



King Saud University College of Dentistry

CODE OF ETHICS

2011-2012

FOREWORD

I would like to express my gratitude to the members of the Ethics Unit in College of Dentistry, King Saud University for their great effort and hard work in establishing this unit.

Also my gratitude goes to the College of Dentistry Research Center (CDRC) for their great work to establish and document the ethics in dental research.

I hope that this work and the following work will help raise the ethical standards in different departments in College of Dentistry, King Saud University.

Special thanks to the printing and designing committee for their effort in putting the final touches for this document.

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There are three distinct ethical codes within this manuscript namely:

- **ETHICS IN TEACHING AND LEARNING**
- **ETHICS IN DENTAL PRACTICE**
- **ETHICS FOR RESEARCH IN THE COLLEGE OF DENTISTRY**



**King Saud University
College of Dentistry**

**ETHICS IN TEACHING
AND LEARNING**

2011-2012

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INTRODUCTION

Ethical principles are conceptualized here as general guidelines, ideals or expectations that need to be taken into account, along with other relevant conditions and circumstances, in the design and analysis of university teaching.

Implementation of this ethical code will be advantageous to university teachers in removing ambiguity concerning teaching responsibilities and will contribute significantly to improvement of teaching.

The following nine ethical principles for teaching and learning were adopted from **The Society for Teaching and Learning in Higher Education (STLHE)** with minor modifications.

1. Content Competence

A college teacher maintains a high level of subject matter knowledge and ensures that course content is current, accurate, representative, and appropriate to the position of the course within the student's program of studies.

Achievement of content competence requires that the teacher take active steps to be up-to-date in content areas relevant to his/her courses; to be informed of the content of prerequisite courses and of courses for which the teacher's course is prerequisite; and to provide adequate representation of important topic areas and points of view.

An Academic staff member should appreciate the nature of evaluation and utilizes effective evaluation techniques in relation to curriculum teaching and learning.

2. Pedagogical Competence

A pedagogically competent teacher communicates the objectives of the course to students, is aware of alternative instructional methods or strategies, and selects methods of instruction

that, according to research evidence (including personal or self-reflective research), are effective in helping students to achieve the course objectives.

An Academic staff member should understand a variety of teaching and learning approaches and strategies, and endeavors to maintain awareness of pedagogical advances.

This principle implies that, in addition to knowing the subject matter, a teacher has adequate pedagogical knowledge and skills, including communication of objectives, selection of effective instructional methods, provision of practice and feedback opportunities, and accommodation of student diversity. If mastery of a certain skill (Example: critical analysis, design of experiments) is part of the course objectives and will be considered in evaluation and grading of students, the teacher provides students with adequate opportunity to practice and receive feedback on that skill during the course.

Learning styles differ significantly for different students. Therefore, the teacher should be aware of these differences and, if feasible, modifies his/her style of teaching accordingly.

To maintain pedagogical competence, and instructor takes active steps to stay current regarding teaching strategies that will help students learn relevant knowledge and skills and will provide equal educational opportunity for diverse groups. This might involve reading general or discipline-specific educational literature, attending workshops and conferences, or experimentation with alternative methods of teaching a given course or a specific group of students.

3. Dealing with Sensitive Topics

Topics that students are likely to find sensitive or discomfoting are dealt with in an open, honest, and positive way respecting cultural principles and values.

The teacher should invite all students to state their position on the issue, sets ground rules for discussion, is respectful of students even when it is necessary to disagree, and encourages students to be respectful of one another.

4. Student Development

The overriding responsibility of the teacher is to contribute to the intellectual development of the student, at least in the context of the teacher's own area of expertise, and to avoid actions such as exploitation and discrimination that detract from student development.

According to this principle, the teacher's most basic responsibility is to design instruction that facilitates learning and encourages autonomy and independent thinking of students, to treat students with respect and dignity, and to avoid actions that detract unjustifiably from student development.

5. Dual Relationships with Students

To avoid conflict of interest, a teacher does not enter into dual-role relationships with students that are likely to detract from student development or lead to actual or perceived favoritism on the part of the teacher.

This principle means that it is the responsibility of the teacher to keep relationships with students focused on pedagogical goals and academic requirements. Even if the teacher believes that she or he is maintaining objectivity, the perception of favoritism on the part of other students is as educationally disastrous as actual favoritism or unfairness. If a teacher does become involved in a dual relationship with a student, such as business or financial relationships, blood or marital relatedness, it is the responsibility of the teacher to notify his or her supervisor of the situation as soon as possible, so that alternative arrangements can be made for supervision or evaluation of the student.

Although there are definite pedagogical benefits to establishing good rapport with students and interacting with students both inside and outside the classroom, there are also serious risks of exploitation, compromise of academic standards, and harm to student development. It is the responsibility of the teacher to prevent these risks from materializing into real or perceived conflicts of interest.

6. Confidentiality

Student grades, attendance records, and private communications are treated as confidential materials, and are released only with student consent, or for legitimate academic purposes, or if there are reasonable grounds for believing that releasing such information will be beneficial to the student or will prevent harm to others.

This principle suggests that students are entitled to the same level of confidentiality in their relationships with teachers as would exist in a lawyer-client or doctor-patient relationship. Violation of confidentiality in the teacher-student relationship can cause students to distrust teachers and to show decreased academic motivation. Whatever rules or policies are followed with respect to confidentiality of student records, these should be disclosed in full to students at the beginning of the academic term.

7. Respect for Colleagues

A college teacher respects the dignity of her or his colleagues and works cooperatively with colleagues in the interest of fostering student development.

This principle means that in interactions among colleagues with respect to teaching, the overriding concern is the development of students. Disagreements between colleagues relating to teaching are settled privately, if possible, with no harm to student development. If a teacher suspects that a colleague has shown incompetence or ethical violations in teaching, the teacher takes responsibility for raising the matter to higher authority.

8. Valid Assessment of Students

Given the importance of assessment of student performance in college teaching and in students' lives and careers, instructors are responsible for taking adequate steps to ensure that assessment of students is valid, open, fair, and congruent with course objectives.

This principle means that the teacher is aware of research (including personal or self-reflective research) on the advantages and disadvantages of alternative methods of assessment, and based on this knowledge, the teacher selects assessment techniques that are consistent with the objectives of the course and at the same time are as reliable and valid as possible. Furthermore, assessment procedures and grading standards are communicated clearly to students at the beginning of the course, and except in rare circumstances, there is no deviation from the announced procedures. Student exams, papers, and assignments are graded carefully and fairly through the use of a rational marking system that can be communicated to students. By means appropriate for the size of the class, students are provided with prompt and accurate feedback on their performance at regular intervals throughout the course, plus an explanation as to how their work was graded, and constructive suggestions as to how to improve their standing in the course. In a similar vein, teachers are fair and objective in writing letters of reference for students.

9. *Respect for Institution*

In the interests of student development, a college teacher is aware of and respects the educational goals, policies, and standards of the institution in which he or she teaches.

This principle implies that a teacher shares a collective responsibility to work for the good of the college as a whole, to uphold the educational goals and standards of the college, and to abide by college policies and regulations pertaining to the education of students and patient care.

10. *Ethics on education on patients*

Dental education is based on practical clinical training that relies heavily on interaction with patients. There are sets of ethical principles related to training on patients that faculty members should observe which include:

1. The faculty member must respect patient's privacy thereby should avoid discuss issues infringing on the patient's privacy in front of a group of trainees to ensure respecting patient's right to privacy and confidentiality

2. The faculty member should be committed to prevent harm to the patient of any sort during the education of trainees.
3. The faculty member should avoid approaching the patient with a large number of students or multiple physical examinations by students in a short time period.
4. The faculty member should avoid blaming or reprimanding a trainee in front of the patient, in order to preserve the dignity of the trainee on one hand, and not to confuse the patient on the other hand, especially if all spoke a language not understood by the patient.
5. The faculty member should respect gradual progression in patient care assignments to the trainees. In addition, the supervising faculty member remains responsible for providing adequate supervision to ensure that the patient will receive appropriate care.

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King Saud University College of Dentistry

ETHICS IN DENTAL PRACTICE

2011-2012

INTRODUCTION

Dentists should follow high ethical standards considering the benefits of the patient as their primary goal. The privilege of being a dentist comes with a responsibility to society and to fellow members of the profession to conduct ones professional activities in a highly ethical manner. The dentist –patient relationship is the cornerstone of dental ethics.

This document is supplementary to the ethics in medical profession document by the Saudi Commission for health specialties which is the reference for ethics in medical profession.

Respect and Equal Treatment

Dental treatment should be provided without discrimination based on the basis of on patient's gender, racial, religious, or ethnic characteristic. Service to the public includes the delivery of quality, component, and timely care within the bounds of the clinical circumstances presented by the patient.

Professional Esteem

While serving the public, a dentist has the obligation to act in a manner that maintains or elevate the esteem of the profession.

Standard of care

It is unethical for a dentist to render, or cause to be rendered, dental treatment of a quality that falls short of best available scientific evidence.

Informed Consent

Fully informed consent is essential to the ethical practice of dentistry and reflects the patient's right of self –decision. A dentist must get valid consent before starting treatment or physical investigation, or providing personal care, for a patient. Dentists must provide all the information patients need to make their decisions. This involve explaining complex dental diagnosis, prognoses and treatment regimes in simple language, confirming or correcting

information that the patients may have obtained elsewhere (e.g., from another health practitioner, magazines or the internet), ensuring that patients understand the treatment options (including the option of no treatment) advantages and disadvantages of each, answering any questions they may have, and understanding whatever decision the patient has reached and, if possible, the reasons for it.

Any competent mature adult person may fully consent to treatment. A person is considered competent if he/she has sufficient understanding and capacity to make and communicate reasonable decisions. A legally appointed guardian may consent to the treatment for an incompetent adult.

A parent or legally appointed guardian must consent to the treatment for young children and mentally disabled adults. Parents or legal guardians have a right to an explanation regarding the options for behavioral management of children, and are responsible to ask for additional information if they do not understand explanations. Siblings, friends, or any person other than a parent or legal guardian cannot provide consent.

Confidentiality

Dentists are obliged to safeguard the confidentiality of patient records. Dentists shall maintain patient records in a manner consistent with the protection of the welfare of the patient. Upon request of a patient or another dental practitioner, dentists shall provide any information in accordance with applicable law that will be beneficial for the future treatment of that patient.

Refuse of patient treatment

The Dentist may, in non-emergency cases, refuse to treat a patient for justified personal or professional reasons which might compromise the quality of the service rendered to the patient. Provided that such refusal should not cause harm to the patient's health, and that there is another Dentist who could perform the treatment. The justification of such action must be documented and authorized by the higher clinical authority.

Patient referral

When deemed necessary, a dentist having undertaken the care of a patient shall not discontinue that care without notifying the patient and make proper arrangement for continuity of treatment. The dentist should refer the patient in any situation he/she can't provide good quality type of treatment or when he/she feels that another dentist can provide a better service.

Patient should be referred to another dentist specialized in the treatment of the patient condition or to the dentist who has more advanced and effective means if the condition of the patient so requires. The dentist should not delay the referral, whenever such referral is in the best interest of the patient.

- When referring the patient to another dentist, the information which he/she believes necessary for the treatment should be provided.
- When a patient wishes to consult another dentist (in respect of the condition of his disease), the dentist should not refuse fulfilling such wish, but should rather facilitate furnishing the patient with the necessary dental reports and information for such consultation.
- To realize the fact that the patient is entitled for the right of consulting another dentist, and also for the right of obtaining the recorded information in his medical record or the necessary medical report describing the condition of his disease.

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King Saud University College of Dentistry

CODE OF ETHICS FOR RESEARCH IN COLLEGE OF DENTISTRY

Prepared by the CDRC
Revised and modified by the Ethics Unit

2011-2012

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1.0 INTRODUCTION

The College of Dentistry, King Saud University is the one of the dental colleges in the Kingdom of Saudi Arabia and the Gulf Countries that carries the responsibility of educating students, providing oral health services to the patients, conducting research and servicing the community. These responsibilities are conducted under the good ethical principles that guide the educational process in King Saud University.

The Research Center within the College of Dentistry (CDRC) is the product of the University's aspiration of bringing about a more research-oriented institution especially in the area of dentistry. Founded in 1981, its primary goal is the encouragement of viable research Potentials from among the dental professionals in the Kingdom. The Center realizes that this objective can be achieved by extending support to all kinds of research work and providing state-of-the-art equipment complemented by highly trained technical staff in all its laboratories. This report will explain the code of ethics for dental research.

2.0 RESEARCH and ETHICS

The relationship between research and ethics is unique. The practice of research requires ethical principles at the same time ethical principles are needed to guide the good conduct of research.

Research is systematic investigation designed to develop or contribute to generalizable knowledge. Systematic investigation means that there is intention, plan and procedures to be followed in predetermined steps. Contributing to generalizable knowledge means that the results and conclusions will be published and made available to the others to benefit from these results.

2.1 *Purpose of the Code of Ethics*

The purpose of the code of ethics in dental research is to establish a set of codes or principles that should help the dental student, intern staff or researcher to reach a

professional standard, guided by legal and ethical principles. Research ethics is the application of ethical codes or principles in scientific investigation.

2.2 Importance of the code of ethics in dental research

Researchers should be familiar with the code of ethics designed to ensure good conduct and prevent sloppy or irresponsible research. There are several reasons why it is important to adhere to the code of ethics in dental research.

- 1) The code of ethics **promotes the aims of research**, such as knowledge, the truth, and avoidance of error. For example, prohibitions against fabricating, falsifying, or misrepresenting research data promote the truth and avoid error.
- 2) Research often involves a great deal of cooperation and coordination among many different people in different disciplines and institutions, the code of ethics promote the **values that are essential to collaborative work**, such as respect, trust, accountability, and fairness.
- 3) The code of ethics in research for authorship, copyright and patenting, data monitoring, and confidentiality **protects the intellectual property interests** and encourages collaboration. Researchers want to receive credit for their contributions and protect their intellectual property.
- 4) The code of ethics in research **enhances the concept of confidentiality** that most researchers want to receive credit and do not want to have their ideas stolen or disclosed prematurely.
- 5) The ethical codes ensure that the dental researcher is **accountable to the public**. For instance research misconduct, conflicts of interest, human participant protections, and animal care and use are necessary in order to make sure that the researcher can be held accountable to the public.
- 6) The code of ethics in research builds the **public support** for research. The public are more likely to support and participate in research projects if they can trust the quality and integrity of the research.

- 7) Finally, the code of ethics in research promotes a variety of other important **moral and social values**, such as social responsibility, human rights, and animal welfare, compliance with the law, and health and safety.

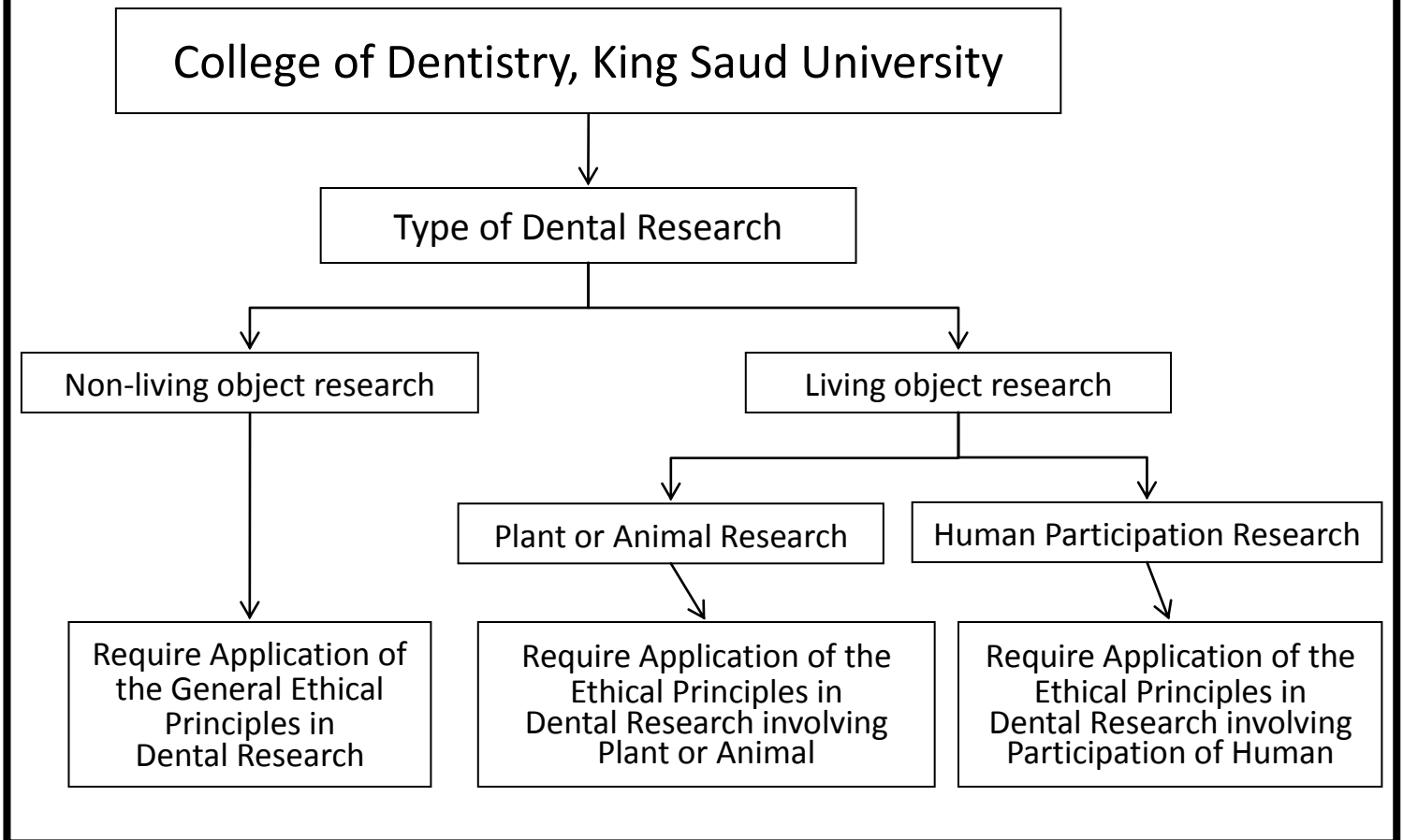
3.0 TYPES of RESEARCH

The custodian of the two Holy Mosques, King Abdullah Bin Abdulaziz Al-Saud gave his royal order numbered 59/M dated 14-9-1431H to implement the system for the ethics of research involving living objects. In accordance with this, the research center College of Dentistry adopted two categories of research:

- 1) The non-living objects category
- 2) The living objects category.

Figure 2 describes these categories.

Fig. (2) Type of Dental Research



Note: Each require should read 'requires'

4.0 **RESEARCH INVOLVING NON-LIVING OBJECTS**

Non-living object research represents a large percentage of scientific research. It is used mainly to test materials and ranges from nano level to larger scale materials. Teaching institutions throughout the world now consider that it is essential for students in the universities and even at school level to perform laboratory research on non-living objects.

4.1 Ethics in Dental Research Involving non-living objects

The dental researchers working in research involving non-living objects will spend most of their time in the laboratories. The dental researcher should be familiar with the basic principles regarding the safety procedures in each laboratory. The dental researcher will use some equipment and machines to perform the research so it is necessary to understand their operation and the safety procedures regarding the hazardous materials. He should learn how to deal with the personnel and technicians he will meet on a daily basis and learn how to fit his time with their schedule and respect arrangements made by others.

4.2 Code of ethics in Dental Research Involving non-living objects.

The code of ethics adopted by the College of Dentistry Research Center for the dental research are applicable to the dental research conducted by students, interns, academic or clinical staff, or affiliated researcher of the College of Dentistry, King Saud University. This is true regardless of the location where the research is conducted. The general code of ethics in dental research includes and is not limited to the following:

1. **Legality:** Legal, scientifically sound and ethical conduct of dental research.
2. **Honesty:** Honest thinking and conduct of dental research from start to finish.
3. **Respect:** Self-respect and respect to individuals, property and agreements.
4. **Responsible:** Responsible person and responsible conduct in dental research.
5. **Competence:** Professional competence in conducting, promoting and mentoring dental research.
6. **Objectivity:** Objective, unbiased, clear interests in dental research.
7. **Carefulness:** Careful performance, avoid careless errors and negligence.
8. **Confidentiality:** Protect the requirements of confidential communications.
9. **Openness:** Open attitude and openness to criticism and new ideas.
10. **Integrity:** Act with sincerity and consistency of thought and action.
11. **Safety:** Proper and safe procedures in dental research and disposal of waste products.

These general codes are required for the good conduct of research, however conducting research on living objects require additional codes of ethics that are specified for each category.

5.0 RESEARCH INVOLVING NON-LIVING OBJECTS, PLANTS or ANIMALS

The use of plants in dental health is related to the beginning of human beings. Plant material was used for the relief of pain and symptoms from orofacial structure. The use of plants, utilizing scientific method and planned research, in dentistry resulted in the development of known medications and anesthesia.

The use of animal in scientific research formed a lifeline for medical and dental research and played a vital role in the development of human health sciences. The use of laboratory animals in Scientific Research began about 100 years ago, when vaccines for polio and rabies came up for production. Since then, animals have been used in research investigation and have played an important role in discovering vital information that helped in the advancement of medicine and dentistry. The use of animals in dental research is inevitable and cannot be abandoned in the interest of human dental health.

5.1 Ethics in Dental Research Involving Plants or Animals

The dental researcher working in research involving plants and animals should be deeply concerned about the rationale and the humane use of plant resources and animals in research. Careful consideration of ethical principles and sound scientific planning are the basis for justifying the use of plants and animals in dental research. The consideration of the greenery resources of the plant and the reservations of such resources are essentials in the good conduct of research. The conservation of the environment and the safety of the sample including animals and humans in research and the avoidance of the toxic effects of the plant are ethical principles in research.

5.2 Code of ethics in Dental Research Involving Plants or Animals

The code of ethics adopted by the College of Dentistry Research Center for the dental research involving plants and animals are in addition to the general code of ethics in dental research stated in part 4.2, they are applicable and not limited to the dental research involving animals conducted by students, interns, academic or clinical staff, or affiliated researcher of the College of Dentistry, King Saud University. This is true regardless of the location where the research is conducted. The codes of ethics in dental research involving animals are:

- 1) Respect for the animal. The ethics of animal experimentation is based on the humane respect to animals as living and sensitive objects.
- 2) Responsibility. The use of animal for experimentation is an ethical responsibility of each individual involved in dental research. The College of Dentistry, King Saud University is the responsible institution for the experiments carried out on animals within its premises and authorization.
- 3) Skills. It is mandatory that technicians involved in dental research with animals have appropriate skills and training

5.3 Consideration for Use of Animals in Dental Research

The use of animals for dental research must be preceded by careful consideration of:

1. Animal experiments should be undertaken only after due consideration of their relevance for human health and the advancement of knowledge.
2. The selected animals for the experiment should be of an appropriate species and quality.
3. Minimum number of animals should be used to obtain scientifically and statistically valid results.
4. Investigators and other personnel should treat animals with kindness and should take proper care by avoiding or minimizing discomfort, distress or pain.
5. Investigators should assume that all procedures which would cause pain in human beings may also cause pain in animals.

6. Procedures that may cause more than momentary pain or distress should be performed with appropriate sedation, analgesia or anesthesia in accordance with accepted veterinary practice.
7. Surgical or other painful procedures should be performed under anesthesia.
8. At the end of the experiment, or when appropriate during an experiment, the animal that would otherwise suffer severe pain, distress, discomfort, or disablement should be painlessly killed under anesthesia.
9. The care of animals should be under the supervision of a veterinarian or a person having adequate experience in laboratory animal care.
10. The best possible living condition should be provided to animals used for research purpose.
11. It is the responsibility of the investigator to ensure that personnel conducting experiments on animals possess appropriate qualifications or experience for conducting the required procedures.
12. Adequate opportunities have to be provided by the institution for in-service training for scientific and technical staff in this respect.
13. In-vitro systems to replace or reduce the number of animals should be used wherever possible.

6.0 RESEARCH INVOLVING HUMAN PARTICIPANTS

The development of a code of ethics in research involving human participation is comparatively recent. The first international code of ethics for research involving human participants, the Nuremberg Code, was issued in 1947 and laid down standards for carrying out human research, emphasizing the voluntary consent. In 1964 the World Medical Association adopted the Declaration of Helsinki, most recently revised in 2010, requiring that the proposed research on humans should be approved by a committee. The Belmont report published in 1979 forms the basis of all human research regulation. The report sets three basic ethical principles, respect for persons, beneficence, and justice. These principles are accepted internationally as the three essential requirements for ethical conduct of research involving human participants. Most

recently, the Council for International Organizations of Medical Sciences (CIOMS), working with the World Health Organization, issued the third edition of biomedical research ethical guidelines in 2002 which feature recommendations on ethical review committees and the issue of safeguarding confidentiality.

6.1 Definition

Human participant is a living human being participating in a dental research project from which a researcher can obtain data through (1) intervention (2) interaction (3) private information. Intervention includes dental procedures and/or manipulations of the environment for research purposes. Interaction includes communication or interpersonal contact between the dental researcher and the human participant. Private information includes information that is individually identifiable and not expected to be made public. Private information is identifiable when the identity of the human participant must be exposed or associated with the collected information. Thus, an interaction with or an intervention involving a living human being happening within the context of research experimentation must be in compliance with the ethical principles within the Kingdom of Saudi Arabia. The ethical principles that govern human subjects research apply no matter where, with what populations, and how the research is being conducted. All researchers should assure that their research methods maintain these principles and maximize human subjects' protection. Beyond these ethical principles are rules and laws that govern research.

6.2 Ethics in Dental Research Involving Human Participants

The dental researcher should strive for the ethical principles that identify good, desirable and acceptable conduct of research involving human participant. The researcher should protect the welfare and rights of research participants, and reflect the basic ethical values of respect, beneficence and justice for human.

6.3 Code of ethics in Dental Research Involving Human Participants

The codes of ethics in Dental Research Involving Human Participants are in addition to the general code of ethics in dental research stated in part 4.2, they are applicable but not limited to dental research conducted by students, interns, academic or clinical staff, or affiliated researcher of the College of Dentistry, King Saud University. This is true regardless of the location where the research is conducted. The codes of ethics in dental research involving humans are:

- 1) Respect for persons incorporates at least two fundamental ethical considerations, namely:
 - a. Respect for autonomy which requires that those who are capable of self-determination about their choices should be treated with respect for their capacity of self-determination.
 - b. Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded full security against harm or abuse.
- 2) Beneficence and non-maleficence refers to the ethical obligation to maximize benefits and to minimize harms. This gives rise to norms requiring the risks of research to be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent to conduct the research and to safeguard the welfare of the research subjects.
- 3) Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper; to give each person what is due to him or her. In the ethics of research involving human participants, the principle refers primarily to distributive justice, which requires equitable distribution of both the burdens and the benefits of participation in research.

6.4 Establishment of the Dental Ethics Review Board (DERB)

The Dean of the College of Dentistry, King Saud University is responsible for establishing the Dental Ethics Review Board (DERB) to review, approve and monitor research that involves human participants. The DERB consists of a chairman and members from the different specialties within the College of Dentistry.

6.5 Authorities of the Dental Ethics Review Board (DERB)

DERB has the obligation to ensure that dental research is designed and conducted in such a manner that the rights and welfare of participating human subjects is well protected. The authorities of the DERB are the following:

- Determination of the level of review required for the presented research proposal. This is, the authority of the DERB chairman.
- Review, approve, and request modifications of a research proposal
- Restrict or omit steps or parts of a research proposal for participants' protection.
- Follow-up of the approved research by conducting continuing ethical review for ongoing research at an appropriate interval.
- Inspect research facilities, equipment, and data and other relevant information relating to the use of human participants in dental research
- Observe or have a third party observe the informed consent process.
- Suspend or terminate previously approved research that is not being conducted in accordance with the DERB's required standards
- Suspend or terminate previously approved research that is associated with unexpected serious harm to participants.
- Review, accept, and/or reject reports, including but not limited to reports of serious adverse events and unanticipated problems involving risks to subjects and others.
- Disapprove a research proposal that is expected to cause serious harm to participants.

- Approve the inclusion of the college member in other research teams within or outside the premises of King Saud University.
- Research that has been reviewed and approved by the DERB may be subject to disapproval by King Saud University officials or higher authorities.
- King Saud University officials may not authorize or approve the conduct of dental research involving human participants that has not been approved by the DERB.
- Research approved by the DERB may be subject, if requested by King Saud University officials or higher authorities, to further review and approval or disapproval by officials of the institution.
- Members are expected to treat as confidential all applications, meeting deliberations, information on research participants/volunteers and related matters.
- When a committee member believe that he/she has a conflict of interest on a subject which will compromise his/her ability to make a decision, he/she should declare that conflict of interest and withdraw him/herself from the discussion and/or decision making.

The DERB has the mandate to act as an independent entity within the College of Dentistry, King Saud University. As such, the DERB is the final authority for all decisions regarding safeguarding the rights and welfare of humans who are subjects of dental research conducted under the auspices of the University.

6.7 Types of Review

A dental research proposal involving human participation is reviewed initially by the DERB chairman to determine the appropriate level of review. The level of review is determined by the probability and magnitude of expected risk to the human. **Risk** is defined as the harm or injury that is expected to occur to the human resulted from

participating in the planned dental research. The probability of risk may vary from no or minimal risk to significant.

6.7.1 Minimal Risk

Minimal risk is defined as follows: "The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." For example, the risk of bleeding during the examination of gingival pocket depth in a healthy human participating in dental research is not greater than the risk of bleeding in a routine gingival examination of a healthy human. The risks of psychological, social, or economic harm are difficult to assess in dental research. However, unethical breaches of confidentiality such as HIV infection status or drug and alcohol intake can place the human participating in dental research at the risk of damage to their employability, or reputation. Many risks can be minimized considerably with careful planning.

In broad terms, a project involves minimal risk if:

- 1) The participant experiences no pain or physical danger.
- 2) The participant experiences no emotional arousal or psychological stress beyond the levels normally to be expected in everyday life.
- 3) The project neither includes nor attempts to induce long-term significant change in the participant's behavior (including attitude towards self and others).
- 4) The data would not embarrass or socially disadvantage the participant, were confidentiality to be violated.
- 5) If the investigator conceals information about specific purpose of the project, there is no reason to believe the subject would choose not to participate if he or she had known that information initially.

6.7.2 Determining the Level of Review

There are three levels of review for a research proposal depending on the risk expected to the human participating in the planned research. The three levels are:

- (1) Full Dental Ethical Board Review.
- (2) Exempt from the full dental ethical board review.
- (3) Expedited from the full dental ethical board review.

6.7.2.1 Full Dental Ethical Board Review

Any protocol that uses a methodology that is sensitive and of higher probability for causing harm or distress to participants is subject to full board review. Additionally, any protocol using prisoners as participants or involving pregnant women, fetuses, and human in vitro fertilization will be reviewed by the full board. Research in which the risks versus the expected benefits are relatively high is also likely to be reviewed by the full board.

Dental research proposals that require full dental ethical board review included, but are not necessarily limited to the following:

- 1) Clinical trials involving human participants
- 2) New treatments or interventions
- 3) Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta), biological fluids
- 4) Physiological studies
- 5) Comparing an established procedure, whether therapeutic, non-therapeutic or diagnostic, with other procedures which are not recognized as established by virtue of their recent development, discovery or use in a new or unfamiliar way
- 6) Innovative practices in health and disability services
- 7) Research conducted by students, which includes all activities that meet the definition of research with human participants (As supervised student research is conducted primarily for the purpose of educating students on research techniques and methodologies, DERB should review research protocols with a view to

- contributing to the students' education concerning scientific and ethical principles governing research).
- 8) Observational clinical research
 - 9) Access to personal information by means of questionnaires, interviews or other techniques of information gathering
 - 10) Research involving the secondary use of data (use of data not collected for that research purpose), if any form of identifier is involved and/or if health information pertaining to individuals is involved
 - 11) Case studies, when a series of subject observations allow possible extrapolation of generalization of the results from the reported cases and when there is intent to publish or disseminate the data.

6.7.2.2 Exempt from the full ethical board review

The determination of which proposals will be exempt from the full ethical board review is the sole authority of the DERB chairman. The exempt status of a research proposal means that the proposed protocol for the dental research is exempt from full authority of the DERB in research involving the participation of the human. Any change in the protocol of the approved proposal must be re-submitted to the DERB chairman to determine further exempt status. The dental researcher must submit to the DERB secretary the full documentations required for the review by the DERB, including the research proposal, informed consent and the CV's of the investigators.

To determine exempt status, the research must qualify as one or more of the categories listed below. To qualify for a category, the research must meet all of the conditions of that category.

1. Research conducted in established or commonly accepted educational settings involving normal educational practices such as (a) regular and special education

- instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving use of educational tests, survey or interview procedures, or observation of public behavior *unless* information obtained from these sources is recorded in such a manner that subjects can be identified, *and* disclosure of the subject's responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to his or her financial standing, employability, or reputation.
 3. Research involving the use of education tests, survey procedures, interview procedures, or observation of public behavior *if* (a) the human subjects are elected or appointed public officials or candidates for public office; *or* (b) federal statutes require, without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. Children *may not* be involved in this research.
 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, (a) *if* these sources are publicly available, or (b) *if* the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
 5. Research and demonstration projects that are designed to study, evaluate, or otherwise examine (a) public benefit or service programs; (b) procedures for obtaining benefits or services under these programs; (c) possible changes or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payments for benefits or services under those programs.
 6. Tests and food quality evaluation and consumer studies (a) if wholesome food without additives is consumed, or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

6.7.2.3 Expedited from the full ethical board review

The determination of the expedited status for any research proposal is the authority of the DERB chairman. A dental research proposal eligible expedited from the full ethical board review means that the proposed dental research is to be reviewed by a single member of the DERB panel. The single member is designated by the DERB chairman. Like the exempt review, the research must be of minimal risk or no more than minimal risk and all aspects of a protocol must fit within one or more expedited categories to be reviewed in this manner. The dental researcher must submit to the DERB secretary the full documentations required for the review by the DERB, including the research proposal, informed consent and the CV's of the investigators.

An expedited review process is available for research activities that present no more than **minimal risk** to human participants **or** that request a minor change in previously approved research that involves no additional risk **and** that involve only procedures in one or more of the categories listed below. Some of the categories overlap with those used to assess exempt status. The distinction between exempt and expedited review is based on the sensitivity of the data and/or the risk of compromised confidentiality (such as a relatively small sample size).

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. Furthermore, the expedited review procedure may not be used for classified research involving human participants.

To determine expedited status, the research must qualify as one or more of the categories listed below. To qualify for a category, the research must meet all of the conditions of that category.

1. Clinical studies of drugs and medical devices. (a) Research on drugs where the application for investigation of new drug is not required. (b) Research on medical devices where; (i) the application for investigation of new medical device is not required, (ii) the medical device is cleared/approved for marketing. Examples: Review of dental implant results to assess for indicators of successful outcome.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture. Example: (i) Measurement of CRP levels before and after treatment for gingivitis. Requires 10 mL of blood drawn twice over a 3-month period.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) deciduous and permanent teeth if routine patient care indicates a need for extraction; (b) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (c) supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (d) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (e) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures routinely employed in dental clinical practice, excluding procedures involving x-rays. The medical/dental devices employed must be cleared/approved for marketing. Example: Analysis of measurements of blood pressure and heart rate using an automated blood pressure monitor every 10 minutes during tooth extraction, a comparison between routine local anesthesia and routine local anesthesia with hypnosis.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes. Example: (i) Prospective review of dental records to determine the outcome of standard treatment of oral ulcers in HIV-positive patients. (ii) Review of medical records and pathology samples of patients with parotid tumors to determine predictors of malignancy.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Examples: (i) Survey of children in a Headstart program to determine knowledge about dental care. (ii) Focus group of multiple ethnic groups to determine attitudes and practices about oral health.
8. Continuing review of research previously approved by the full DERB review as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the DERB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

6.8 Conflict of Interest

Dental researchers hold trustful relationships with research participants, research sponsors, their institution, professional bodies and society. This trust can be put at risk by a conflict of interest that influences their independent and objective judgment.

Conflict of Interest is when the professional judgment concerning research is influenced by a secondary interest such as personal or financial gain. The dental researchers and DERB members should disclose any actual, perceived or potential conflicts of interest to the DERB. The DERB should develop mechanisms to address and manage such conflicts of interest.

6.9 Informed Consent

Informed consent means that a participant has been informed about the risks and benefits of the research, understands such risks and benefits and is able to give consent to participation, without coercion, undue influence or inappropriate incentives. It represents a signed agreement between the dental researcher and the human participant or their legally authorized representative to participate in the research before the start of the research. The informed consent process should provide the necessary information to the participants in simple, clear language that they understand and in terms they comprehend. It should provide the freedom of choice, the respect of participant's autonomy, the voluntariness to participate and the protection of privacy and confidentiality. The information is given in a document known as the Informed Consent Form.

The informed consent form should have the following as may be applicable:

- 1) Nature and purpose of study, stating it as research.
- 2) Duration of participation with number of participants.
- 3) Procedures to be followed.
- 4) Investigations, if any, to be performed.
- 5) Foreseeable risks and discomforts adequately described and whether the project involves more than minimal risk.
- 6) Benefits to participants, community or the dental profession as may be applicable.
- 7) Policy on compensation.

- 8) Availability of dental or alternative treatments if available for injuries or risk management.
- 9) Steps taken for ensuring confidentiality.
- 10) Freedom to withdraw without any consequences or loss of benefits.
- 11) Contact details of researchers for seeking more information related to the research or in case of injury.
- 12) Contact details for appeal against violation of rights.
- 13) Voluntary participation.
- 14) If test for genetics and HIV is to be done, counseling for consent for testing must be given as per Kingdom of Saudi Arabia guidelines.
- 15) Storage period of biological sample and related data with choice offered to participant regarding future use of samples, refusal for storage and receipt of its results.

A copy of the informed consent form should be given to the participant for personal record. Note; in the UK we call the above 'the patient information leaflet' the last page of which being where the signatures of patient and consent taker are required

6.9.1 Re-consent

Re-consent is taken in following conditions:

- 1) Availability of new information that necessitate changes in the research protocol.
- 2) When a research participant regains consciousness from an unconscious state or become mentally competent to understand the study.
- 3) Follow-up of the results of previous research.
- 4) Not finished research that requires extension of the allowed time.
- 5) When there is a change in treatment modality, procedures and site visits.
- 6) Before publication if there is possibility of disclosure of identity through data presentation or photographs that should be camouflaged adequately.

6.9.2 Waiver of consent

Voluntary informed consent is a requirement for any research proposal that involves human participation. However, there are situations when the requirements for informed consent can be waived. If it is justified that the research involves not more than minimal risk or when the participant and the researcher do not come into contact or when it is necessitated in emergency situations. If such studies have the appropriate protection for both privacy and confidentiality, and do not violate the rights of the participants then the DERB may waive the requirement for informed consent in the following instances:

- a) When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout the research.
- b) Research on publicly available information, documents, records, works, performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies.
- c) Research on anonymised biological samples from left over samples after clinical investigation.
- d) In emergency situations when informed consent can be taken. Do you mean cannot be taken? (yes cannot, but I think we need to define the emergency situations)

7.0 Research Participants Requiring Additional Attention

Humans with limited autonomy or in subordinate positions are considered participants that require additional attention and are in need of greater protection. These may include children, pregnant women and fetus, prisoners, and human highly dependent on medical care. Does this cover mentally impaired people?

7.1 Research involving children, adolescents and mentally impaired people

Dental treatment and research on children, adolescents and mentally impaired person is part of the dental discipline. A child is a person who has not yet reached puberty

whereas an adolescent is a person who is reaching or has reached puberty. Mentally impaired person is a person who has impairment of intelligence and social functioning which appears to be permanent or temporary. Children, adolescents and mentally impaired person are considered participants who require additional attention because of their limited intellectual and emotional capacities. They cannot give a legal consent; therefore permission from the parent(s) is essential. Children, adolescents and mentally impaired person should participate in research only where their participation is indispensable to the research and where participation is not contrary to the individual's best interests. The research proposal must provide sufficient information to justify clearly why children, adolescents or mentally impaired person should be included as participants. Refusal of a child, adolescent or mentally impaired person to participate in the research must be respected.

7.1.1 Approval of research involving children and adolescents

Research involving a child, adolescent or mentally impaired person should be approved only if:

- 1) The research, including observational research, places the child , adolescent or mentally impaired person at no more than minimal risk (that is, the risk commensurate with daily life or routine dental examinations – referred to as 'negligible risk' in some guidelines).
- 2) The research involves more than minimal risk but provides possible benefit for the child, adolescent or mentally impaired person participant. The degree of risk must be justified by the potential benefit.
- 3) The research involves greater than minimal risk, with no prospect of direct benefit to the child, adolescent or mentally impaired person, but has a high probability of providing significant knowledge. The risk should be justified by the risk-knowledge ratio and the risk must represent no more than a minor increase over minimal risk.

7.1.2 Consent for children or adolescents

Consent for children, adolescents or mentally impaired person to participate in research must be obtained from:

- a) The parents or legal guardian in all but exceptional circumstances such as emergencies.
- b) The child or adolescent that is competent to make the decision.
- c) Any organization or person required by authorization.
- d) No other caregiver can act on behalf of a child in providing consent to participate.

7.2 Research involving pregnant women

The DERB must give extra attention to research that involves pregnant women or those who may become pregnant, because of the additional health concerns during pregnancy and the need to avoid unnecessary risk to the fetus. The policy of the college of dentistry research center is that; no pregnant woman may be involved as a participant in any dental research activity unless:

- The purpose of the research is to meet the health needs of the mother and the fetus will be placed at no risk, or
- The risk to the fetus is minimal.

The DERB should consider the following regulatory protections before approval of the research proposal.

- Appropriate studies conducted on animals and non-pregnant women have provided data for assessing potential risks.
- Risks and prospects of benefit to the fetus and mother (separately or together) and the purpose of the research have been determined.
- Any risk is the least possible for achieving the objectives of the research.

The research activity may be permitted to be conducted only if the mother is legally competent and has given informed consent after having been fully informed about the possible impact on the fetus. The father's informed consent needs to be secured if the research has any risk to the fetus.

7.3 Research involving a fetus

Dental research usually do not involve fetuses as participants, however, in research involve investigations on the craniofacial malformations such as cleft lip and palate the dental researcher may be involved as a member of a larger research group including medical researchers. The dental researcher must abide by the ethical codes and the regulatory procedures of the medical research team.

The policy of the Research Center College of Dentistry for the dental research involving fetus is that; no fetus in utero may be involved as a participant in any dental research activity. The inclusion of any member of the college of dentistry in research activity involving fetuses as a member of larger team must be approved by the DERB. The approval of the DERB must be granted before the member start any research activity within the research team.

7.4 Research involving Prisoners

A Prisoner is an individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities such as treatment of addiction. The condition of imprisonment may make it difficult to ensure voluntary consent and confidentiality. There is a need for special consideration to provide protection to prisoner participating in research. The college of dentistry research center policy requires that all dental research involving prisoners should be reviewed by the full board.

7.4.1 Considerations regarding research involving prisoners

The DERB will approve research proposals involving prisoners if:

1. Research will probably improve oral health or well-being of the prisoners.
2. Minimal risk and no more than inconvenience caused and the research is a study of causes and effects.

3. Minimal risk and no more than inconvenience caused and research is a study of prisons as institutional structures or of prisoners as incarcerated persons.
4. Research on conditions affecting prisoners as a class.

7.4.2 Approval of research involving prisoners

- 1) Advantages through participation compared to their current situation.
- 2) Risk of participation is the same as those that would be accepted by non-prisoners.
- 3) Procedure of selection is fair to all prisoners.
- 4) Language for obtaining informed consent must be understandable to prisoners.
- 5) When studies need follow-up, the provision for follow-up must include a consideration of the length of individual sentences, and prisoners must be informed about follow-up.

7.5 Research involving humans highly dependent on medical care

Dental research on humans who are highly dependent on medical care raises ethical issues that deserve special attention. Researchers need to acknowledge that informed consent may be compromised by the effect of the medical condition or fear of affecting the level of medical care in case of refusal to participate. The following conditions are considered for possible dental research activities.

1. Research activities on humans under emergency care
2. Research activities on humans in the intensive care unit
3. Research activities on neonatals in the intensive care unit
4. Research activities on humans in the terminal care unit
5. Research activities on decisionally impaired humans
6. Research activities on unconscious human

The policy of the college of dentistry research center is that; no dental research should be carried out on the above mentioned conditions. However, The DERB, within its authority can approve dental research in the following conditions;

- The research is based on valid scientific hypotheses which support a reasonable possibility of benefit over standard care.
- The research is intended to be therapeutic and the research intervention poses no more than a risk that is expected in alternative methods of treatment.

7.6 Other groups requiring additional attention

The discussion of the dental research participants requiring additional attention should not be limited to those already mentioned. Other groups that require additional attention include: traumatized and comatose patients, terminally ill patients, elderly or aged patients, minorities, students, and employees. The DERB must ensure that special consideration is given to all these groups, especially with regard to the risks, benefits and obtaining informed consent.

8.0 EPIDEMIOLOGICAL RESEARCH

Epidemiological research describes the health status in a population or subgroup of the population. Epidemiological research studies the distribution and determinants of health related problems in populations, and the application of the research results to prevent, control or eliminate such health problems. It is concerned with improvement of the health status and welfare in human populations and with the improvement in the efficiency and performance of health services. Epidemiological research is carried out with human participants, or data or biological samples from them, and such research provides important new knowledge that is not readily obtainable in other ways. Perhaps the second most significant dental discoveries, after local anesthesia, were the effects of naturally occurring fluoride on reducing the incidence of dental caries as revealed by epidemiological research. Such epidemiological studies provided the motive for several clinical and laboratory research studies on the relationships between fluoride and dental caries. The findings from these researches laid the ground for the current understanding of the relationship between fluoride and oral disease.

The main objective of epidemiological research is to collect information in order to throw light on the nature and occurrence of disease, and to suggest hypotheses that may be tested later through other research. Dental health problems suitable for epidemiological research include

The measurement of dental disease prevalence and incidence within the population of Saudi Arabia,

The identification of oral health care needs within the population of Saudi Arabia,

The establishment of baseline information regarding the Saudi's oral health and disease status, and

The development and evaluation of various disease control procedures within the population of Saudi Arabia.

The policy of the College of Dentistry Research Center is to encourage such epidemiological research that is expected to result in the prevention, control or elimination of dental diseases and oral health problems, such as caries, malocclusions, TMJ problems, oral cancer and other oral health related problems. Such research usually has priority in support and funding because of the expected local and national impact. The DERB should approve research proposals of dental epidemiological research provided that the ethical principles of respect, informed consent, confidentiality, and publication of the information are well covered.

9.0 Human genetic research

Dental researches on human genetics involve the study of the inheritance pattern of the dento-facial trait and characteristics. Participation of families rather than individuals is required for genetic research studies. Genetic research enhances our understanding of how genes and environmental factors interact to influence the health of individuals and communities. Genetic research can reveal information about an individual's susceptibility to disease and future

health. Such information may be of interest and benefit to research participants, especially where preventive strategies exist.

In addition to ethical considerations applied to all research involving humans, there are ethical issues unique to genetic research. They arise from the nature of the information which may be shared with other family members and with unrelated individuals in the population. Research results may be of significance to the health of blood relatives and others not participating in the research. Individuals may have an interest in the genetic information that may create new options for life decisions. Participants may be at risk of harm, including unfair discrimination or exclusion. The results of genetic information about future health could be used, potentially, by third parties such as insurance companies and employers.

Researcher must recognize that obtaining informed consent and the collection of genetic information from families require specific attention. The researcher must abide by the policy to protect the privacy, confidentiality, storage and publication of genetic information. The DERB within its authority should not approve any proposal for dental research study if it might lead to a potential harm to participants, and if the competence and qualification of the researcher or any member of the research team is in doubt.

10.0 Human tissue samples

Dental research on human tissue sample, blood and saliva include research on the various aspects of oral health such as oral cancer and the effect of smoking to the oral tissue. The CDRC Histopathology laboratory receives biopsies from dental clinics and other research centers for processing of the specimens. The histopathology laboratory collected over the last 26 years large numbers of biopsy specimens and research slides that is estimated around 25,000 human tissue samples. 50% of these human tissue samples are biopsy cases that come from the dental clinic at King Saud University and other clinics and hospitals. They are filed according to the histopathology laboratory number assigned for each biopsy case per year. The other 40% are research cases that come from researchers from the college and other provinces of Saudi

Arabia. Most of the research cases are animal research including soft tissue, hard tissue, teeth and bone. The remaining 10% of the human tissue samples are teaching slides and filed according to the microscopic diagnosis. The CDRC histopathology lab follows a very strict policy regarding receiving, processing, handling and storage of human tissue samples. The CDRC histopathology laboratory abides by very strict policy regarding the communication and dissemination of the information of human tissue samples.

The CDRC histopathology laboratory is a bank of human tissue samples that can be considered as a main resource for researchers interested in such kind of studies. The dental ethics review board should approve research proposals providing strict adherence to the ethical principles of confidentiality and privacy of the information in addition to the other code of ethics for dental researchers.

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