doors of the small animal facilities. Exterior windows are not recommended for small animal facilities. However, where power failures are frequent and backup power is not available, they may be necessary to provide alternate source of light and ventilation. In primate rooms, windows can be provided. Floors should be smooth, moisture proof, non-absorbent, skid-proof, resistant to wear, acid, solvents, adverse effects of detergents and disinfectants. They should be capable of supporting racks, equipment, and stored items without becoming gouged, cracked, or pitted, with minimum number of joints. A continuous moisture-proof membrane might be needed. If sills are installed at the entrance to a room, they should be designed to allow for convenient passage of equipment.

Floor drains are not essential in all rooms used exclusively for housing rodents. Floor in such rooms can be maintained satisfactorily by wet vacuuming or mopping with appropriate disinfectants or cleaning compounds. Where floor drains are used, the floors should be sloped and drain taps kept filled with water or corrosion free mesh. To prevent high humidity, drainage must be adequate to allow rapid removal of water and drying of surfaces.

Walls should be free of cracks, unsealed utility penetrations, or imperfect junctions with doors, ceilings, floors and corners. Surface materials should be capable of withstanding scrubbing with detergents ad disinfectants and the impact of water under high pressure. Separate storage areas should be designed for feed, bedding, cages and materials not in use. Refrigerated storage, separated from other cold storage, is essential for storage of dead animals and animal tissue waste.

An area for sanitizing cages and ancillary equipment is essential with adequate water supply Experimental procedures in small animals should be carried out in a separate area away from the place where animals are housed. For larger animal functional areas for aseptic surgery should include a separate

surgical support area, a preparation area, the operating room or rooms, and an area for intensive care and supportive treatment of animals.

ENVIRONMENT

Air conditioning is an effective means of regulating these environmental parameters for laboratory animals. Temperature and humidity control prevents variations due to changing climatic conditions or differences in the number and kind of room occupants. Ideally, capability should be provided to allow variations within the range of approximately 18 to 29°C (64.4 to 84.2øF), which includes the temperature ranges usually recommended for common laboratory animals. The relative humidity should be controllable within the range of 30% to 70% throughout the year. For larger animals a comfortable zone (18 to 37°C) should be maintained during extreme summer by appropriate methods for cooling. In renovating existing or in building new animal facilities, consideration should be given to the ventilation of the animals' primary enclosures.

Heating, ventilating, and air-conditioning systems should be designed so that operation can be continued with a standby

system. The animal facility and human occupancy areas should be ventilated separately. The electrical system should be safe and provide appropriate lighting and a sufficient number of power outlets. It suggested that a lighting system be installed that provides adequate illumination while people are working in the animal rooms and a lowered intensity of light for the animals. Fluorescent lights are efficient and available in a variety of acceptable fixtures. A time-controlled lighting system should be used to ensure a regular diurnal lighting cycle wherever required. Emergency power should be available in the event of power failure. The facility should be provided with noise free environment. Noise control is an important consideration in designing an animal facility. Concrete walls are more effective than metal or plaster walls containing noise because their density reduces sound transmission. The caging or housing system is one of the most important elements in the physical and social environment of research animals. It should be designed carefully to facilitate animal well being, meet research requirements, and minimize experimental variables. The housing system should: Provide space that is adequate, permit freedom of movement and normal postural adjustments, and have a resting place

appropriate to the species; (Annexure 3) Provide a comfortable environment Provide an escape proof enclosure that confines animal safety Provide easy access to food and water; Provide adequate ventilation Meet the biological needs of the animals, e.g., maintenance of body temperature, urination, defecation, and reproduction; Keep the animals dry and clean, consistent with species requirements ; Facilitate research while maintaining good health of the animals.

They should be constructed of sturdy, durable materials and designed to minimize cross-infection between adjoining units. Polypropylene, polycarbonate and stainless steel cages should be used to house small lab animals, Monkeys should be housed in cages made of steel or painted mild steel and for other animals such as sheep, horses, the details can be seen in Annexure 3.

To simplify servicing and sanitation, cages should have smooth, impervious surfaces that neither attract nor retain dirt and a minimum number of ledges, angles, and corners in which dirt or water can accumulate. The design should allow inspection of cage occupants without disturbing them. Feeding and watering devices should be easily accessible for filling, changing, cleaning and servicing. Cages, runs and pens

must be kept in good condition to prevent injuries to animals, promote physical comfort, and facilitate sanitation and servicing. Particular attention must be given to eliminate sharp edges and broken wires, keeping cage floors in good condition. When animals are maintained in outdoor runs, pens, or other large enclosures, there must be protection from extremes in temperature or other harsh whether conditions and adequate protective and escape mechanism for submissive animals, as in case of monkeys by way of an indoor portion of a run, should be provided. Shelter should be accessible to all animals, have sufficient ventilation, and be designed to prevent build up of waste materials and excessive moisture. Houses, dens, boxes, shelves, perches, and other furnishings should be constructed in a manner and made of materials that allow cleaning or replacement in accordance with generally accepted husbandry practices when the furnishings are soiled or worn-out. Ground-level surfaces of outdoor housing facilities can be covered with absorbent bedding, sand, gravel, grass, or similar material that can be removed or replaced when that is needed to ensure appropriate sanitation. Build up of animal waste and stagnant water should be avoided by, for example, using contoured or drained surface. Other surfaces

should be able to withstand the elements and be easily maintained. The social environment includes all interactions among individuals of a group or among those able to communicate. The effects of social environment on caged animals vary with the species and experience of the animals. In selecting a suitable social environment, attention should be given to whether the animals are naturally territorial or communal and whether they will be housed singly or in groups.

When appropriate, group housing should be considered for communal animals. In grouping animals, it is important to take into account population density and ability to disperse; initial familiarity among animals; and age, sex, and social rank. Population density can affect reproduction, metabolism, immune responses, and behaviour. Group composition should be held as stable as possible, particularly for canine, non-human primates, and other highly social mammals, because mixing of groups or introducing new members can alter behavioural and physiological functions. Non-human primates should have a run for free ranging activities:

Activity provision should be made for animals with specialized locomotors pattern to express these patterns,

especially when the animals are held for long periods. For e.g., ropes, bars, and perches are appropriate for branching non-human primates. Cages are often used for short-term (up to 3 months) housing of dogs and may be necessary for postsurgical care, isolation of sick dogs, and metabolic studies. Pens, runs, or other out-of-cage space provide more opportunity for exercise, and their use is encouraged when holding dogs for long periods.

FOOD

Animals should be fed palatable, non-contaminated, and nutritionally adequate food daily unless the experimental protocol requires otherwise. Feeders should allow easy access to food, while avoiding contamination by urine and faeces. Food should be available in a mounts sufficient to ensure normal growth in immature animals and maintenance of normal body weight, reproduction, and lactation in adults. Food should contain adequate nutrition, including formulation and preparation; freedom from chemical and microbial contaminants; bio-availability of nutrients should be at par with the nutritional requirement of the animal. Laboratory animal diets should not be manufactured or stored in facilities

used for farm feeds or any products containing additives such as rodenticides, insecticides, hormones, antibiotics, fumigants, or other potential toxicants. Areas in which diets are processed or stored should be kept clean and enclosed to prevent entry of insects or other animals. Precautions should be taken if perishable items such as meats, fruits, and vegetables are fed, because these are potential sources of biological and

Chemical contamination and can also lead to variation in the amount of nutrients consumed. Diet should be free from heavy metals (e.g., lead, arsenic, cadmium, nickel, mercury), naturally occurring toxins and other contaminants. Exposure to extremes in relative humidity, unsanitary conditions, light, oxygen, and insects hasten the deterioration of food. Meats, fruits, vegetables, and other perishable items should be refrigerated if required to be stored. Unused, open food should be stored in vermin – proof condition to minimize contamination and to avoid potential spread of disease agents. Food hoppers should not be transferred from room to room unless cleaned and sanitized. The animal feed should contain moisture, crude fibre, crude protein, essential vitamins,

minerals crude fat and carbohydrate for providing appropriate nutrition.

BEDDING

Bedding should be absorbent, free of toxic chemicals or other substances that could injure animals or personnel, and of a type not readily eaten by animals. Bedding should be used in amounts sufficient to keep animals dry between cage changes without coming into contact with watering tubes. Bedding should be removed and replaced with fresh materials as often as necessary to keep the animals clean and dry. The frequency is a matter of professional judgement of the animal care personnel in consultation with the investigation depending on the number of animals and size of cages. The desirable criteria for rodent contact bedding is ammonia binding, sterillizable, deleterious products not formed as a result of sterilization, easily stored, non – desiccating to the animal, uncontaminated, unlikely to be chewed or mouthed, non – toxic, non – malodorous, nestable, disposable by incineration, readily available, remains chemically stable during use, manifests batch uniformity, optimizes normal animal behaviour, non – deleterious to cage – washers, non – injurious and non – hazardous to personnel, non – nutritious

and non – palatable. Nesting materials for newly delivered pups wherever can be provided (e.g. Paper, tissue paper, cotton etc.).

WATER

Ordinarily animals should have continuous access to fresh, potable, uncontaminated drinking water, according to their particular requirements. Periodic monitoring of microbial contamination in water is necessary. 14 Watering devices, such as drinking tubes and automatic waterers if used should be examined routinely to ensure their proper operation. Sometimes it is necessary to train animals to use automatic watering devices. It is better to replace water bottles than to refill them, however, if bottles are refilled, care should be taken that each bottle is replaced on the cage which it was removed.

SANITATION AND CLEANLINESS

Sanitation is essential in an animal facility. Animal rooms, corridors, storage spaces, and other areas should be cleaned with appropriate detergents and disinfectants as often as necessary to keep them free of dirt, debris , and harmful contamination. Cleaning utensils, such as mops, pails, and brooms, should not be transported between animal rooms.

Where animal waste is removed by hosting or flushing, this should be done at least twice a day. Animals should be kept dry during such procedures. For larger animals, such as dogs, cats, and non – human primates, soiled litter material should be removed twice daily. Cages should be sanitized before animals are placed in them. Animal cages, racks, and accessory equipments, such as feeders and watering devices, should be washed and sanitized frequently to keep them clean and contamination free. Ordinarily this can be achieved by washing solid bottom rodent cages and accessories once or twice a week and cages, racks at least monthly. Wire – bottom rodent cages for all other animals should be washed at least every 2 weeks. It is good practice to have extra cages available at all times so that a systematic cage-washing schedule can be maintained. Cages can be disinfected by rinsing at a temperature of 82.2C (180 F) or higher for a period long enough to ensure the destruction of vegetative pathogenic organisms. Disinfection can also be accomplished with appropriate chemicals; equipments should be rinsed free of chemicals prior to use. Periodic microbiologic monitoring is useful to determine the efficacy of disinfection or sterilization procedures. Rabbits and some rodents, such as

guinea pigs and hamsters, produce urine with high concentration of proteins and minerals. Minerals and organic compounds in the urine from these animals often adhere to cage surfaces and necessitate treatment with acid solutions before washing. Water bottles, sipper tubes, stoppers, and other watering equipment should be washed and then sanitized by rinsing with water of at least 82.2C (180F) or appropriated chemicals agents (e.g. hyperchlorite) to destroy pathogenic organisms, if bottles are washed by hand, powered rotating brushes at the washing sink are useful, and provision should be made for dipping or soaking the water bottles in detergents and disinfectant solutions. A two – compartment sink or tub is adequate for this purpose. Some means for sterilizing equipments and supplies, such as an autoclave or gas sterilizer, is essential when pathogenic organisms are present. Routine sterilization of cages, food and bedding is not considered essential if care is taken to use clean materials from reliable sources. Where hazardous biological, chemical, or physical agents are used, a system of equipment monitoring might be appropriate. Deodorizers or chemical agents other than germicidal should not be used to mask animal odors. Such products are not a substitute for good sanitation.

ASSESSING THE EFFECTIVENESS OF SANITATION

Monitoring of sanitation practices should be appropriate to the process and materials being cleaned; it can include visual inspection of the materials, monitoring of water temperatures, or microbiologic monitoring. The intensity of animal odors, particularly that of ammonia, should not be used as the sole means of assessing the effectiveness of the sanitation program. A decision to alter the frequency of cage – bedding changes or cage – washing should be based on such factors as the concentration of ammonia, the appearance of the cage, the condition of the bedding and the number and size of animals housed in the cage.

WASTE DISPOSAL

Wastes should be removed regularly and frequently. All waste should be collected and disposed of in a safe and sanitary manner. The most preferred method of waste disposal is incineration. Incinerators should be in compliance with all central, state, and local regulations. Waste cans containing animal tissues, carcasses, and hazardous wastes should be lined with leak – proof, disposable liners. If wastes must be stored before removal, the waste storage area should be separated from other storage facilities and free of flies,

cockroaches, rodents, and other vermin. Cold storage might be necessary to prevent decomposition of biological wastes. Hazardous wastes should be rendered safe by sterilization, contamination, or other appropriate means before they are removed from an animal facility for disposal.

PEST CONTROL

Programs designed to prevent, control, or eliminate the presence of or infestations by pests are essential in an animal environment. Animals should be cared for by qualified personnel every day, including weekends and holidays, to safeguards their well – being including emergency veterinary care. In the event of an emergency, institutional security personnel and fire or police officials should be able to reach people responsible for the animals. That can be enhanced by prominently posting emergency procedures, names, or telephone numbers in animals facilities or by placing them in the security department or telephone center. A disaster plan that takes into account both personnel and animals should be prepared as part of the overall safety plan for the animal facility.

RECORD KEEPING

The Animal House should maintain following records: Animal House plans, which includes typical floor plan, all fixtures etc. Animal House staff record – both technical and non – technical Health record of staff/ animals All SOPs relevant to the animals Breeding, stock, purchase and sales records Minutes of institute Animals Ethics Committee Meetings Records of experiments conducted with the number of animals used. Death Record Clinical record of sick animals, training record of staff involved in animal activities, water analysis report Standard Operating Procedures (SOPs) / Guidelines the institute shall maintain SOPs describing procedures / methods adapted with regard to Animal Husbandry, maintenance, breeding, animal house microbial analysis and experimentation records.

PERSONNEL AND TRAINING

The selection of animal facility staff, particularly the staff working in animal rooms or involved in transportation, is a critical component in the management of an animal facility. The staff must be provided with all required protective clothing (masks, aprons, gloves, gumboots, other footwears etc.) while working in animal rooms. Facilities should be provided for change over with lockers, wash basin, toilets and

bathrooms to maintain personal hygiene. It is also important a regular medical check-up is arranged for the workers to ensure that they have not picked up any zoonotic infection and also that they are not acting as a source of transmission of infection to the animals. The animal house in-charge should ensure that persons working in animal house don't eat, drink, smoke in animal room and have all required vaccination, particularly against tetanus and other zoonotic diseases. Initial in-house training of staff at all levels is essential. A few weeks must be spent on the training of the newly recruited staff, teaching them the animal handling techniques, cleaning of cages and importance of hygiene, disinfection and sterilization. They should also be made familiar with the activities of normal healthy and sick animals so that they are able to spot the sick animal during their daily routine check up for cages .

TRANSPORT OF LABORATORY ANIMALS

The transport of animals from one place to another is very important and must be undertaken with care. The main considerations for transport of animals are, the mode of transport, the containers, the animal density in cages, food and water during transit, protection from transit infections, injuries

and stress. The mode of transport of animals depends on the distance, seasonal and climatic conditions and the species of animals. Animals can be transported by road, rail or air taking into consideration of above factors. In any case the transport stress should be avoided and the containers should be of an appropriate size so as to enable these animals to have a comfortable, free movement and protection from possible injuries. The food and water should be provided in suitable containers or in suitable form so as to ensure that they get adequate food and more particularly water during transit. The transport containers (cages or crates) should be of appropriate size and only a permissible number of animals should only be accommodated in each container to avoid overcrowding and infighting (Annexure 4) .

TRANSGENIC ANIMALS

Transgenic animals are those animals, into whose germ line foreign gene(s) have been engineered, whereas knockout animals are those whose specific gene(s) have been disrupted leading to loss of function. These animals can be bred to establish transgenic animal strains. Transgenic animals are used to study the biological functions of specific genes, to develop animal models for diseases of humans or animals, to

produce therapeutic products, vaccines and for biological screening, etc. These can be either developed in the laboratory or produced for R&D purpose from registered scientific/academic institutions or commercial firms, and generally from abroad with approval from appropriate authorities.

MAINTENANCE

Housing, feeding, ventilation, lighting, sanitation and routine management practices for such animals are similar to those for the other animals of the species as given in guidelines. However, special care has to be taken with transgenic/gene knockout animals where the animals can become susceptible to diseases where special conditions of maintenance are required due to the altered metabolic activities. The transgenic and knockout animals carry additional genes or lack genes compared to the wild population. To avoid the spread of the genes in wild population care should be taken to ensure that these are not inadvertently released in the wild to prevent cross breeding with other animals. The transgenic and knockout animals should be maintained in clean room environment or in animal isolators. DISPOSAL The transgenic and knockout animals

should be first enthanized and then disposed off as prescribed elsewhere in the guidelines. A record of disposal and the manner of disposal should be kept as a matter of routine.

Annexure – 1

HAEMATOLOGICAL DATA OF COMMONLY USED LABORATORY ANIMALS

	Mouse	Rat	Hamster	G.pig	Rabbit	Cat	Dog (Beagle)	Monkey (Rhesus)
RBC(x10⁶/mm³)	7 – 12.5	7 –10	6 – 10	4.5 – 7	4 –7	5 –10	5.5 – 8.5	3.56-6.96
CV(%)	39 – 49	36 – 18	36 – 55	37 – 48	36 – 48	30 – 15	37 – 55	26 – 48
lb(g/dl)	10.2 – 16.6	11 – 18	10 – 16	11 – 15	10 – 15.5	8 – 15	12 – 18	8.8 – 16.5
BBC(X10³/mm³)	6 –15	6 – 17	3 – 11	7 – 18	9 – 11	5.5 – 19.5	6 – 17	2.5 – 26.7
Neutrophlis(%)	10 – 40	9 – 34	10 – 42	28 – 44	20 – 75*	35 – 75	60 – 70	5 – 88
Lymphocytes(%)	55 – 95	65 – 85	50 - 95	39 – 72	30 – 85	20 – 55	12 – 30	8 – 92
Eosinophils(%)	0 – 4	0 – 6	0 – 4.5	1 – 5	0 – 4	2 –12	2 – 10	0 – 14
Monocytes(%)	0.1 – 3.5	0 – 5	0 – 3	3 – 12	1 – 4	1 – 4	3 – 10	0 – 11
Basophils(%)	0 – 0.3	0 – 1.5	0 – 1	0 – 3	2 – 7	rare	rare	0 – 6
Platelets(X10³/mm³)	160 –410	500-1300	200-500	250-850	250-656	300-700	200-900	109-597

* Neutrophils often resemble eosinophils due to granules
(NOTE- The range of normal values may vary in a laboratory using specific species, strain or substrain of these animals. Any major deviation on higher or lower side may be considered as a condition and not a disease per se)

Annexure – 2

BIOCHEMICAL DATA OF COMMONLY USED LABORATORY ANIMALS

	Mouse	Rat	Hamster	G.pig	Rabbit	Cat	Dog	Monkey
Protein (g/dl)	3.5 – 7.2	5.6 –7.6	4.5 –7.5	4.6 – 6.2	5.4 – 7.5	6 – 7.5	6 – 7.5	4.9 – 9.3
n (g/dl)	2.5 – 4.8	2.8 – 4.8	2.6 – 4.1	2.1 – 3.9	2.7 – 4.6	2.5 – 4.0	3 – 4	2.8 – 5.2
n (g/dl)	0.6	1.8 – 3	2.7 – 4.2	1.7 – 2.6	1.5 – 2.8	2.5 – 3.8	2.4 –3.7	1.2 – 5.8
c (mg/dl)	62 – 175	50 – 135	60 – 150	60 – 125	75 – 150	81 – 108	54 – 99	46 – 178
Urea nitrogen	12 – 28	15 – 21	12 – 25	9 – 31.5	17 – 23.5	3.5 – 8.0	3.5 – 7.5	8 – 40
nine (mg/dl)	0.3 – 1	0.2 – 0.8	0.91 – 0.99	0.6 – 2.2	0.8 – 1.8	<180 (n mol/l)	<120 (n mol/l)	0.1 – 2.8
bilirubin (mg/dl)	0.1 – 0.9	0.2 – 0.55	0.25 – 0.6	0.3 – 0.9	0.25 – 0.74	<4.0 (m mol/l)	<5.0 (n mol/l)	0.1 – 2
sterol (mg/dl)	26 –82	40 – 130	25 – 135	20 – 43	35 – 53	2 – 4 (m mol/l)	4 – 7 (m mol/l)	108 – 263

The range of normal values may vary in a laboratory using specific species, strain or sub strain of these animals. Any major deviation on higher or side may be considered as a condition and not a disease per se).

Annexure – 3A

Minimum floor area recommended for laboratory animals (based on their weight/size and behavioral activity)

Animal	Weight In grams	Floor area/ Animal (cm^2)	Cage height (cm^2)
Mice	<10	38.7	
	upto15	1.6	
	upto25	7.4	
	>25	96.7	12
Rats	<100	109.6	
	upto200	148.3	
	upto300	187.0	
	upto400	258.0	
	upto500	387.0	
	>500	>=451.5	14
Hamsters/Gerbils/ Mastomys/Cotton rats	>60	64.5	
	upto 80	83.8	
	upto100	103.2	
	>100	122.5	12
Guinea pigs	<350	387.0	
	>350	>=651.4	18

		Floor area (Sq.ft)	Floor area (Sq.meter)	Height (inches)
Rabbits	<2000	1.5	0.135	14
	Upto 4000	3.0	0.27	14
	Upto 5400	4.0	0.36	14
	>5400	5.0	0.45	14
	Mother with kids	4.5	0.40	14

Annexure – 3B

Example for calculating the number of Mice to be kept per cage, based on floor area recommended for animal according to their weight (size) and size of the cage

Recommended floor Area per animal (Cm^2)	38.7	51.6	77.4	96.7
Weight of animals (Grams)	<10	upto15	upto25	>25
Example I Cage Size 24 x 14 cm i.e. floor area of 336 cm^2 maximum number of animals	8	7	4	3*
Example II Cage Size 32.5 x 21 cm i.e floor area of 682 cm^2 maximum number of animals	17	14	9	7

Note: Cage size, specially length and breadth may vary. However, the minimum Floor area and cage height recommended for group housing has to be taken into consideration. Thus, the number of animals which can be housed in a particular cage (of different sizes) can be calculated on the basis of a) floor area of the cage, b) recommended floor area per animal and c) weight of animal.

* In case of breeding pairs, three adults (i.e. 1 male and 2 females) along with the pups from delivery up to weaning stage are permitted.

ANNEXURE – 4

REQUIREMENTS FOR TRANSPORT OF LABORATORY ANIMALS BY ROAD, RAIL AND AIR

	Mouse	Rat	Hamster	G. pig	Rabbit	Cat	Dog	Monkey
Maximum No. of Animals per cage	25	25	25	12	2	1 or 2	1 or 2	1
Material Used in Transport box	Metal Cardboard, Synthetic material	Metal Cardboard, Synthetic material	Metal Cardboard, Synthetic material	Metal Cardboard, Synthetic material	Metal Cardboard, Synthetic material	Metal	Metal	Bamboo / wood / metal
Space per Animal (Cm. Sq.)	20 – 25	80 – 100	80 – 100	160 – 180	1000 – 1200	1400 – 1500	3000	2000 – 4000
Minimum height of box (cm)	12	14	12	15	30	40	50	48

ANAESTHESIA AND EUTHANASIA

A fundamental responsibility of individuals that use animals in research, teaching or testing is to anticipate and eliminate or minimize any potential that procedures may cause animal pain, distress, or discomfort. Although animals that are in pain may not behave like humans, (e.g., pain in animals may be accompanied by immobility and silence, in contrast to the groans and cries of human patients), it is assumed that procedures that cause pain in humans cause pain in animals. The presence of pain in animals can be recognized by alterations in animal behavior (e.g., reduced activity,

reduced grooming, hunched- up posture, altered gait, changes in temperament, vocalizations, reduced food and water intake, reduced urinary and fecal output), and in physiological variables, (e.g., reduced depth of respiration, increased heart rate, and reduced hydration status). Animal pain, distress, and discomfort can produce a range of undesirable physiological changes, which may radically alter measured responses to experimental stimuli, as well as the rate of recovery from surgical procedures; hence, its avoidance and alleviation are in the best interest of both the animal and researcher.

Reducing post-procedural/post-operative pain, distress, and discomfort is accomplished by good nursing care, (e.g., keeping the animal warm, clean, dry and well padded), and by the administration of analgesic drugs. In addition to the avoidance and alleviation of pain and discomfort, adequate post-procedural /postoperative animal care also includes efforts to prevent and/or treat post-anaesthetic complications, (e.g., aspiration, hypostatic pneumonia, cardiovascular and respiratory depression, dehydration, and infection). The prevention or minimization of animal pain, distress, or discomfort by the proper use of tranquilizers, anaesthetics, and analgesics is scientifically and ethically essential to the

humane care, use, and treatment of research animals. The use of these classes of drugs must effectively prevent or minimize suffering and discomfort of animals during potentially painful procedures. The use of these three classes of drugs must be in accordance with currently accepted veterinary medical practice and produce in the subject animal an appropriate level of tranquilization, anaesthesia, or analgesia consistent with the protocol or design of the experiment.

ANAESTHESIA

The word anaesthesia has been derived from Greek word that means “without perception of insensibility”, is the act of providing sensation-free relief from pain or pain-producing procedures. It must be performed by a person with knowledge of and familiarity with the drugs to be used in the animal species under consideration. The following factors are affecting the activity of anaesthetics Many factors can affect the activity of anaesthetics. The species, strain, sex, age, nutritional and disease status, relative body size, disposition/demeanour, presence of concurrent pain or distress, or medication are known to cause a variation in the

amount of drug needed to produce a desired effect in an individual animal.

A suitable, effective and free of complications anesthetic protocol is very important in experimental studies on animal models since it could bias the outcome of a trial. To date there is no universally accepted protocol for induction, maintenance and recovery from anaesthesia. The endotracheal intubation with the use of inhalation anaesthesia is used very especially in the form of large size laboratory animals, because it is a secure and easy control mode. However, it is not common for small laboratory animals because of the high technical skills required. Laboratory animals are sometimes used in experimental clinical studies such as pre-marketing of a drug or a medical-surgical device or in regenerative medicine and surgery. The anaesthesia protocols influence the survival of laboratory animals and can also greatly affect the experimental data results.

Anaesthetic agents which are most frequently used (Annexure 5) (ketamine, propofol, isoflurane/halothane) to induce and maintain anaesthesia in laboratory animals influence the carbon dioxide tension in arterial blood (PaCO2) or exhaled (as ETCO2) and can cause respiratory acidosis.

They must therefore be carefully monitored all the vital parameters of the animal and restoring fluid and electrolyte balance in the event that it were altered.

CLASSIFICATION OF ANESTHETICS

Injectables – Effects of these agents cannot be reversed quickly. The drug must be metabolized, excreted, or counteracted by another drug to terminate anaesthetic action. Examples include sodium pentobarbital, ketamine/xylazine cocktail. Some are controlled substances. Logs must be kept of usage and are subject to audit by the DEA (Drug Enforcement Agency).

Inhalants – Effects of these agents can be reversed quickly. The agent is eliminated when the administration is discontinued as the animal exhales. The most common inhalant is isoflurane.

Dissociatives – Agents that depress the central nervous system and produce a state of catalepsy (ketamine). These are most effective when combined with tranquilizers and sedatives (e.g., xylazine, diazepam).

EUTHANASIA

The term euthanasia is derived from the Greek terms eu meaning good and than atos meaning death. A “good death”

would be one that occurs with minimal pain and distress. In the context. Euthanasia is the act of inducing humane death in an animal. “Sacrificing the experimental animal after use by gentle procedure causing minimum of physical and mental suffering is called euthanasia (Painless killing). The primary criteria for euthanasia in terms of animal welfare are that the method be painless, achieve rapid unconsciousness and death, require minimum restraint, avoid excitement, is appropriate for the age, species, and health of the animal, must minimize fear and psychological stress in the animal, be reliable, reproducible, irreversible, simple to administer (in small doses if possible) and safe for the operator, and, so far as possible, be aesthetically acceptable for the operator.

METHODS OF EUTHANASIA

Barbiturate overdose, CO_2 asphyxiation Must always be followed by a physical means to ensure death, such as cervical dislocation or pneumothorax. Use CO_2 from tanks, not from dry ice, Cervical dislocation Must be preceded by anaesthesia or CO_2 asphyxiation unless scientifically justified in the protocol. If cervical dislocation alone is done, it must be performed by well- trained personnel and Decapitation Must be preceded by anesthesia or CO_2 asphyxiation unless

scientifically justified in the protocol (Annexure 6). If at any stage during the experiment the investigator feels that he has to abandon the experiment or he has inflicted irrepairable injury, the animal should be sacrificed. Neuromuscular blocking agents must not be used without adequate general anaesthesia (Annexure 5). In the event of a decision to sacrifice an animal on termination of an experiment or otherwise an approved method of euthanasia should be adopted (Annexure 6) and the investigator must ensure that the animal is clinically dead before it is sent for disposal. The data about large animals, which have been euthanised, should be maintained. Anaesthesia Unless contrary to the achievement of the results of study, sedatives, analgesics and anaesthetics should be used to control pain or distress under experiment. Anaesthetic agents generally affect cardiovascular, respiratory and thermoregulatory mechanism in addition to central nervous system. Before using actual anaesthetics the animals is prepared for anaesthesia by over night fasting and using pre-anaesthetics, which block parasympathetic stimulation of cardio-pulmonary system and reduce salivary secretion. Atropine is most commonly used anti-cholinergic agent. Local or general anaesthesia may be

used, depending on the type of surgical procedure. Local anaesthetics are used to block the nerve supply to a limited area and are used only for minor and rapid procedures. This should be carried out under expert supervision for regional infiltration of surgical site, nerve blocks and for epidural and spinal anaesthesia. A number of general anaesthetic agents are used in the form of inhalants. General anaesthetics are also used in the form of intravenous or intra-muscular injections such as barbiturates. Species characteristics and variation must be kept in mind while using an anaesthetic. Side-effects such as excessive salivation, convulsions, excitement and disorientation should be suitably prevented and controlled. The animal should remain under veterinary care till it completely recovers from anaesthesia and postoperative stress. Euthanasia is resorted to events where an animal is required to be sacrificed on termination of an experiment or otherwise for ethical reasons. The procedure should be carried out quickly and painlessly in an atmosphere free from fear or anxiety. For accepting a euthanasia method as humane it should have an initial depressive action on the central nervous system for immediate insensitivity to pain. The choice of a

method will depend on the nature of study, the species of animal to be killed (Annexure 6).

The method should in all cases meet the following requirements: Death, without causing anxiety, pain or distress with minimum time lag phase. (b) Minimum physiological and psychological disturbances. (c) Compatibility with the purpose of study and minimum emotional effect on the operator. (d) Location should be separate from animal rooms and free from environmental contaminants. Tranquilizers have to be administered to larger species such as monkeys, dogs and cats before a euthanasia procedure.

ANNEXURE – 5

COMMONLY USED ANAESTHETIC DRUGS FOR LABORATORY ANIMALS

Drugs (mg/kg)	Mouse	Rat	Hamster	Guinea pig	Rabbit	Cat	Dog	Monkey
KTEAMINE Hel	22 – 24 i/m	22 – 24 i/m	-	22 – 24	22 – 24	30 i/m	30 i/m	15 – 40
PENTOBAR -BITONE SODIUM	35 i/v 50 i/p	25 i/v 50 i/p	35 i/v -	30 i/v 40 i/p	30 i/v 40 i/p	25 i/v -	20 – 30 i/v -	35 i/v -
THIOPENT-ONE SODIUM	25 i/v 50 i/p	20 i/v 40 i/p	20 i/v 40 i/p	20 i/v 55 i/p	20 i/v	25 i/v	25 i/v	25 i/v 60 i/p
URETHANE	-	0.75 i/p	-	1.5 i/p	1.0 i/p, i/v	1.25 i/v 1.50 i/p	1.00 i/v	1.0 i/v

ATROPINE: Dose 0.02 – 0.05 mg/kg for all species by s/c or i/m or i/v routes used to reduce salivary and bronchial secretions and protect heart from vagal inhibition, given prior to anaesthesia.

i/m = intramuscular, i/v = intravenous, i/p = intraperitoneal, s/c = subcutaneous

ANNEXURE – 6

EUTHANASIA OF LABORATORY ANIMALS

(A – Methods Acceptable for species of animals indicated NR – Not Recommended)

Species	Mouse	Rat	Hamster	Guinea pig	Rabbit	Cat	Dog	Monkey
a) **PHYSICAL METHODS**								
Electrocution	NR	NR	NR	NR	NR	NR	NR	NR
Exsanguination	NR	A	A	A	A	A	NR	NR
Decapitation (for analysis of stress)	A	A	A	NR	NR	NR	NR	NR
Cervical dislocation	A	A	A	NR	NR	NR	NR	NR
b) **INHALATION OF GASES**								
Carbon Monoxide	A	A	A	A	A	A	A	A
Carbon Dioxide	A	A	A	A	A	A	NR	NR
Carbon Dioxide plus Chloroform	A	A	A	A	A	A	NR	NR
Helothane	A	A	A	A	A	A	A	A
c) **DRUG ADMINISTRATION**								
Barbiturate Overdose (route)	A(IP)	A(IP)	A(IP)	A(IP)	A(IV,IP)	A(IV,IP)	A(IV,IP)	A(IV,IP)
Chloral hydrate Overdose (route)	NR	NR	NR	NR	A(IV)	A(IV)	A(IV)	A(IV)
Ketamine Overdose (route)	A(IM/P)	A(IM/IP)	A(IM/IP)	A(IM/IP)	A(IM/IV)	A(IM/IV)	A(IM/IV)	A(IM/IV)
Sodium Pentothol [Overdose (route)]	IP	IP	IP	IP	IV	IV	IV	IV

Methods Not Acceptable for any species of animals
a) PHYSICAL METHODS:
(i) Decompression (ii) Stunning
b) INHALATION OF GASES
(i) Nitrogen Flushing (ii) Argon Flushing
c) DRUG ADMINISTRATION
(i) Curariform drugs (ii) Nicotine Sulphate (iii) Magnesium Sulphate (iv) Potassium Chloride (v) Strychnine (vi) Paraquat (vii) Dichlorvos (vii) Air Embosium

IP = intraperitioneal
IV = Intravenous
IM = Intramuscular

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CHAPTER–V

Composition of institutional Ethical Committee (IEC), General ethical issues. Specific principles for chemical evaluation of drugs and human genetics research, Ethics in food and drug safety. Environmental release of microorganisms and genetically engineered organisms. Ethical issues in human gene therapy and human cloning.

COMPOSITION OF INSTITUTIONAL ETHICAL COMMITTEE (IEC):

- INTRODUCTION

Institutional Ethics Committee (IEC), also referred to as, Institutional Review Board (IRB), Ethics Review Board (ERB) and Research Ethics Board (REB) in many countries and situations, serves as an independent representative and competent body to review, evaluate and decide on the scientific and ethical merits of research proposals. The primary purpose of this committee is to protect the rights, safety and wellbeing of human subjects who participate in a research project. The Ethics Committees are entrusted with the initial review of the proposed research protocols prior to initiation of the projects and also have a continuing responsibility of regular monitoring of the approved programmers till the same are completed. Such an ongoing review is in accordance with the Declaration of Helsinki and all the international guidelines for biomedical research.

BASIC RESPONSIBILITIES

The basic responsibility of an Institutional Ethics Committee (IEC) is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. IECs should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through appropriate
Scientific Review Committee.

Small institutions could form alliance with other IECs or approach registered IEC. Large institutions/Universities with large number of proposals can have more than one suitably constituted IECs for different research areas for which large number of research proposals are submitted. The main IEC may review proposals submitted by undergraduate or post-graduate students or if necessary, a committee may be separately constituted for the purpose, which will review proposals in the same manner as described above.

The responsibilities of an IEC can be defined as follows:-

• To protect the dignity, rights and wellbeing of the potential research participants.

• To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.

• To assist in the development and the education of a research community responsive to local health care requirements.

➢ COMPOSITION

The IECs should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC. The number of persons in an ethics committee should be kept fairly small (8 - 12 members). It is generally accepted that a minimum of five persons is required to form the quorum without which a decision regarding the research should not be taken. The members should be a mix of medical/ non-medical, scientific and non-scientific persons including lay persons to represent the differed points of view.

The composition may be as follows: -

1. Chairperson
2. One - two persons from basic medical science area
3. One - two clinicians from various Institutes
4. One legal expert or retired judge

5. One social scientist / representative of non-governmental voluntary agency

6. One philosopher / ethicist /theologian

7. One lay person from the community

8. Member Secretary

As per revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005, the ethics committee approving drug trials should have in the quorum at least one representative from the following groups:

1. One basic medical scientist (preferably one pharmacologist).

2. One clinician

3. One legal expert or retired judge

4. One social scientist/ representative of non-governmental organization / philosopher / ethicist / theologian or a similar person

5. One lay person from the community.

The Ethics Committee (EC) can have as its members, individuals from other institutions or communities with adequate representation of age and gender to safeguard the interests and welfare of all sections of the community/society.

GENERAL ETHICAL ISSUES

Research is the pillar of knowledge, and it constitutes an integral part of progress. In the fast-expanding field of research, this has improved the quality and quantity of life. Historically, researchers have been in the privileged position to carry out research, they were able to control "life and death" and have free access to their confidential information. This has resulted in some researchers conducting unethical researches. In the light of these ethical controversies few ethical issues to be studied are as follows:

1) Study design and ethics approval
2) Data analysis
3) Authorship
4) Conflicts of interest
5) Redundant publication and plagiarism

1. Study design and ethics approval: "Good research should be well adjusted, well-planned, appropriately designed, and ethically approved". It is essential to obtain approval from the Institutional Ethics Committee (IEC), of the respective organisations for studies involving people, medical records, and anonymised human tissues. The research proposal should

discuss potential ethical issues pertaining to the research and pay special attention to vulnerable subjects to avoid breech of ethical codes.

2. Data analysis: It is the responsibility of the researcher to collect and analyze the data appropriately. Although inappropriate analysis does not necessarily amount to misconduct, intentional omission of result may cause misinterpretation and mislead the readers. Fabrication and falsification of data do constitute misconduct. To ensure appropriate data analysis, all sources and methods used to obtain and analyze data should be fully disclosed. Failure to do so may lead the readers to misinterpret the results without considering possibility of the study being underpowered

3. Authorship: There is no universally agreed definition of authorship and is generally agreed that an author should have made substantial contribution to the intellectual content, including conceptualizing and designing the study, acquiring, analyzing and interpreting the data. The author should also take responsibility to certify that the manuscript represents valid work and take public responsibility for the work. Finally, an author is usually involved in drafting or revising

the manuscript, as well as approving the submitted manuscript.

4. Conflicts of interest: This happens when researchers have interests that are not fully apparent and that may influence their judgments on what is published. These conflicts include personal, commercial, political, academic or financial interest. Financial interests may include employment, research funding, stock or share ownership, payment for lecture or travel, consultancies and company support for staff. This issue is especially pertinent in biomedical research where a substantial number of clinical trials are funded by pharmaceutical company. The researchers need to take extra effort to ensure that their conflicts of interest do not influence the methodology and outcome of the research. It would be useful to consult an independent researcher, or Ethics Committee, on this issue if in doubt.

5. Redundant publication and plagiarism: Redundant publication occurs when two or more papers, without full cross reference, share the same hypothesis, data, discussion points, or conclusions. However, previous publication of an abstract during the proceedings of meetings does not preclude subsequent submission for publication, but full disclosure

should be made at the time of submission. This is also known as self-plagiarism. On the other hand, plagiarism ranges from unreferenced use of others' published and unpublished ideas, including research grant applications to submission under "new" authorship of a complete paper, sometimes in different language. Therefore, it is important to disclose all sources of information, and if large amount of other people's written or illustrative materials is to be used, permission must be sought.

SPECIFIC PRINCIPLES FOR CHEMICAL EVALUATION OF DRUGS AND HUMAN GENETICS RESEARCH

Evaluation of a drug ensure the identity of a drug and determines the quality and purity of drugs. The main reasons behind the need for evaluation of crude drugs are biochemical variation in the drug, effect of treatment and storage of drugs, and the adulterations and substitutions.

1) Organoleptic Evaluation
2) Microscopic Evaluation
3) Chemical Evaluation
4) Physical Evaluation

5) Biological Evaluation

- Chemical Evaluation of Drugs:

The chemical evaluation includes qualitative chemical tests, quantitative chemical tests, chemical assays and instrumental analysis. The isolation, purification and identification of active constituents are chemical methods of evaluation.

Qualitative chemical tests include identification tests for various phyto constituents like alkaloids, glycosides, tannins etc. and Quantitative chemical tests such as acid value(resins, balsams), saponification value(balsams), ester value (balsams, volatile oils), acetyl value (volatile oils), etc. are also useful in evaluation of a drug by means of chemical treatment. Chemical assay include assays for alkaloid, resin, volatile oils, glycoside, vitamins or other constituent. Instrumental analyses are used to analyze the chemical groups of phyto-constituents using chromatographic spectroscopic methods.

Principles of Human Genetics research

Ever since the discovery of Mendel's laws of inheritance and subsequently the double helical structure of DNA by Watson and Crick, genomic research has made great strides to an extent that genomic era is a real possibility in the near future. Genomic research is an upcoming field which is fast emerging after the results of human genome project were made publicly accessible. Human genetics refers to the study of individual genes, their role and function in disease, and their mode of inheritance. Genomics refers to an organism's entire genetic information, the genome, and the function and interaction of DNA within the genome, as well as with environmental or non-genetic factors, such as a person's lifestyle. With the characterization of the human genome, genomics not only complements traditional genetics in our efforts to elucidate the etiology and pathogenesis of disease, but it plays an increasingly prominent role in diagnostics, prevention, and therapy. These transformative developments, emerging from the Human Genome Project, have been variably designated genomic medicine, personalized medicine, or precision medicine. Precision medicine aims at customizing medical decisions to an individual patient. For

example, a patient's genetic characteristics (genotype) can be used to optimize drug therapy and predict efficacy, adverse events, and drug dosing of selected medications (pharmacogenomics). The characterization of the mutational profile of a malignancy allows to identify driver mutations or overexpressed signaling molecules, which then facilitates the selection of targeted therapies. Genomic risk prediction models for common diseases are also beginning to emerge. It involves the study of genes which code for a protein, enzyme, or a transporter in a particular individual, and to find out if there is any mutation, single nucleotide polymorphism, or copy number variations which may determine the susceptibility of the individual to a disease or the response to drugs. Advances in technology and ample funding opportunities, both national and international, increase in commercial interest, more public awareness on personalized medicine (yet to evolve in a big way in India), and media coverage have increased genetic research as well as whole genome research. These developments have raised many ethical issues associated with genetic research. The two main tools which ensure protection of the participants of any clinical research in general are written informed consent and

ethics committee (EC) review. The ECs have a major role in ensuring that the rights of the subjects involved in clinical trials are preserved. This is a major concern in India given the fact that very few ECs in India are properly constituted and functioning and there is no legal requirement for the members of the ECs to declare conflict of interest.

➢ Existing Guidelines and Recommendations

ICMR has provided comprehensive guidelines for Indian researchers working in genomic area, and a separate chapter has been included in the 2006 issue of "Ethical guidelines for biomedical research on human subjects." In India, the Guidelines for Good Clinical Practice (2001) emphasizes upon the principles which govern the ethical code of conduct, namely, non-maleficence, beneficence, institutional arrangement, risk minimization, ethical review, voluntariness, and compliance. It states that the staff engaged in biomedical sciences or research should be aware of their ethical responsibilities and comply with the ethical principles mentioned below:

- Informed consent: Informed consent involves explaining to the research participant about the research activity, the expected results of the research, the beneficiaries of the

result, the risk and benefits of participation. This can enable the participant to make a voluntary decision about participating in the research. However, the implementation of the "real" informed process is difficult to achieve unless the investigator takes extra effort to clearly explain in simple language about the benefits and risks of participating in the research.

- Withdrawal from research: A subject must be allowed to withdraw from research at any time of the study. This information needs to be mentioned during informed consent process. When a subject decides to withdraw from the study, it is implied that he/she wants all the samples to be destroyed and all results if obtained to be destroyed both in the electronic and print form.
- Addressing incidental findings in genomic research: Lots of information can be gathered during whole genome analysis about the subject's genetic profile. This information could either relate to the phenotype under study when it is pertinent information or it could be additional data relating to a new health problem, an incidental finding. The subject has the right to know the results of genetic testing – both the pertinent and the

incidental findings. In India, the researcher has the additional responsibility of putting across the results in a simple and understandable language taking into consideration the moral, religious, and cultural beliefs of the population to which the research subject belongs.

- Role of Ethical Committees (ECs): The role of ECs in genetic or genome-related studies is no different from that of other clinical research. ECs should ensure protection of research participants in general. They should ensure that all the information pertaining to future use of sample and data sharing has been provided to the subject before obtaining blanket consent. With expanding research in the field of genetics, the only way to ensure good-quality conduct of ECs is mandatory registration and an accreditation process.
- Biobanks and data abuse: Biobanks are private or public structured resources that contain long-term collection of human tissue and/or other medically relevant data and information connected to the collected tissue. The utilization of this data for forensic purposes by governmental sources can lead to its abuse for political purposes to control and punish citizens or distinct

segments of the population. Biobanks are also essential for genetic and genomic research because it is possible to study rare genetic variants or those with modest association with phenotypic traits or the effect of combination of genetic traits from the large size of data available in these banks.

- Compensation for participants: According to ICMR guidelines on genomic research, it state that "undue inducement through compensation for individual participants, families and populations should be prohibited. This prohibition, however, does not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, and provision of health care or of information infrastructure, reimbursement costs of travel and loss of wages and the possible use of a percentage of any royalties for humanitarian purposes".
- Sharing the benefits of human genetic research: Biological Diversity Convention text states that benefits of genomic research can be thought of as those arising from the use, whether commercial or not, of genetic

resources, and may include both monetary and non-monetary returns to the individual or the society. Schroeder[17] states that there are essentially four different justification models that cover the main possibilities with regards to benefit sharing in genomic research:

- ✓ The outcomes of human genetic research are sufficient benefits for both cooperators and the public at large.
- ✓ Cooperators who cannot benefit directly from genetic research, qualify for some form of additional benefits, whereas cooperators who can benefit directly are not eligible.
- ✓ All cooperators qualify for additional benefits (owing to the risks involved or because their property is being used).
- ✓ Altruism should be the guiding principle for contributors to human genetic research

With all the above discussions, we can say that, there is a real need to provide more clarity and build upon the specific principles and regulations with regards to ethical issues surrounding genomic research