

Basic Tenets of Clinical Research

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ABSTRACT

Objective: Scientific research is the cornerstone of development and conducting research in a systematic and structured manner which is mandatory for universal acceptance.

Aims: The objective of the article is to give a ring-side view of research in dentistry for the clinicians interested in research and publication.

Discussion: The research methodology, results, summarization and publication of the results are the basic tenets which this article elaborates upon. The ethics of conducting animal and human experimentation and what constitutes good practice during such research, needs to be stressed. As important as the research itself is the ownership issue. Intellectual property rights, copyright and trademarks with their infringement and publication guidelines, are also discussed.

Conclusion: Clinical research has to be done under an ethical ambit for scientific acceptance and as a trendsetting phenomenon for ethical work.

Keywords: Research, Intellectual, Publishing, Dentistry, Ethical, Clinical.

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INTRODUCTION

Research is deemed as a mathematical or scientific tool used to explore various avenues of reaching a goal, to eliminate bias toward a particular product/technique or event and to assess the variability involved in a system.¹ Such research goes a long way in validating and refuting claims, stimulating further thought on the issue involved and registering data. Claims of 'ownership' of the results of the research and at times the process itself, is a separate issue.

Research promotes innovation, day to day application and overall benefits in terms of scientific validation. Governments and private funding labs/agencies are equipped with committees to assess a particular blueprint for the project, allot funds and publish the research, apply for 'ownership' (patent) and encourage further thoughts on the subject. This article elaborates on the tenets that govern research projects. As clinicians (who belong to any specialty), we need to be aware of the requirements and the tenets of scientific submissions.

How to Start a Research Project?

Extensive reading of research and scholarly articles, journal discussions and comments on controversial articles, triggers ideas.

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Students need to shift from passive listening and learning to active or critical listening to lectures and seminars. How did this author/speaker come to this conclusion? Are these results acceptable? Is there a possible next step? Such questions widen the horizon of thinking deeply and ideas begin to form.

Role of an Advisor/Guide

With the help of a guide (who is certified by the university/governing body as eligible to guide students) or a program advisor, the basic idea has to be developed into a multilayered proposal. Open problems have to be identified. Possible pitfalls need to be foreseen and a backup plan has to be in place. A pilot study to evaluate the feasibility of the study, on a large scale, must be done. Such feasibility appraisal can go a long way in identifying problems that may be encountered during research.

What is a Thesis?

The word has Greek etymology—meaning 'a proposition' or 'an assertion'.¹ It is actually 'a new evidence for an old assertion or support from an unlikely source with a wide range of reference materials.'

Thesis is submitted in support of candidature for a degree or professional qualification presenting the author's original research and findings to support or refute an established proposition.

Are Thesis and Dissertation the Same?

In some countries, thesis/cognate is applied to bachelor's or master's level research project that has to be submitted and dissertation is applied to doctorate level research that has to be submitted and defended in an oral examination.¹

In most countries, this distinction is missing and guidelines exist for submission only. Every university has its own guidelines for research projects/grants/thesis.

What Constitutes a Good Thesis?

- Subjects to be adequately covered in the format
- All aspects of title and research addressed
- Researcher’s own conclusion based on the results/evidence
- Anticipate and refute counter-arguments
- Simple language
- Focus on topic and method of study
- Are future studies and applications possible?

‘A work well-begun is a work half-finished.’ On narrowing down the research possibilities and charting out the methodology, a sequence needs to be followed for optimization of time limit (Fig. 1). The researcher should complete the thesis well before the deadline as dictated by the university or funding agency as defence of the thesis/further funding may depend on it.

Key Article(s)

This forms the nidus of the study. It may be one article or two more articles that would have described a related or similar study and that would be a platform on which the current study will be based. Caution needs to be exercised here as there is no point in being biased or favorable toward the results exhibited by the previous studies. The research has to be original and the key article should be only used as a base on which one’s ‘own’ conclusions have to be drawn. It is pertinent to cite indexed journals with a high impact factor.

Literature Search

Recent articles and journals relevant to the study should definitely be extensively cited, recent being 10 to 15 years according to universities and grant committees.² But, there may be landmark articles and discussions on the study that may be

cited even if they are more than 50 years old. The very basis of the study may be dependent on that article. Previous dissertations and even unpublished data must be duly stated so.

Data cards/index cards are available where the collected information, i.e. journal, year, pages, etc. can be written or typed. They are ready reckoners when arranged according to its significance and year.

Software is available to assist in research. Online articles can also be duly incorporated by citing the original website and retrieval information. The researcher should definitely not ‘cut and paste’ articles and use diagrams or tabulations of copyright material without prior permission.³

MATERIALS AND METHODS

A detailed description of the method used in the study, a working model, and all the brands used, volume, particular degree or weight and percentage employed, etc. should be included. The measures should be in the format acceptable by the publication.

Studies involving humans should incorporate a consent form and an ethical committee approval. Most institutions have an ethical committee that examines the research proposal and grants approval for the research. Any injury that may be accidentally inflicted on the patient or accumulated insults that may have hereditary effects (radiographic techniques) or disadvantages of the treatment should be elaborated upon and the consent form should also be inclusive of such details.

Such details are mandatory as legal battles have risen in the recent years and research must not be overshadowed by mundane aspects. Every research must be able to sustain on its own, reproducible and new methods/devices can be patented.

Results, Statistics and Discussion

Genuine results must be tabulated and presented in a simple way so as to be understood even by nonspecialty persons. This is important if grants are further required or the research is being considered by another agency.

Statistics must be done by a professional after assessing which analysis is needed for the particular study. Is a group being compared? Intra- or inter- ? How many variables are involved? Is the difference significant (p-value)? What is the average and is a range available? Suitable graphs can accompany the statistics. Softwares are available for aiding the statistician.

The values that are not confirming with the data from previous studies also should be listed as skewing the results would not give a good picture in the long run. No major decision can be taken on such results as a replication of the same model would be negative. In the discussion, this matter could be addressed and the possibilities of nonconformation can be elaborated upon.

Futurology

The study done may not be an ‘end result’, rather a continuation or some more variables or time bound observations may be possible yet. Such probabilities can be cited as future studies.

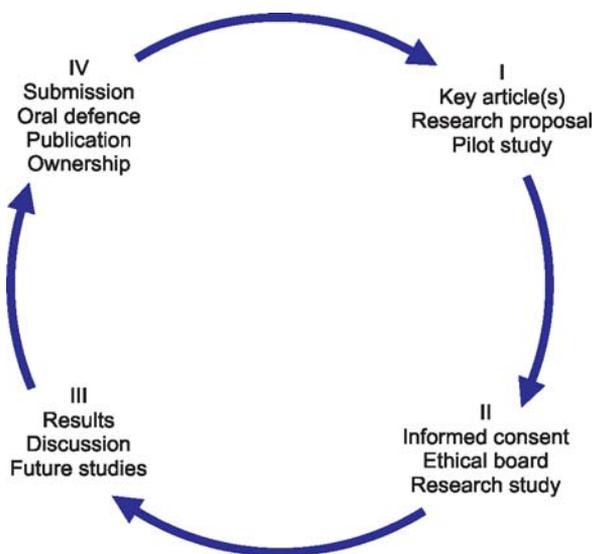


Fig. 1: Sequence of research

BIBLIOGRAPHY

In Greek, bibliography means 'book writing'. It is a systematic list of books and other works such as journal articles, seminars and written communication. Bibliographic databases are also available in present day.³

REFERENCES

It is defined as 'a standardized way of acknowledging the source of information and ideas that have been used in the current assignment which allows the source to be identified'. Referencing is done to avoid plagiarism, verify data and quotations and more follow-up on the idea if needed.⁴ Referencing software is available that enables authors to accurately manage the references. Some of the universally accepted reference styles are:

Vancouver Style

This is also known as 'author-number' system.⁴ Citations in the text are by Arabic numbers in round brackets or superscripts. The reference appears in the order they are cited in the article. The same number is used regardless of the number of times the author is cited or the position of original citation.

Books: Author(s)- title- editor- year-place of publishing- chapter/page.

Articles: Author(s) -title- journal- year-edition/volume-page.

Electronic: Author- website-date of original citation- accessed.

Newspaper article: Title- author- newspaper-year-date.

E-mail: Author-title- e-mail to whom-date (e-mail has to be saved).

Personal communication: Only used in text of article (not referenced), author-date.

Conference papers, lectures, seminars, proceedings that have been published or unpublished also may be referenced as-author/speaker-title- date-place.⁵

Harvard System

This is also known as 'author-date/year' system.⁴ The author and year are cited in round brackets at the end of the sentence in the text and in the reference section they are in alphabetical order.

British and AMA system are some of the other styles of referencing that are also in use.

The system followed depends on the journal publishing the article/university under which the thesis is put up for submission.

The Matter of Ethics

A system of moral principles that apply values and judgments to the practice of medicine is known as medical ethics. Thomas Percival is considered as the father of medical ethics and he is said to have coined this term too. 1847 saw the dawn of code of ethics in the American Medical Association.⁶ Largely toward the end of the seventies, ethics was incorporated in research

institutions as Ethical Committees procedural consent and it also found its way into medical/dental school curriculum.⁵ The basic tenets of medical ethics are as follows:

- Autonomy—the patient has the right to refuse or choose their treatment
- Beneficence—a practitioner should act in the best interest of the patient
- Non-maleficence—'first, do no harm'
- Justice—concerns the distribution of scarce health resources and the decision of who gets what treatment (fairness and equality)
- Dignity—the patient and the person treating the patient, have the right to dignity and privacy
- Truthfulness and honesty—the concept of informed consent has increased in importance in recent times.

Informed Consent

A person must be fully-informed (in a language understood by the patient) about the benefits and risks of the treatment or diagnostic procedure. Patients can make their own medical decisions or can transfer their decision-making power to another person if they are incapable of making their own like when they are minors or they are unconscious. Obtaining an informed consent from the subject, with the signature of at least two witnesses has to be given priority and this has to be reviewed by the Ethical Committee.^{2,7} Ethical conflicts arise only due to improper communication between subjects and the researcher/doctor or between the kin and the researcher. Communication in the vernacular language is imperative and translators have to be very efficient where this is lacking. Double effect, i.e the same drug could be both beneficial and nonbeneficial (e.g. morphine as a pain killer), should also be carefully explained.

Confidentiality

Subject's confidentiality also has to be maintained by both the research team as well as the ethical board members.⁸ This is in view of 'Intellectual Property Rights' exercise and the board members must exhibit high integrity in such situations.

Human Research

Humans have been used for both observational and interventional studies. Though observational studies are noninterfering, the methodology has to be approved by the ethical committee and a consent form obtained from patient.

Early 11th and 12th century witnessed Persian Surgeons Avicenna and Avenzoar conducted randomized clinical trials, drug testing and surgical methods on humans.⁹ Later physicians did use humans albeit 'unethically', according to present standards, as the concept of ethics and consent were unknown then. This was the case even in 18th century research. The smallpox experiments of Jenner and drug dosage experiments of Jorg were all done on the scientists themselves/their wards/slaves/neighbors, who seek treatment.⁹ The effects of the drugs/microorganism/treatment were not explained to the patients.

The infamous use of war prisoners and natives, for human subject research, was evinced in Nazi-related war crimes and Japanese war overtures. Various organizations, that dealt with ethical conduct of humans, were a fall-out of these massacres. The Nuremberg code of ethical conduct of human subjects in research was one of the pioneer methods for people embarking on such studies.¹⁰

Dental experiments were also conducted on humans and not all subjects were volunteers! The Vipeholm studies were conducted on 'retarded' (differently abled) subjects and they were given extreme sugary substances to assess the development of dental caries.¹¹ Studies on war prisoners, slaves and natives of distant conquests were usually monitored but the practice of 'consent' was still not in vogue.¹² As the governments were into political aspects, the testing of effects of poisonous gases, drugs and treatment methods were done in secluded conditions and the results mostly, were classified army material.

By mid- 20th century, medical boards were formed to advice over careful monitoring and getting patients/ kin's approval for the experiments/surgical procedures.¹¹ The section of humans most vulnerable to such unethical excesses was children in orphanages, differently abled persons, brain-damaged patients, war prisoners and economically backward natives. Recent past too has witnessed drug company giants accused of conducting drug trails without disclosing to the subject, the nature and effects of the drug.

Formation of Research Boards

The World Medical Association published a code of research ethics in 1964, the declaration of Helsinki, focusing on medical research with therapeutic intent.¹³ Medical professionals and researchers had to follow a set of principles outlined in the declaration. This led to the implementation of the institutional review board (IRB) process, wherein every university or research center had to register the pilot study, approved by the ways of an examining committee and then only the research was considered to be done. The Helsinki declaration has been amended six times and the 2008 version is the most recent.¹³ This version has laid down clearly many guidelines for clinical research and protection of human subjects:

- Public health issues
- Risks and burdens of the subjects
- Representation of all populations
- Maintenance of privacy of volunteers
- Informed consent guideline.

Human volunteers can consent to be subjects for invasive experiments which may involve, for example, the taking of tissue samples, implants which require surgery on the volunteer or penetrate the tissues like radiation. These procedures must be approved by ethical review and carried out in an approved manner that minimizes pain and long-term health risks to the subject. Three basic ethical principles that underlie human experimentation (Belmont Principles-1979)¹³ are:

- Respect for persons and privacy

- Beneficence
- Justice.

Distinction must be made between 'human participants' and 'human subjects of research'.¹⁴ The ethical committee/institutional review board can determine whether or not the subject, the altered environment of the study, require clearance/consent. All studies on humans require careful monitoring regardless of whether they are interventional/noninterventional.

Intricate documentation, maintenance of private details of the subject and a detailed explanation of the procedures, written consent in a language understood by the patient are absolute requirements for the present day researcher. The publishing journals too are very vigilant in terms of any violations to these protocols as most have peer review committees that are well versed in such areas.

On explanation of the course of action/expected results/side effects of the treatment if any, the subject of research will usually be well-informed and cooperation is maximum. The first book on medical ethics was written by Ali Rahawi (Conduct of a Physician).¹⁵ Our very own Hippocratic Oath is a simple ethical format. Clinical trials in most countries have to be registered with consort, a forum of clinical researchers.¹⁶

In orthodontics for example, clinical studies (*in vitro*) are done in growth-related areas, implants, tooth movement, genetic and appliance try outs. Bio-mathematical research also has gained much popularity these days. Pedodontic research may involve application and trying of various anticaries agents, root canal medicaments, implants and appliances. Hence 'clinical research' is a favored option among students and faculty.

Institutional Ethical Board/Committee

Every institution, that is serious about research, has an ethical board in place. The research proposal has to reach the committee members well in advance so that the members have adequate time to peruse the material. The pros and cons of the methods and materials to be used, projected results, expected pitfalls and funding if needed, etc. have to be analyzed. All the discussions need to be minuted and absolute secrecy should be maintained. A clear yes/no for the project and a re-appraisal if needed must be communicated to the researcher, guide and all the members.^{2,17}

In India, ICMR (Indian Council for Medical Research) has given clear guidelines regarding constitution of the committee and the conduct of the meetings. They specifically deal with the ethics involved in research and who can decide on such ethics.

The chairperson of the IEC (Institutional Ethical Committee) is not advised to be the dean of the same university (not employed by or otherwise connected to the institution) and the members should be of a multifaceted origin—one from the same specialty, one well-educated lay person (aware of societal norms), one member who is well-versed with law, a veterinarian if animal studies are proposed, a human rights specialist, a religious head, etc.² A total of 7 to 9 members are allowed.

Both genders can be given equal representation if possible. An approval can be reached if consent is obtained from at least five members. Most boards' worldwide has almost the same guidelines with minor additions/deletions. Any legality arising out of miscommunication can also be resolved by third part mediators. A legal coordinator's services may be sought if medicolegal issues need to be resolved.

The student/researcher also has to be advised about publication, first authorship, informed consent and confidentiality to prevent future embarrassment to the organization.¹⁸

Animal Experimentation

Both vertebrate and invertebrate animals are used for various research purposes. In dentistry-related research, mice, rats, guinea pigs are commonly used. Mice are the most favored for dental research owing to their size, low cost of breeding and handling and fast reproduction rate. It is also considered as the best research model as they share 99% of human genes.¹⁹

Rats are also used in a number of experiments but genetic manipulation is harder. Nonhuman primates, though are more similar to humans, it is for that very reason that more ethical clearance is needed and their usefulness has to be demonstrated as 'absolutely essential' for that particular research.²⁰ Management of primates is also extremely difficult. Rhesus, squirrel and cynomolgus monkeys are some of the species that were used.

Animals are euthanized after being used in experiments. Most animals are purposely bred (in veterinary universities or breeding centers) but some are caught (in the wild) or supplied by dealers. Universities, medical schools, drug companies, firms and defence establishments conduct genetic, pharmaceutical, behavioral, cosmetic, treatment mechanics and toxicology studies on these animals.²¹

Animal rights organizations are against the use of animals for experiments, because they are of the opinion that:

- Animals are living beings
- Cannot give consent
- Results cannot be predicted to be the same in humans
- Costs of maintenance outweigh the benefits.

Animals form the first line of testing in most industry research labs—be it drugs, modified or altered environment, space expeditions, genetic modifications and even as production of vaccines and drugs. Galen, Aristotle and Avenzoar were pioneers in medicine and surgery who conducted trials and treatment on animals (home bred/purchased) before try outs on humans.^{19,22} After sulfanilide and thalidomide tragedies, laws were passed that required safety tests on animals prior to human trials.²³

'Benefits to humans did not justify the harm done to animals'—this seemed to be the path followed by animal-centric researchers and scientists in late twentieth century.²⁴ Henry Berg founded the ASPCA and antivivisection organizations came into existence in the mid-nineteenth century. SPCA, CPSEA are some of the organizations actively involved in animal rights

in India. They in fact have been advocating an Institutional Animal Ethical Committee in all research institutions.²⁵ The research organizations that reared/used animals for research came under the ambit of Laboratory Animals Welfare Act (1966). The act promoted the use of animals for experiments if:

- Their use was scientifically justified
- They are as humanely treated as possible
- Reared under utmost care
- Management of pain is made priority.

Animals are bred in controlled environments as dictated by the research to be conducted. Anesthesia in the form of CO₂ in a chamber or face mask can be administered and the animal is killed before regaining consciousness. Then the experiments are conducted. Physical methods like cervical dislocation, decapitation, high intensity microwave and electric current can also be used.²³

Expansion appliances, implant studies, drugs related to pain management, condylar growth studies, radiation experiments, genetic studies, craniofacial disorders, etc. are some of the research being done in animals.

A student who partakes in animal research, has to get an animal ethical clearance certificate and a veterinary opinion regarding the project. The lab will be under surveillance to check whether all the aspects of animal care are followed as regards with food, pain, space and safe disposal after experiment is over.

The following points have to be adhered to, while using animals for research:²

- Trained lab assistants and absolute sterility
- Specified food and environment
- Veterinary specialist attendance
- 24 × 7 monitoring
- As pain free techniques as possible
- Administration of analgesics if the results are not deemed to be altered by the analgesic
- Stringent records
- Animal Ethical Clearance Board approval for the study
- Minimal usage of animals and maximization of the sample
- Clean and sterilized disposal.

Intellectual Property Rights

Intellectual property (IP) denotes a product of the mind or the intellect. These could be in the form of patents, trademarks, geographical indications, industrial designs, layout of integrated circuits, plant variety protection and copyrights.⁸

World Intellectual Property Organization (WIPO) is headquartered in Geneva. India is a member of the WIPO. India is also member of two major treaties, namely, Paris Convention for the Protection of Industrial Property (relating to patents, trademarks, designs, etc.) of 1883 and the Berne Convention for the Protection of Literary and Artistic Works (relating to copyright) of 1886.²⁶ Apart from these, India is also a member of the Patent Cooperation Treaty (PCT) which facilitates obtaining of patents in several countries by filing a single application. India is a member of the TRIPS agreement (Trade

Related Aspects of Intellectual Property). Copyrights are awarded by a regulatory body for academic, literary and artistic work. They are given for a certain period of time and once the time period elapses, the copyright can be overlooked and the name/design/figure/academic work can be reworked.²⁷

Intellectual property rights are the most important aspect of research. Protection of scientific discoveries with or without commercial potential, patenting discoveries, registering product rights and methods, etc. are currently observed to claim 'ownership'. In any discussion on collaborative agreements between different institutions, public and private, the first question asked is: 'Has our IPR been protected?'.²⁸ Students/researchers, in fact, these days, are being advised to patent their discoveries before publishing.

To do research in orthodontics, or for that matter any specialty, is quite an expensive option and most researchers are attached to universities, labs or private companies. Some universities have commercial exploitation of academic ideas. Research these days, is a product of industry/drug company/material company sponsorship. Government sponsored research may not be for commercial exploitation but used for policy making and fund allotments.

Hence, the research done, unless done only by the individual solely by his or her own funding, cannot be claimed as 'own' by one individual. Research labs and drug companies have their own contractual agreements. These have to be adhered to while seeking to publish the results. The commercial use of these research products also are governed by these regulations. Hence the individual who has actually done the research or invented the product does not have sole 'ownership' of the research. Moreover, one can claim ownership for 'the expression of idea' and not the 'idea' itself.³

Universities on the other hand do not enforce such contractual agreements.²⁹ Individual freedom and expressive abilities are thought to be curtailed on imposing strict rules regarding 'ownership' of teaching material, research work and the very 'idea' of the research. But there are universities that insist that the work done during the course of employment/studies belongs to the 'employer' only. These rules have led to a lot of legal battles as researchers feel that 'intellectual investments' cannot come under 'contracts' as all teachers or students/researchers do not come up with ideas or inventions under similar environments provided by the university.³⁰

As a student, the research work done during the graduate/postgraduate/doctoral course, which may be a dissertation/thesis, using the provided material, experimented on patients who attended the clinic, getting inputs from the department staff, etc. belong to the 'guide' technically. The head of the department is not the 'owner' of the research if he/she is not the guide but his/her name is to be included as a 'head of department' in the publications as it is being done in the department.⁸ This is unless the researcher has ample proof that the research was not conducted in the course of employment. Inclusion of the head of the department or a very senior member in the department,

though they have had little or no say in the research conducted in that institution, in the thesis or publication, is seen by some as an inevitable 'pressured' authorship.³¹

Few staff/technical persons/people outside the university who had a say in the research, should be included in acknowledgments.³¹ The thesis author would own the copyrights of the research until he/she transfers it for the sake of publication or commercial exploitation.^{8,31,32}

Research, if done in a private lab and not involving any organization/hierarchy, belongs to the researcher(s) only and it is with the individual to maintain ownership.^{33,34} A consent and clearance has to be obtained still, as the case may be, as ownership and human rights are mutually exclusive.

Publishing the Research Work

Publishing ensures that the scientific world gets to know about the research, methodology and results and this paves way for further research and improvement in techniques. In many American universities, for example, research is given utmost importance and evaluation for grants for research goes on at a national level. Individual research is expensive to say the least. Company sponsored research does prove less arduous but it has its inherent pitfalls like priority and possible bias of the sponsoring companies products, not to mention benefits for the clinician. This tug-of-war between institution sponsored and company sponsored research will go well into the next century.

Publication is also seen as an individual's scientific progression and yardstick to assess the ascension of the individual and the university. A few unethical practices and lack of governance in research circles saw the dawn of the International Committee of Medical Journal Editors (ICMJE) also called 'the Vancouver group'. This committee ensures honest authorship across the length and breadth of scientific publishing and research.

According to ICMJE, first authors have substantially contributed to the research by way of conception, data acquisition, research and writing. This includes drafting, critical evaluation and final approval of the research. Those who do not fill most of these criteria should be 'acknowledged'.^{5,31}

A co-author is one who has made some intellectual/experimental contributions to the research. Co-authors exhibit the next level of commitment to the project.⁵ Some journals do list all the authors involved in that particular study (e.g. multi-center studies), whereas some limit the number of authors to three or six. Co-authorship position is a joint decision among the authors. The last author usually is the seniormost member/head who may not be directly involved in the research. Guest authorship is also described to be one wherein that author's name may carry weight in research circles or who has overseen the research.³¹

Most journals have their own guidelines in place for format, photographs, diagrams and size of the material. Since, the advent

of online journal servers, medical publishing has seen a quantum jump in recent times.

COPYRIGHTS

Ownership of literary, academic and artistic work is maintained by obtaining copyrights. Copyright agreements and transfer of ownership of the published research (not the research itself) are requested by journals prior to publishing to avoid legal hassles. The research which is published in a particular journal cannot be used again by the authors ‘in part or as a whole’ in any another journal in any other format also. Whereas the original publishers can reprint, use parts or whole material in another publishing medium. This is in effect the ‘transfer of ownership’ clause (Fig. 2).

Different countries have varying copyright laws. Infringement of copyright is actionable by the copyright owner and the law views it seriously.³⁵ Quoting a copyright material has to be done with permission from the original publisher/owner. Usage of such material is called ‘fair dealing’. Copyrights, Designs and Patents Act (CDPA- 1998, amended 2010) is in place in the United Kingdom and Copyright and Related Rights Regulations is followed in the US (1996).³⁵

Infringement of copyright is the term used when copyright to a particular product is ignored and the original author is not acknowledged or the product/material is used without prior consent. Academic lectures, slides, new surgical techniques and new treatment products cannot be claimed by the department or the university for ‘ownership’ rights as these are because of the thinking and intellectual exertions of the researcher, if he/she was working alone.³⁶⁻³⁸ Human Rights Act (1998) purports

that ‘rights of persons to the peaceful enjoyment of their possessions, including intellectual ones’ should be the norm to allow more creativity and development of society.³⁹ Some may wonder about online search portals that supply information for the party that searches for that particular information. Websites such as ‘wikipedia’ are governed by a ‘creative common attribution license’ that allow the knowledge to be shared by citing references, copyrights and links. Open source websites also belong to the same category.

TRADEMARK, REGISTRATION AND PATENTS

There are also different types of ownership (Fig. 3). Different countries have their own laws regarding patents. ‘Patent’ is the legal right exercised by the inventor/discoverer of the material/item. An innovation can be patented. A process/mechanism can be registered and the result of such process can be registered as a trademark. Industrial designs, innovations, logos and new mechanics come under this envelope. Trademarks and patents are protected from misuse for a certain period of time, after which, they can be renewed often. Trademarks, publishing rights, patents and intellectual property rights can be gifted, sold, inherited or transferred.²⁶ These are done legally and they can be owned for generations also, if registered and re-registered, when the time of registration elapses.

Geographical indication is given out for a particular product that cannot be replicated elsewhere, as their indigenouness is unique to that area only. There are innumerable medical plants and their drugs that are protected by this law. Basmati rice and Darjeeling tea are the more famous products that made the whole world aware of this law.

The trade related aspects of intellectual property rights (TRIPS) agreement is a minimum standards agreement, which allows members (countries, organizations/individuals) to provide extensive protection of intellectual property.^{25,37} Trademarks can be registered and renewed any number of times. Patent rights, their validity time, trade secrets management,

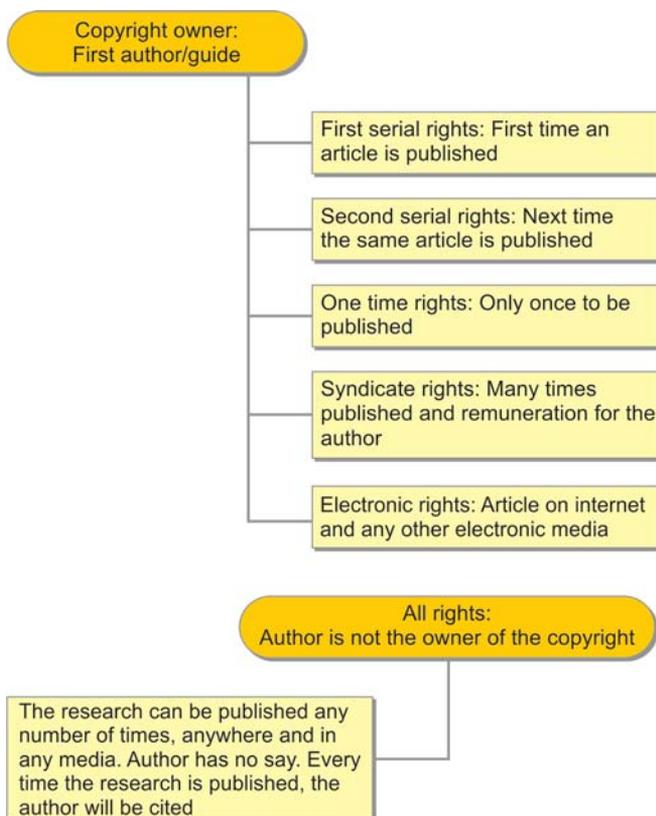


Fig. 2: Copyrights

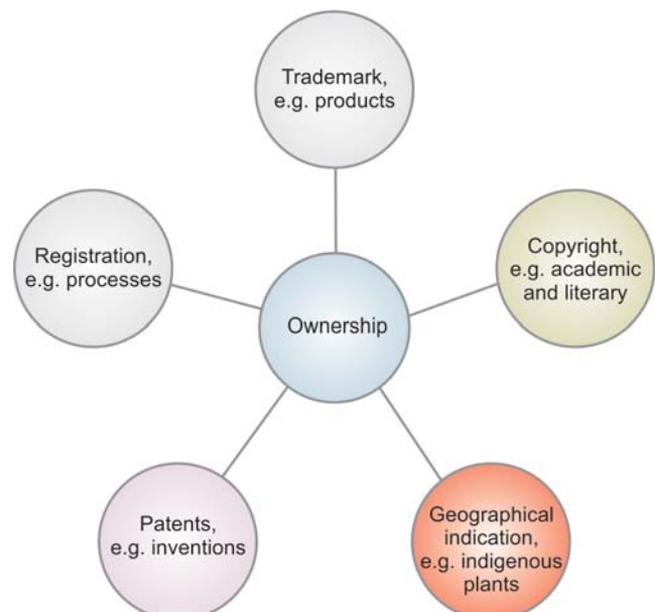


Fig. 3: Ownership

redressal forums, etc. were espoused in the Berne convention, Uruguay agreements and many amendments were made in between also. They are all related to agreements on macro and micro 'ownership' of products/academic and artistic work. With this agreement in place countries/individuals cannot crossover into registered aspects and misuse or infringement is avoided. Countries that are part of TRIPS, usually have knowledge sharing and legal methods of information exchange.³⁷

Protection of copyrights is imperative in present days where internet and other modes of data transfer ensure rapid dispersion of information. Citation of original website is important as part of acknowledgment where online articles are concerned.³⁷ Patent issuing authorities also have guidelines for issue of patents. They check the viability, sustenance of natural environment, prejudice if any to human or animal life, processes or therapies that may be beneficial to humans etc. New surgical techniques, corollary to original theory and mathematical methods are not patentable. After the date of filing, it takes roughly eighteen months for the patency examination to be completed and grant of patency.

There are a number of offices and boards in various countries that settle copyright, trademark and patent claims. The Indian Copyright Act is an extension of the British Copyright Act (Imperial Act of 1911). Recent times have seen European Union Directives and Madrid system of trademark registration (filing in one country is enough and this is valid across multiple countries).^{26,39}

CONCLUSION

As important as the research itself, is the ability to guard its privacy, publication and identifying potential commercial aspects if any. The path to the submission of the thesis/dissertation is filled with cornucopia of bioethical concerns, which if the student fails to comply, can lead to nullification of the research and embarrassment. A clear vision is the absolute need of the hour. Humane approach to patients, clear communication, due acknowledgment and a working knowledge of applied law are requisites for the novice researcher.

'The achievements of great men were not achieved overnight; when the whole world had slept, they had burnt the midnight oil...'⁴⁰

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