



PM&DC
Professional Ethics and Code of
Conduct

Table of Contents

Section 1: Introduction to Professional Ethics and Code of Conduct

1. Introduction	8
2. Purpose	8
2.1. What Is the ‘Professional Ethics and Code of Conduct’?	8
2.2. Why to Have the Code of Conduct?.....	8
2.3. Who Needs to Follow the Code of Conduct?.....	9
2.4. Who is it for?.....	9
2.5. What Are the Code of Conduct Requirements?	9
3. Upholding Standards of Professionalism, Integrity and Quality	9
4. Standards of Professionalism in dealing with the patients	10
5. Standards of Integrity for the process of dealing with the patients	11
5.1. Individual Integrity	11
5.2. Respect for the Freedom and Privileges of Others	12
5.3. Statement of Non-Discrimination	12
5.4. Gender Harassment	12
6. Standards of Quality	13
6.1. Freedom of Expression and for continuous professional development.....	13
6.2. Protest.....	13
6.3. The Teaching of Medical Ethics.....	13
6.3.1. Proposed methodology.....	13
6.3.2. Mechanism to support the teaching of Medical Ethics	14
6.4. Membership in Relevant Medical Societies.....	14
6.5. Attending conferences for continuous professional development	14
7. Standards of Confidentiality and Privacy of Information	14
8. Standards of Disclosing Conflict of Interest and Commitment	15
8.1. Respecting available Resources	15
8.2. Complying with the Law.....	15
8.2.1. Environmental Health and Safety, including Workplace Health and Safety.....	15
8.2.2. Communication Policies.....	15
9. Standards of Appropriately Reporting Suspected Violations	16
10. Procedures for Review of the Code	16
11. Whom to Contact with Questions?	16

Section 2: A Brief Historical Background and Key Principles of Medical Ethics

1. Introduction to Medical Ethics	18
1.1. What is Ethics: A Historical Perspective	18
1.2. What does it do?	18
1.3. How does it work?	18
2. Principles of Medical Ethics	19
2.1. Respect for Autonomy	19
2.2. Non-maleficence	19
2.3. Beneficence	19
2.4. Justice	19

Section 3: Principles of Medical Ethics in Social Context

1. Jurisdiction	21
2. Oath	21
2.1. Allegiance to the profession	22
2.2. Implementation	22
3. Principles of Medical Ethics	23
3.1. General Principles	23
3.2. Applicability of Medical Ethics	23
3.3. Framework for Ethical Decision Making	24
3.4. Medical Professionalism	25
4. Social Contract	26
4.1. Reciprocal relationship between Medicine and Society	26
4.1.1. Society's Expectation from the profession of Medicine	26
5.1.2. Medical profession's Expectations from Society	26
4.2. Legal and Moral Obligations	27
5. Social Justice	27
5.1. Access to Care	27
5.2. Allocation of Resources	27
5.3. Patient engagement and shared decision making	27
6.4. The consent	28

Section 4: Patient Centeredness

1. The duties of a doctor registered with PM&DC.....	30
2. Ethical Standards of Professional Competence, Care and Conduct:	30
3. Maintaining good medical practice: Knowledge, Skill and performance:	31
3.1 Maintaining and improving performance by updating knowledge and skills.....	31
3.2. Application of Knowledge and Experience for Patient’s benefit	31
3.3. Maintenance of Patient Records (Clarity, Regularity, Legibility):	32
3.4. Teaching and training, appraising and assessing:	32
4. Safety and Quality.....	33
4.1 Response to patient safety risks	33
4.2. Contribute to and comply with systems to protect patients.....	33
4.3 Protection of patient and other colleagues from Practitioner's health risks	33
4.4. Effective Communication.....	34
5. Conduct: Communication, Partnership and Team work	34
5.1. Collaboration with Colleagues for improved patient care.....	34
5.2. Conduct and performance of colleagues.....	35
5.3. Mutual Respect and Safeguarding Patient’s Dignity & Patient Rights.....	35
5.3.1. Correct information about his/her health condition:	35
5.3.2. Decision making about his/her health:	35
5.3.3 Dignity and Respect:.....	36
5.3.4. Second Opinion:	36
5.3.5 Patient Satisfaction:	36
5.4. Professional Trustworthiness.....	36
5.5 Performing Procedures on the Recently Deceased:	36
5.6. Continuity of Care	37
6. Care: Establishment and Maintenance of Trust	38
6.1 Children and young people	38
6.2. Relatives, carers and partners	38
6.3. Being open and honest with patients if things go wrong	38
6.4. Maintaining trust in the profession	39
7. Confidentiality-good practice in handling patient information:	42
7.1. Ethical and legal issues of confidentiality:	42
7.2. Ending professional relationship with a patient:	43

8. Writing reports and CVs, giving evidence and signing documents	43
9. Financial and commercial dealings.....	44

Section 5: Disciplinary Issues and Working with other health care Professionals and Community

1. Disciplinary Issues and Its Management Process	47
1.1. Introduction to PM&DC disciplinary committee	47
1.2. Adverse Events.....	47
1.3 Good Faith Reporting of Suspected Wrongdoing	48
1.4 Complaints by the Patients or families:	48
1.5 Process for Initiating Complaints	48
1.6 Constitution of the Disciplinary Committee	48
2. Advertisement and Social Media	49
3. Self-Regulation of the Profession	49
4. Working within Health Care System.....	50
4.1. Prudent Use of Health Care Resources:.....	50
4.2 Health Advocacy:	50
4.3 Public Health:.....	51

Section 6: The Ethical Issues relating to Research

1. Medical Research	53
1.1. Scope/Over review.....	53
1.2. Approval from Institutional Review Board & Ethics Committee/National Bio	53
1.3. Research Ethics	53
1.4 ICH/GCP Compliance.....	54
1.5 Registration of research (Trials.gov, DRAP)	54
1.6 Informed Consent Elements	54
1.6.1 Complete Elements of Informed Consent	55
1.6.2 “Waiver”:.....	56
1.7 Insurance/Indemnity.....	56
2. Research Vulnerabilities	56
2.1 Research on Infant/children/teenager/adult	56
2.2 Research on Pregnant Women	57
2.3 Vulnerable Population	57

3. Research Funding	57
3.1 Sponsored Research.....	58
3.2 Non Sponsored Research	58
4. Regulatory Issues	58
4.1 Observational Studies	58
4.2 Experimental/Analytical Studies	58
5. Research Misconduct	58
5.1 Fraud	58
5.2 Biasness.....	58
5.3 Kick back.....	58
5.4 Bribery.....	58
7. Research Medium	59
7.1 Clinics (Personal, Combined, Private)	59
7.2 THQ, DHQ, Poly Clinics/Equivalent	59
7.3 Hospital Clinics	59
7.4 Telemedicine/Using Electronic medium (any).....	59
8. Disclosure of Research Information.....	59
8.1. Legal/regulatory agencies	60
8.2. Outbreak of communicable disease	60
8.3. Patients families, colleagues	60
8.4. Hospital/health care Professionals	60
8.5. Sponsors/Other Competent Authority	61

List of Abbreviations

- 1 ICH-GCP (International Conference on Harmonization-Good Clinical Practice)
- 2 PM&DC (Pakistan Medical and Dental Council)
- 3 IRB&EC (Institutional Review Board and Ethics Committee)
- 4 NBEC (National Bioethics Committee)
- 5 DRAP (Drug Regulatory Authority of Pakistan)

SECTION 1

Introduction to Professional Ethics and Code of Conduct

Standards of Professionalism in Dealing with the Patients

This section deals with the introduction, applicability and need for having Professional Ethics and Code of Conduct. Moreover, it presents the standards of professionalism in dealing with the patients, other healthcare professionals and public.

1. Introduction

As a regulatory body, the Pakistan Medical and Dental Council (PM&DC) feels responsible for upholding the highest ethical standards in the community of health care providers. The PM&DC values professionalism, integrity, quality, fairness, and endeavors to assimilate these values into its working, communication and regulation activities.

The PM&DC operates to maintain the register of Medical and Dental practitioners, regulates the standards of medical practice, protects the interests of the patients, supervises medical education, and gives guidelines on ethical issues.

Both major stakeholders in the healthcare profession i.e. doctors and patients have rights as well as obligations towards each other. This code of ethics aims to provide a set of standards, principles and guidelines, which all doctors can use as broader parameters in varying situations, along with their decision making based on experience, knowledge and skills. Though the standards and principles regulating medical practices have stayed unchanged, the advancement in technology and the changing dynamics of life in general pose new challenges which require revisiting this document for up-to-date revisions and publication.

This revised 'Professional Ethics and Code of Conduct' has been formulated after extensive research on the latest best practices of similar organizations around the world, however, the local context and culture were kept in view.

2. Purpose

The main purpose of this document is to provide the basis of the ethical standards and principles guiding everyday professional activities of the registered medical and dental practitioner (RMPD) and to lay down the code of conduct to standardize and facilitate the decision making for ethical issues.

2.1. What Is the 'Professional Ethics and Code of Conduct'?

The 'Professional Ethics and Code of Conduct', is a collective statement of the commitment to uphold the ethical, professional and legal standards and principles to be transparent and judicial in the daily practices. It covers both the everyday activities as well as the decisions required to be taken by the RMDP in varying situations in his/her professional life.

2.2. Why to Have the Code of Conduct?

The Code of Conduct is meant to provide the relevant standards, policies, laws and regulations that guide the work of the RMDP. The doctors are individually accountable for their own actions and, as members of the medical and dental community, are collectively responsible too for upholding these standards of behavior and compliance to all applicable laws and policies.

2.3. Who Needs to Follow the Code of Conduct?

The Code of conduct applies to all members of the medical and dental profession. This code of conduct is applicable to undergraduates as well as graduate medical and dental students, residents, consultants, faculty of the medical colleges and the practitioners working in teaching hospitals registered with the PM&DC.

2.4. Who is it for?

The guidance in this code is for every individual of the medical and allied professions and is intended to:

- Inform medical and dental students about the basic duties of a good doctor and serve as a source of education and reflection.
- Set forth for the doctors a basis to monitor and reflect on their conduct, and that of their colleagues.
- Provide guidance to the patients, the public, and the service providers to assess the minimum ethical and clinical conduct expected of RMDP.
- Provide a framework for the expected outcomes of education and the CPD principles.
- Provide a 'benchmark' to evaluate doctors' fitness to practice when complaints are made to the PM&DC.
- Underpins local appraisal systems and revalidation.

2.5. What Are the Code of Conduct Requirements?

As a registered member of the PM&DC, the RMDP will be required to read and sign the Professional Ethics and Code of Conduct document at the time of registration to confirm and verify their commitment to adhere to the professional ethics governing the profession of medicine. Adherence to this Code will also make them responsible for bringing suspected violations of applicable standards, policies, laws or regulations to the attention of PM&DC. Raising such concerns is a service to the public at large. Confirmed violations will result in appropriate disciplinary actions and may include termination of employment. In some circumstances, civil and criminal charges and penalties may also apply.

3. Upholding Standards of Professionalism, Integrity and Quality

The PM&DC recognizes the importance of earning and maintaining a reputation of integrity that includes, but is not limited to compliance with laws and regulations of the land because the emergence of misconduct or impropriety can be very damaging to the reputation of the medical profession. The PM&DC must strive at all times in its dealings, and working in general, to maintain the principles and the highest standards of professionalism, integrity and quality.

The standards spelled out in this document are those which the public and the profession expect a competent RMDP to meet. Where relevant, this document also provides guidance to assist the RMDP understand, and comply with, the requirements of legislation. However, there may be situations or obligations that are not specifically stipulated. In such circumstances, an RMDP's first priority should always be the care of his or her patient.

Accepting the obligation to maintain and improve standards the members should:

- Act in accordance with relevant standards.
- Keep their professional knowledge and skills up to date.
- Recognize, and work within, the limits of their competence.
- Be committed to autonomous maintenance and improvement in their clinical standards in line with the best evidence-based practices.
- Demonstrate reflectiveness, personal awareness, the ability to seek and respond constructively to feedback and the willingness to share their knowledge and to learn from others.
- Accept responsibility for maintaining the standards of the profession.

4. Standards of Professionalism in dealing with the patients

Patients trust their doctors with their health and wellbeing, and even their lives in serious situations. To justify the patients' trust, follow the standards outlined below and the principles and duties outlined in the rest of this document.

4.1. Caring for patients

- Make the care of patients your first concern.
- Protect and promote the health of patients in particular and the public in general.

4.2. Respecting patients and other healthcare professionals

- Be respectful of cultural diversity, and function effectively and respectfully when working with other healthcare professionals and treating people of different cultural backgrounds.

4.3. Treat patients as individuals and respect their dignity

- Treat them with respect.
- Respect their right to confidentiality and privacy.

4.4. Working in partnership with patients and colleagues

- Work in partnership with patients.
- Listen to them and respond to their concerns and preferences.

- Give them the information they want or need in a way they can understand and ensure they understand it.
- Respect their right to reach decisions jointly about their treatment and care.
- Support them in caring for themselves to improve and maintain their health.
- Maintain the trust of colleagues, and treat them respectfully.
- Work with colleagues in ways that best serve the patients' interests.

4.5 Acting honestly and ethically

- Be honest and open when working with patients; act ethically and with integrity.
- Act without delay to prevent risk to patients specially if there is good reason to believe that a colleague may be putting patients at risk.
- Never discriminate against patients or colleagues.
- Never breach the patients' or the public's trust of the profession.

4.6. "It must be remembered that medical and dental practitioners are personally accountable for their professional practice

– they must always be prepared to explain their decisions and actions".

The standards that must necessarily underpin this aim include respect for the integrity of the process of dealing with the patients; individual integrity and self-respect, respect for the freedom and privileges of others, respect for the available resources.

5. Standards of Integrity for the process of dealing with the patients

The rights and responsibilities of the doctors and the public are the top responsibilities of the PM&DC. The conduct of the doctors' community should protect and promote the pursuit of the PM&DC's mission. All stakeholders are therefore, expected to conduct themselves with integrity in their dealing, teaching, and research, and in the ways in which they can manage and support these endeavors.

5.1. Individual Integrity

In order to ensure that the PM&DC can dedicate itself fully to its regulation and educational mission, it is expected that an individual's personal integrity will be reflected not only in honest and responsible actions, but also the willingness to offer direction to others whose actions may be harmful to themselves or the community. The PM&DC expects that all registered members will be truthful and forthright. The PM&DC also expects that the registered members will not engage in behavior that endangers their own sustained effectiveness or that has serious ramifications for their own or others' safety, welfare, well-being or professional obligations.

5.2. Respect for the Freedom and Privileges of Others

The PM&DC aspires to create an environment in which the individual members' can grow professionally and progress by cultivating mutual respect, tolerance and mutual understanding. The PM&DC values and fosters individuality yet at the same time realizes the need to develop an environment in which professional activities and collegiality can be freely pursued. Such congenial environment provides a structure within which freedom of individuals can thrive without threatening the privileges or freedom of other individuals or groups.

5.3. Statement of Non-Discrimination

The PM&DC delineates not to discriminate on the basis of age, color, race, sex, religion, disability, ethnic origin, gender identity or any other category protected by the applicable law, in dealing with the patients and public at large. The PM&DC advocates honesty, openness and impartial dealings with racial, religious, gender, ethnic, sexual orientation and other differences and aims to promote an environment of tolerance and acceptance incorporating all disparities.

5.4. Gender Harassment

In adopting standards and values from philosophy and religion, the field of medicine has historically formed the concepts of sexual ethics, sometimes creating doctrines influencing the paradoxical changes.

From the viewpoint of psychoanalysis, empathy and devotion have been described as a fundamental part of the therapeutic relationship in the doctor-patient relationship. However, it is pertinent to regulate it through professional management to be beneficial to the patients and safeguard the patients from any kind of gender harassment.

Gender harassment within the doctor-patient relationship can be based on four parameters:

- Doctor's characteristics i.e. sex, age, specialty, college.
- Accuser's characteristics i.e. sex and development phase.
- Accusation characteristics i.e. registration year, place of the alleged act, the time within the professional relationship in which the alleged harassment occurred, time gap between the abuse and the accusation, number of other victims of the same professional.
- Evaluation by the Medicine Council i.e. Ethical evaluation: number of proceeding and non-proceeding charges, evaluation of non-proceeding and proceeding charges, and medical science ethical code infringement.

6. Standards of Quality

6.1. Freedom of Expression and for continuous professional development

The PM&DC encourages the freedom of expression and inquiry for continuing medical education and to the pursuit of research and scholarship. This includes freedom of religious belief, of speech, of press, of association, the right to petition the authorities when needed. The time, place, and manner of exercising these rights shall be subject to reasonable regulation only to prevent interference with the normal functions of the PM&D and to safeguard the rights of others to make use of the facilities offered.

6.2. Protest

Picket lines which permit free passage of those who wish to pass, and signs, banners and peaceful assemblies are acceptable. However, the following actions are unacceptable: blocking; obstructing or impeding passage of a person or vehicle; actions that result in bodily harm; erecting or placing of obstructions that result in depriving others of their rights. Halting a lecture, debate, or any public forum is an unacceptable form of protest. "Halting" means directly or indirectly preventing a speaker from speaking - even for a brief period of time - or seizing control of a public forum for one's own purposes.

6.3. The Teaching of Medical Ethics

There is a major deficit in the awareness and perception of medical ethics by the undergraduate students. This translates later into attainment of unethical habits and practices which are difficult to rectify and can become major threat to patient safety. Thus professionalism and medical ethics should be taught as mainstream subjects both at the undergraduate and post graduate levels. Some successful strategies proposed by evidence based best practices are role play, case studies, group discussion and projects. The medical teachers should act as role models and set examples for the undergraduates by practicing medicine ethically. Ultimately, the onus of understanding the principles of ethics and incorporating these into clinical practice lies with the medical students, thus it is strongly recommended to address the situation.

6.3.1. Proposed methodology

The Curriculum Committee of the PMDC should ensure that adequate information/courses on Professional Ethics and Code of Conduct is included in the undergraduate medical college curriculum.

The goal of teaching professional ethics is to improve the quality of patient care by enhancing professional performance through a consideration of the clinician's values, beliefs, knowledge of ethical and legal construct, ability to recognize and

analyses ethical problems, and interpersonal and communication skills; and consideration of the patient. Students should be able to identify, analyze and should attempt to resolve common ethical problems of medical and clinical nature.

6.3.2. Mechanism to support the teaching of Medical Ethics

- All medical and dental colleges offering MBBS and BDS Courses, College of Physician and Surgeons of Pakistan and Universities running the Postgraduate Medical Courses in Pakistan are advised to incorporate Professional Ethics, inclusive of medical ethics into their curriculum.
- Relevant books and journals should be made available in the central and departmental libraries of the medical institutions, and publication of papers on issues related to professionalism and medical ethics must be encouraged.

The PMDC exhorts its members to develop strategies for dissemination of information about professional ethics to highlight the contextual issues and their resolution to their colleagues and students, public and patients; and specifically when teaching medical students.

6.4. Membership in Relevant Medical Societies

For the advancement of their profession, the RMDP should get memberships of relevant national and international associations and societies and be actively involved in the functioning of such bodies.

6.5. Attending conferences for continuous professional development

The RMDP should participate in national and international conferences, seminars, symposia and professional meetings organized by reputed professional academic bodies or any other authorized organizations as part of their continuous professional development plan.

7. Standards of Confidentiality and Privacy of Information

As a registered member of the PM&DC, various types of confidential, proprietary and private information is disseminated. Access to confidential information should be limited to those who require it to discharge their duties. When confidential information is received there is a responsibility to maintain and safeguard this information and use it with consideration and ethical regard for others.

By-passing or attempting to avoid restrictions on the use and dissemination of confidential information is considered a serious offense. It is imperative that all registered members comply with all laws, policies and principles pertaining to the use, protection and disclosure of confidential information.

8. Standards of Disclosing Conflict of Interest and Commitment

All decisions and actions taken by a registered member of PM&DC, in the conduct of their usual work will be made in a manner that promotes the best interests of the PM&DC. Should a conflict of interest and commitment arise it should be disclosed to an appropriate authority and section?

PM&DC defines conflict of interest as:

A conflict of interest may take many forms but arises when a registered member of the PM&DC, may be able to use their personal, fiscal or positional authority to:

- Influence the PM&DC decisions in ways to give improper advantage or financial benefit to their self, a family member or associate, or;
- Obtain for their self, a family member, or an associate a positional or personal benefit beyond what is authorized for performing their usual responsibilities.

8.1. Respecting available Resources

As members of the PM&DC, the medical and dental practitioners must commit to conserve the general & equipment resources allocated to them for the benefit of the public. Thus a judicious use of the resources should be made and should only involve activities that are lawful or appropriate; and should never be used in a way that seems to indicate personal gains.

8.2. Complying with the Law

All activities conducted while registered with the PM&DC must adhere to the ethical and professional standards. It is the responsibility of each individual to comply with legal and regulatory requirements, policies and procedures that apply to an individual's particular duty.

8.2.1. Environmental Health and Safety, including Workplace Health and Safety

Members registered with the PM&DC have a shared responsibility to ensure a safe workplace and to protect the health and safety of all the patients, their families, colleagues and public at large. This means that there must be an adherence to good health and safety policies and practices; complying with all environmental health and safety laws, regulations and related governmental policies; attend required training; and report unsafe conditions, equipment, or practices to the responsible officials.

8.2.2. Communication Policies

Privacy laws require permissions for the use of an individual's image or likeness for research, marketing or promotional use. Individuals or units who violate these laws in their communications may be subject to individual or joint liability.

9. Standards of Appropriately Reporting Suspected Violations

The PM&DC is committed to the highest standards of ethical conduct and integrity in all areas of patient care. Registered members of PM&DC should therefore report suspected violations of applicable laws, regulations, and government contracts and of this Code of Conduct. It is expected that all reports will be made in good faith and in an effort to address legitimate issues needing correction, or to otherwise provide reliable information.

When the information in question is in the form of a complaint by a person or body charging the practitioner with infamous conduct in any professional respect or professional negligence, such a complaint shall be made in writing on a stamp paper attested by a magistrate addressed to the registrar, and shall contain that grounds of complaint and shall preferably be accompanied by one or more declarations of witnesses as to the facts of the case. Complaint can be sent to the Ethics Committee of PM&DC.

Details about the process of complaints will be found in the ensuing sections of this document

10. Procedures for Review of the Code

The Code will be reviewed every five years by a committee set up by the PMDC

11. Whom to Contact with Questions?

Questions regarding the intent or applicability of this 'Professional Ethics and Code of Conduct' can be forwarded to the Ethics Committee of the Council.

SECTION 2

What Is Ethics? A Brief Historical Background and Key

Principles of Medical Ethics

This section deals with the historical background of Ethics, the four key principles of Medical Ethics and their significance

1. Introduction to Medical Ethics

1.1. What is Ethics: A Historical Perspective

The term ethics is derived from the Greek word 'ethos' which means character. Ethics is a branch of the social sciences, which deals with contrasts such as good and bad, right and wrong, fair and unfair, legal and illegal, just and unjust, proper and improper, moral and immoral, while describing human actions. In short, ethics refers to a defined code of conduct.

1.2. What does it do?

Ethics is not only about understanding the nature of conflicts arising from moral grounds but also about how one can deal with them best. It highlights as to how we should act best in the light of our duties and obligations on moral grounds. Clinicians have well defined duties of care to their patients and to the society in general. Most of the time it is propagated that clinicians should always act in the best interest of their patients; but sometimes a conflict between the obligations to a patient and those owed to the community or to other patients are diametrically opposed. Many times what the clinician believes to be in the best interest of the patient is not what the patient wants or consents to. The core of the medical ethics is the respect for patient autonomy and the fundamental principle of informed consent.

1.3. How does it work?

Ethics not only deal with choices made by the clinicians but patients as well and the duties and obligations of clinicians to their patients. Medical ethics also deals with the choices made by society and the distribution of resources.

Medical Ethics is also about duties and obligations that one has to others, how wide-ranging they are, how best they can be discharged and how we deal with conflicting duties and obligations.

Patients have duties and obligations too, which is why we should respect them as moral agents. Parents have duties of care to their children; however, sometimes a clinician's duty to a child patient may conflict with those of the parents, and this needs an ethical approach to resolve.

Ethical practice is a systematic approach to medical decision making and considering the interests of all affected by the decision.

2. Principles of Medical Ethics

Most experts believe that there are four key principles around which the area of medical ethics revolve:

- Respect for autonomy
- Non-maleficence
- Beneficence
- Justice

2.1. Respect for Autonomy

Health professionals are expected to ask about their patient's desire to receive information and to make decisions. It must always be kept in mind that no matter which culture or community the patient belongs to, the RMDP will uphold the values and beliefs of that community and share information based on the patients' value system.

2.2. Non-maleficence

The principle of non-maleficence requires that no harm should be caused to others. The principles of non-maleficence support several moral rules, which include:

- Do not kill.
- Do not cause pain or suffering.
- Do not incapacitate.
- Do not deprive others of the goods of life.

It must be remembered that the principle of non-maleficence and its specifications in moral rules are prima facie and not absolute.

2.3. Beneficence

It is not only required to abstain from harming the patients, but also to contribute to their welfare. These beneficial actions fall under the heading of 'beneficence'. The principles of beneficence are broader than those of non-maleficence, because doctors must take positive steps to help people and not merely abstain from harm.

2.4. Justice

Justice remains an area which no system of healthcare delivery can ignore. There is a need for continuous reflection on health policies. Unfortunately, countries that lack a comprehensive and inclusive healthcare system will have a greater number of vulnerable citizens and therefore need to improve both utility (efficiency) and justice (fairness and equality).

SECTION 3

Principles of Medical Ethics in Social Context

This section deals with the principles to be followed by the medical and dental practitioners to fulfil the social contract with the society in order to win the trust of the public in the profession. The principles entail that an environment of social justice prevails between a doctor and the patient are duly honored.

1. Jurisdiction

These regulations shall apply to all medical and dental institutions, hospitals and institutions recognized under the Pakistan Medical and Dental Council Ordinance, 1962 (XXXII of 1962) and all admissions into their MBBS and BDS courses, house job and internship undertaken at recognized hospitals.

The Pakistan Medical and Dental Council was duly constituted under the Medical & Dental Council Ordinance No. XXXII, 1962, in June 1964 and is empowered to:

- Look after public interest – by maintaining proper medical/dental standards.
- Supervise Medical/Dental Education in the country.
- Maintain a register of qualified doctors and dentists, qualifying from duly recognized institutions.
- Take such disciplinary actions, which may be required for criminal convictions or serious professional misconduct of a doctor. The Council is not an Association or a Union for protecting professional interests.

2. Oath

Declaration by a Registered Medical or Dental Practitioner

A) I, Doctor _____ (The doctor being inducted publicly announces his/her name here) do sincerely and solemnly declare that as a Registered Medical/Dental Practitioner of Pakistan, I shall exercise the several parts of my profession to the best of my knowledge and ability for the good, safety and welfare of all persons committing themselves to my care and attention, and that I will faithfully obey the rules and regulations of the Pakistan Medical and Dental Council.

[Adapted from the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948 and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968 the 35th World Medical Assembly, Venice, Italy, October 1983 the 46th World Medical Association General Assembly, Stockholm, Sweden, September 1994; and the Islamic Medical Association Oath for Muslim Doctors.]

B) Furthermore, I hereby subscribe to the PHYSICIANS' OATH as follows:

*I solemnly pledge myself to consecrate my life to the service of humanity;
 I will give to my teachers the respect and gratitude which is their due;
 I will practice my profession with conscience and dignity;
 The health of my patient will be my first consideration;
 I will respect the secrets which are confided in me, even after the patient has died;
 I will maintain by all the means in my power, the honor and the noble traditions of the medical profession;
 My colleagues will be my sisters and brothers; and I will pay due respect and honor to them.
 I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, or social standing to intervene between my duty and my patient;
 I will protect human life in all stages and under all circumstances, doing my utmost to rescue it from death, malady, pain and anxiety. To be, all the way, an instrument of Allah's mercy, extending medical care to near and far, virtuous and sinner and friend and enemy."*

Even under threat, I WILL NOT USE my medical knowledge contrary to the laws of humanity; -----

I MAKE THESE PROMISES solemnly, freely and upon my honor.

Signature of the Doctor or Dentist
 who has taken the Oath

Signature of the Head/ Provost or
 the College/University or Faculty of
 Medical or Health Sciences.

Date: _____

 Signature of the Registrar of the Council

2.1. Allegiance to the profession

Every member of the medical and dental profession must endeavor to abide by the dictates of the Physicians 'Oath', and the modern version of the Oath of Hypocrates, which is the foundation of the code of Ethics of the profession. Fundamental to these ethical guidelines is an allegiance which every doctor or dentist mandatorily owes to their profession.

2.2. Implementation

- It is the responsibility of each RMDP to ensure that he/she is aware of the provisions of this code of conduct and adheres to the standards detailed herein and help others to whom this code of conduct applies to do likewise.
- In addition, it is necessary for each recipient to acknowledge the receipt of this code of conduct and the undertaking to comply with the requirements detailed herein (see declaration set out in the Appendix).
- From time to time the Council may assess each Applicant's awareness and knowledge, as well as their compliance with the code of conduct.

3. Principles of Medical Ethics

3.1. General Principles

As individuals, every RMDP will be expected to

- Strive to perform their duties in accordance with the highest standards of integrity, honesty, fairness, respect, loyalty, confidentiality and independence to ensure best medical standards.
- Make decisions based on the public interest and will not act for personal gain or for the benefit of friends, their families or others;
- Make objective decisions on the merits of issues put before them.

3.2. Applicability of Medical Ethics

The code of conduct now describes how these principles are applied in action by the RMDP.

3.2.1. Integrity & Honesty

- Medical or dental practitioner are expected to act with integrity and honesty in carrying out their responsibilities in compliance with the principles set out in this code of conduct.
- A RMDP must confirm their commitment to the disclosure of any employment and/or business interests which may be – or be seen to be - in conflict, or in potential conflict, with the objectives and activities of the Council;
- They disclose the interest and the nature of interest;
- They do not influence or seek to influence a decision to be made in relation to a matter;
- They do not vote on a matter where a conflict of interest arises.

3.2.2. Romantic or Sexual Relationships with Patients

Romantic or sexual interactions between physicians and patients that occur alongside the patient physician relationship are unethical. Such interactions diverge from the goals of the patient-physician relationship and may misuse the susceptibility of the patient, jeopardize the physician's ability to make objective judgments about the patient's health care, and ultimately be damaging to the patient's overall wellbeing.

3.2.3. Lobbying

To avoid taking any action or making any commitment which might indicate their acceptance of the lobbyist's stance.

3.2.4. Gifts, Sponsorship and Hospitality

They may not accept gifts, benefits, sponsorship or hospitality of any kind that could be deemed to influence and/or secure favourable treatment.

3.2.5. Loyalty

The conduct of medical practitioners should be based on loyalty to the system, profession and oneself.

3.2.6. Confidentiality as Principle of professional conduct

- The physician has a right to and should withhold disclosure of information received in a confidential context, from a patient, or review of a paper, except in certain specific circumstances where he/she may carefully and selectively disclose information related to health, safety and life of other individual/.
- The practitioner cannot seek to gain from information received in a confidential context until that information is publicly available.
- There is no legal compulsion on a RMDP to provide information concerning a criminal abortion, venereal disease, attempted suicide, or concealed birth regarding his patient to any other individual or organization. When in doubt concerning matters, which have a legal implication, the practitioner may consult his/her legal adviser
- The professional medical record of a patient should not be handed over to any person without the consent of the patient or his/her legal representative.

3.3. Framework for Ethical Decision Making

In making decisions about ethical issues and the course of action that should be taken in particular cases, RMDP may find the steps and guiding questions

outlined below which may be helpful in reaching decisions as to whether a particular action has ethical issues.

1) Recognising the Event, Taking Decision on Issue

- If you are being asked to do something that they think might be wrong
- If you are trying to make a decision and are unsure about the ethical course of action?
- Consult other practitioners

2) Thinking before Acting

- Summarise and clarify the issues.
- Ask yourself why do you think the dilemma exists?
- Consider the options and consequences.
- Consult other practitioners

3) Deciding on a Course of Action

- Determine their responsibility.
- Review all the relevant facts and information.
- Refer to applicable Council policies or professional standards.
- Assess the risks and analyse how you could reduce them.
- Contemplate the best course of action.

4) Testing their Decision

- Review the "Ethics Questions to Consider".
- Apply the Council's code of values to their decisions.

5) Proceeding with Confidence

- Communicate your decision and rationale to the relevant parties.
- Reflect upon what was learnt.
- Share your success stories with others.

3.4. Medical Professionalism

Medical professionalism is a set of values, behaviors and relationships that underpins the trust the public has in doctors.

This definition and a more detailed description of it embody the three aspects of:

- Knowledge, clinical skills and judgment, maintained by continued effort towards improvement and excellence;
- Set of moral values, involving respect for others, integrity, compassion and altruism;
- Relationship with patients, as well as other healthcare staff, involving service and partnership.

The RMDP as indicated by above expressed parts of medical professionalism should endeavor to be clinically capable, keeping pace with the latest with advancements in restorative science and record keeping.

4. Social Contract

4.1. Reciprocal relationship between Medicine and Society

Professionalism is the basis of medicine's social contract with society. Both medical professionalism as well as the society have legitimate expectations from each other. This contract is both a mix of explicit and the implicit, the written and unwritten.

4.1.1. Society's Expectation from the profession of Medicine

- to fulfill the role of the healer;
- assured competence;
- timely access to care;
- respect for patient autonomy;
- altruistic service;
- morality, integrity, & honesty;
- accountability and transparency;
- team health care;
- source of objective advice;
- Promotion of the public good.

4.1.2. Medical profession's Expectations from Society

- trust;
- autonomy;
- established regulation;
- reasonable lifestyle;
- health care system.

4.2. Legal and Moral Obligations

All RMDP's have legal and moral obligation to understand the importance of patient protection which is not only important but is the prime directives of the profession of medicine. Patients have a right to compassionate, competent and safe treatment from doctors. The safety of patients must therefore come first at all times, and among other legal and moral obligations RMDP's should respect the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion.

5. Social Justice

5.1. Access to Care

All RMDP should make sure that:

- Patient's access to care should not be influenced by patients' characteristics, patients' behavior and doctors' personal convictions. Patient's characteristics such as lifestyle, culture, religion and sexuality should not impact on patient's access to care and that priority should be given on the basis of clinical need and the likely effectiveness of treatment.
- Physicians must challenge any evidence of discrimination.
- Patients' rights to access treatment should not be conditional on their behavior. If a doctor's personal assessment conflict with providing a particular treatment doctors are not obliged to offer it. However, they still have a duty to help the patient find a doctor who will treat them. It should be kept in mind that it the doctor's duty to advise the patient of the possible consequences of not being treated.

5.2. Allocation of Resources

- Physician's primary responsibility is to the patient and if shortage of resources means the provision of inadequate care, this should be made explicit to the patient and to those in control of resources.

5.3. Patient engagement and shared decision making

- A RMDP must respect patients' rights to be fully involved in medical decisions and they must make sure that the patient has understood what is proposed, why, and any significant risks or side effects associated with it.
- RMDP's are responsible to involve patients in decisions about management.
- RMDP's should act decisively but sensitively and always in the best interests of the patient.
- An intrinsic part of facilitating shared decision-making is enabling access to information, which may be carried out in a more or less effective way.

5.4. The consent

- The physician should respect the right of patients to be fully involved in decisions about their care;
- Informed and voluntary consent is important before undertaking an examination, investigation, treatment or research;
- Effectively identify and explore problems to be addressed from a patient encounter, including the patient's context, responses, concerns, and preferences... Engage patients, families, and relevant health professionals in shared decision-making to develop a plan of care;
- Duty to disclose possible conflicts of interests and seek the informed consent from the beneficiary of the relationship.

Section 4

Patient Centeredness

This section deals with the doctor patient relationship including the strategies to follow, and satisfying the patients and safeguarding the public at large. How doctors are expected to keep up to date and maintain their performance through education, keeping up to date with the law and statutory bodies, taking part in audit, training, appraisal and adverse event reporting.

1. The duties of a doctor registered with PM&DC

Patients must be able to trust the doctors & dentists with their lives and health. To justify that trust RMDP must show respect for human life and must:

- Make the care of patients their first concern;
- Protect and promote the health of patients and the public;
- Provide a good standard of practice and care by:
 - Keeping practitioner's professional knowledge and skills up to date;
 - Recognize and work within the limits of RMDP's competence;
 - Work with colleagues in ways that best serve patients' interests;
- Treat patients as individuals and respect their dignity;
- Treat patients politely and considerately;
- Respect patients' right to confidentiality;
- Work in partnership with patients:
 - Listen to patients giving them ample time to reveal their case history and respond to their concerns and preferences;
 - Give patients the information they want or need in a way they can understand;
 - Respect patients' right to reach decisions with the RMDP about their treatment and care;
- Support patients in caring for themselves to improve and maintain their health, in order to improve compliance;
- Be honest and open and act with integrity;
- Act without delay
- Never discriminate unfairly against patients or colleagues;
- Never abuse patients' trust or the public's trust in the profession;
- RMDP is personally accountable for his/her professional practice and must always be prepared to justify his/her decisions and actions.

2. Ethical Standards of Professional Competence, Care and Conduct:

While individual doctors have their own personal beliefs and values, there are certain professional values on which all doctors are expected to base their practice:

- RMDPs have a duty to make the care of patients their first concern and to practice medicine safely and effectively.

- Patients trust their doctors because they believe that in addition to being competent, their doctor will not take advantage of them and will display qualities such as integrity, truthfulness, dependability and compassion.
- Doctors have a responsibility to protect and promote the health of individuals and the community.
- Effective communication underpins every aspect of good medical practice.
- Doctors are expected to reflect regularly on whether they are practicing effectively, on what is happening in their relationships with patients and colleagues, and on their own health and wellbeing. They have a duty to keep their skills and knowledge up to date, refine and develop their clinical judgment as they gain experience, and contribute to their profession.

3. Maintaining good medical practice: Knowledge, Skill and performance:

The RMDP will attempt to maintain the highest levels of competence in their work more specifically the skill in diagnosing, clinical decision-making, planning, implementation, monitoring and evaluation of intervention and teaching; and will accept responsibility for their actions.

3.1 Maintaining and improving performance by updating knowledge and skills as prescribed by PM&DC:

Patient care should be the first concern of the RMDP, with an aim to provide good standard of practice and care. Application of best medical practices is only possible if the RMDP's own knowledge and skills are up to date and he/she works within the limits of his/her competence.

RMDP must keep up to date with, and adhere to, the laws and codes of practice relevant to scope of his/her work.

3.2. Application of Knowledge and Experience for Patient's benefit

RMDP must work with colleagues and patients to maintain and improve the quality of work and promote patient safety. In particular, following must be done:

- Maintenance of a folder of information and evidence, drawn from RMDP's medical practice;
- Reflection on standards of medical practice in accordance with PM&DC guidance on licensing regularly and revalidation;
- Taking part in regular and systematic audit;
- Taking part in systems of quality assurance and quality improvement;
- Responding constructively to the outcome of audit, appraisals and performance reviews, undertaking further training/s where necessary (Continuous Professional & Medical Education Activities);

- Helping to resolve uncertainties about the effects of treatments;
- Making contribution to confidential inquiries and adverse event recognition and reporting, to help reduce risk to patients.
- Co-operation with legitimate requests for information from organizations monitoring public health – when doing so RMDP must follow the guidance in Confidentiality and local policy of PM&DC.

3.3. Maintenance of Patient Records (Clarity, Regularity, Legibility):

- RMDPs must record their work clearly, accurately and legibly. Records should include:
 - relevant clinical findings;
 - decisions made and actions agreed (and show who they were made by);
 - any drugs prescribed or other investigation or treatment;
 - the information given to the patient in a comprehensible fashion.
- RMDP must ensure that the notes written are clear, accurate and legible
- RMDP should delegate to a student or other physician, only those responsibilities that such people, based on their education, training and experience, can reasonably be expected to perform either independently or with the level of supervision provided.

3.4. Teaching and training, appraising and assessing:

- Teaching, training, appraising and assessing doctors and students is important for the care of patients now and in the future. RMDP should be willing to contribute to these activities.
- If RMDPs are involved in teaching they must develop the skills, attitude and practices of a competent teacher.
- RMDPs must make sure that all staff for whom they are responsible, including junior trainees and students, are properly supervised and well trained.
- RMDPs must be honest and objective when appraising or assessing the performance of colleagues, including junior trainees and students. Patients will be put at risk if incompetent health practitioners join the main stream of RMDPs.

- RMDPs must provide only honest, justifiable and accurate comments when giving references for, or writing reports about, colleagues. When providing references, RMDP must do so promptly and include all information that is relevant to one's colleague's competence, performance or conduct. The contrary could amount to moral corruption which could lead to deterioration of healthcare systems in Pakistan.

4. Safety and Quality

The practitioner is expected to provide a quality of care for a patient which is timely, compassionate and respects human privacy and dignity, is non-discriminating and does not exploit vulnerable situations. Gross negligence in respect of professional duties may justify suspension or removal from the Register.

4.1 Response to patient safety risks

RMDP is expected to show utmost level of responsibility and take prompt action if his/her patient's safety, dignity or comfort is being compromised.

4.2. Contribute to and comply with systems to protect patients

- RMDP must not **only comply with rules designed** to protect patients, but also seek to improve the quality of the services they give to patients – both at an individual as well as at a system level.
- RMDP must ensure quality improvement and quality assurance, and will have the opportunity to take part in audits and reviews.
- RMDP must contribute honestly and openly to the process of patient care inquiries if they arise.

4.3 Protection of patient and other colleagues from Practitioner's health risks

- Protection and promotion of the health of patients and the public is the prime responsibility of the RMDP.
- Patient safety is the responsibility of the whole team, which could include clinical and non-clinical members. This is why registered doctors must take action to raise concerns and support others to raise concerns about patient safety.
- Registered doctors must protect patients from any risk posed to their health.
- RMDP might come under emotional impact during their service. At times, they may experience stress and anxiety. Help should be sought in such situation rather than overburdening one's self.

- RMDP should be aware that some conditions that are usually minor – such as the common cold – may have a disproportionate impact on some patients, for example those with compromised immune systems, therefore, relevant precautionary actions like vaccination, Personal Protective Equipment (PPE) for Infection Control etc. and infection prevention regime must be followed.
- RMDP must comply with the health policies and procedures of their workplace and declare any disease that could be transmitted to the patients through them.

4.4. Effective Communication

To communicate effectively RMDP must:

- **Actively listen to patients**, ask for and respect their views about their health, and respond to their concerns and preferences;
- **Share information with patients**, in a way they can understand, what they want or need to know about their condition, its likely progression, and the treatment options available to them, including associated risks and uncertainties;
- **Politely and patiently respond to patients' questions** and keep them informed about the progress of their care;
- **Ensure that language used for communication** is understood by the patient and instructions given are simple and easy to follow for **likely compliance**;
- Make sure that patients are informed about **how information is shared** within teams and among those who will be providing their care.

5. Conduct: Communication, Partnership and Team work

5.1. Collaboration with Colleagues for improved patient care

- Working with colleagues in ways that best serve patient's interests.
- RMDP will deal honestly with colleagues, respecting their rights and privileges and that of other health professionals.
- Most doctors work in teams with colleagues from other professions. Working in teams does not change RMDP's personal accountability for his/her professional conduct and the care he/she provides.
- Respect the skills and contributions of colleagues;
- Communicate effectively with colleagues within and outside the team;
- Make sure that patients and colleagues understand the RMDP's role and responsibilities in the team, and who is responsible for each aspect of patient care;
- Participate in regular reviews and audit of the standards and performance of the team, taking steps to remedy any deficiencies;
- Support colleagues who have problems with performance, conduct or health.

5.2. Conduct and performance of colleagues

- RMDP must protect patients from risk of harm posed by another colleague's conduct, performance or health. The safety of patients must come first at all times. If he/she has concerns that a colleague may not be fit to practice, he/she must take appropriate steps without delay, so that the concerns are investigated and patients remain protected. This means RMDP must give an honest explanation of his/her concerns to an appropriate person from the employing or contracting body, and follow their procedures.
- RMDP must treat colleagues fairly and with respect, should not bully or harass them, or unfairly discriminate against them by allowing personal views to affect adversely the professional relationship with them. RMDP should challenge colleagues if their behavior does not comply with the guidance of PM&DC.
- RMDP must not make malicious and unfounded criticisms of colleagues that may undermine patients' trust in the care or treatment they receive, or in the judgement of those treating them.

5.3. Mutual Respect and Safeguarding Patient's Dignity & Patient Rights

A good doctor–patient partnership requires high standards of professional conduct. Which involves:

- Being courteous, respectful, compassionate and honest;
- Treating each patient as an individual;
- Protecting patients' privacy and right to confidentiality, unless release of information is required by law or by public-interest considerations;
- Encouraging and supporting patients and, when relevant, their career or family, in caring for themselves and managing their health;
- Encouraging and supporting patients to be well informed about their health and to use this information wisely when they are making decisions;
- Recognizing that there is a power imbalance in the doctor–patient relationship, and not exploiting patients physically, emotionally, sexually or financially.

5.3.1. Correct information about his/her health condition:

The patient has the right to receive information from physicians/surgeons/dentists and to discuss the benefits, risks, costs of appropriate treatment alternatives, and optimal course of action. Patients are also entitled to obtain copies or summaries of their medical records, to have their questions answered, and to receive independent additional professional opinions.

5.3.2. Decision making about his/her health:

The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients (or next of kin) may accept or refuse any recommended medical treatment in writing.

5.3.3 Dignity and Respect:

- The patient has the right to courtesy, respect, dignity, and timely responsive to his or her “health needs”.
- A patient during examination especially of intimate areas or otherwise has the right to ask for presence of an attendant (female attendants, patents etc.)
- The patient should not be mocked at for his/her beliefs, knowledge, or understanding of the disease considering the low literacy rate of the general population in Pakistan.

5.3.4. Second Opinion:

The patient has the right to receive second opinion from any other doctor and may or may not come back for treatment to the initial RMDP. In this regard, patient is entitled to get the best possible treatment and is not to be maltreated or refused attention because he/she exercised his/her right to seek second opinion.

5.3.5 Patient Satisfaction:

Patient satisfaction should be the aim of the RMDP. Patient is entitled to allocation of ample time, privacy and empathy to discuss his/her disease/condition.

5.4. Professional Trustworthiness

In all dealings with patients, it is expected that the interest of the patient and the advantage to the patient’s health will be the major consideration to influence the practitioners’ conduct towards them. The physician patient relationship should be developed as one of trust.

5.5 Performing Procedures on the Recently Deceased:

During medical training sometimes practices and procedures have to be made on recently deceased patients, especially, for practicing critical medical skills for which proper educational alternatives are not available. Such training must equalize the protection the interests of recently deceased patients, their families, society, and the profession with the need to provide educational opportunities to the students.

There should be clearly developed institutional policies for performing such procedures on recently deceased patients for training purposes. Before medical trainees practice any procedure on a recently deceased patient, the supervising physician must take into account the ethical guidelines and ensure that the interests of all groups are respected and the risks and benefits of facilitating the procedure have been carefully considered, which include:

- the rights of deceased patients and their families;
- benefits to the trainees and society;

- risks to trainees, staff, the institution, and the profession.

The procedure will be carried out:

- as part of an appropriately structured training sequence; in a manner and an environment that is respectful of the values of all involved parties.
- Permitting trainees to perform the procedure keeping in view the previously expressed preferences of the deceased individual regarding handling of the body or procedures performed after death.
- Permission for a trainee to perform the procedure is obtained from the deceased family if the individual's preferences are not known. Procedures should never be performed for training purposes if the decedent's wishes are not known and permission is not available from an appropriate source.
- The procedure is entered in the medical record.

5.6. Continuity of Care

- The patient has the right to continuity of health care. The RMDP has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient.
- RMDP must be satisfied that, when they are off duty, suitable arrangements have been made for their patients' medical care. These arrangements should include effective hand-over procedures, involving clear communication with healthcare colleagues.
- Sharing information with other healthcare professionals is important for safe and effective continuous patient care.
- When an RMDP refers a patient, he/she should provide all relevant information about the patient, including their medical history and current condition.
- If an RMDP provides treatment or advice for a patient, but is not the patient's general practitioner, he/she should tell the general practitioner the results of the investigations, the treatment provided and any other information necessary for the continuing care of the patient, unless the patient objects.
- **Delegation and referral:** Delegation involves asking a colleague to provide treatment or care on behalf of the primary RMDP. Although the referring RMDP will not be accountable for the decisions and actions of those to whom you delegate, primary RMDP will still be responsible for the overall management of the patient, and accountable for his/her decision to delegate. When the RMDP delegates care or treatment he/she must be satisfied that delegated colleague has the qualifications, experience, knowledge and skills to provide the care or treatment involved. Enough information about the patient and the treatment they need must be provided on referral.
- **Referral** involves transferring some or all of the responsibility for the patient's care, usually temporarily and for a particular purpose, such as additional

investigation, care or treatment that is outside the RMDP's competence. He/she must be satisfied that any healthcare professional to whom patient has been referred is accountable to a statutory regulatory body or employed within a managed environment. If they are not, the transfer of care will be regarded as delegation, not referral. This means the referring RMDP remains responsible for the overall management of the patient, and accountable for his/her decision to delegate.

6. Care: Establishment and Maintenance of Trust

6.1 Children and young people

RMDPs must safeguard and protect the health and well-being of children and young people. They should offer assistance to children and young people if there is a reason to think that their rights have been abused or denied.

When communicating with a child or young person RMDP must:

- Treat them with respect and listen to their views;
- Answer their questions to the best of his/her ability;
- Provide information in a way they can understand.

The guidance in paragraphs here is about children and young people, but the principles also apply to other vulnerable groups.

6.2. Relatives, carers and partners

RMDP must be considerate to relatives, carers, partners and others close to the patient, and be sensitive and responsive in providing information and support, including after a patient has died. In doing this RMDP must bear confidentiality issues in mind.

6.3. Being open and honest with patients if things go wrong

- RMDP will bear in mind the obligation of preserving life and will not discriminate on the basis of age, sex, gender, class, race, ethnicity, national origin, religion, sexual orientation, disability, health conditions, marital discord, domestic or parental status, criminal record, or any other applicable bias as proscribed by law, and ensure that personal beliefs do not prejudice patient care.
- If a patient under the RMDP's care has suffered harm or distress, he/she must act immediately to put matters right, if that is possible. An apology should be offered and situation explained fully to the client, with the likely short-term and long-term effects.
- Patients who complain about the care or treatment they have received have a right to expect a prompt, open, constructive and honest response including an

explanation and, if appropriate, an apology. RMDP must not allow a patient's complaint to affect adversely the care or treatment they provide or arrange.

6.4. Maintaining trust in the profession

- RMDP must not express or impose on patients, his/her personal beliefs, including political, religious or moral beliefs, in ways that exploit their vulnerability or that are likely to cause them distress.
- A physician shall owe his patients complete loyalty and all the resources of his science. Whenever an examination or treatment is beyond the physician's capacity he should consult another physician who has the necessary ability.
- **Prisoners** who are ill must be treated in the same manner as other sick people. However, doctors have a right to take appropriate precautions if they think there is a possibility of physical violence by the patient.
- Where a suspect refuses consent to a medical examination, the doctor unless directed to the contrary by a court of law, should refuse to make any statement based on his
- Observation of the suspect other than to advise the police whether or not the suspect appears to require immediate treatment or removal to hospital.

Consent for physical examination: Doctors should normally ask permission or take consent from a patient before making a physical examination. RMDP must be satisfied that he/she has consent or other valid authority before he/she undertakes any examination or investigation, provides treatment or involve patients in teaching or research. Usually this will involve providing information to patients in a way they can understand, before asking for their consent. In the case of minors, the child's guardian should be present or give permission for the examination. For any intimate examination the patient irrespective of age, is entitled to ask for an attendant to be present.

Confidentiality: Patients have a right to expect that information about them will be held in confidence by their doctors. You must treat information about patients as confidential, including after a patient has died. If the RMDP is considering disclosing confidential information without a patient's consent, he/she must follow the guidance in Confidentiality.

Gender Harassment in the Practice of Medicine: Attraction of doctors to patients is not unusual and makes this relationship more critical yet fragile. Many times, accusers withdraw their accusations, which is evident of human vulnerability.

Conversely, if the accusations are proven they can be deeply damaging to the noble and upright image of a doctor.

The professional who cannot curb the pressures of sexual instincts and also cannot differentiate between professional relationships and other types of affective relationships is more susceptible to the so-called advances, considered as consent. The same can be true for the patient, who is in a weak position because he/she finds themselves bound in the therapeutic relationship, giving his/her intimacy and confidence searching to be aided.

Gender Harassment in doctor patient relationship: Gender harassment can be defined as unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature between both genders.

- It is highly unethical to be involved in any act of sexual harassment in the practice of medicine. Sexual harassment is the misuse of the inequalities of status and power, it abuses the rights of the patients who are subjected to such conduct; impedes with an individual's work performance, and may influence or be seen to be influencing professional advancement, harm professional working relationships, and create a threatening or hostile work environment; and is likely to endanger patient care. Sexual relationships between medical supervisors and trainees are also not acceptable, even if consensual. The supervisory role should be eliminated if the parties wish to pursue their relationship.
- RMDP will ensure that they do not engage in harassment of any person, including employees, patients, students, research assistants and supervisees.
- Abuse of professional knowledge, skills and privileges is unacceptable conduct: Any registered medical/dental practitioner found guilty of performing an illegal abortion or prescribing drugs in violation of the Dangerous Drugs Act, or who becomes addicted to a drug, or is convicted of driving under the influence of alcohol or any other drug, is libeling or being party to the performance to be suspended or have his/her name removed from the Register.
- No RMDP should accept illegal gratification.
- RMDP must be familiar with their PMDC registration/license number and must make sure they are identifiable to their patients and colleagues, for example by using their registered name when signing statutory documents, including prescriptions. They must make their registered name and PMDC registration/license number available to anyone who asks for them. This number should also be printed on the Clinic signboards and prescription pads.
- **Maternity care:** Registered medical practitioners who agree to undertake the antenatal and delivery care of a woman should clearly inform her, in advance, the

arrangements for delivery. In Pakistan, according to law a pregnancy can be terminated only if there lies a serious risk to the life of the pregnant women.

- **Signing Medical Leaves:** A truthful, honest RMDP is under oath to be honest in making decisions and not be biased towards the client/patient's to make unlawful, unauthorized demands of allocating or extending sick/maternity leaves etc.
- **Procedures:** Patients undergoing procedures or treatment of any sort have the right to be informed as to which doctor or doctors are to be involved.
- **Fees:** Doctors fees should be appropriate to the service provided. Patients are entitled to ask how much a doctor is going to charge.

6.5 Consent

Consent is the "autonomous authorization of a medical intervention by individual patients." Patients are entitled to make decisions about their medical care and have the right to be given all available information relevant to such decisions. Patients have the right to refuse treatment and to be given all available information relevant to the refusal.

Consent may be explicit or implied. Explicit consent can be given orally or in writing. Consent is implied when the patient indicates a willingness to undergo a certain procedure or treatment by his or her behavior. For example, consent for venipuncture is implied by the action of rolling up one's sleeve and presenting one's arm. For treatments that entail risk or involve more than mild discomfort, it is expected that the physician will obtain explicit rather than implied consent.

Signed consent forms can document but cannot replace the consent process. There are no fixed rules as to when a signed consent form is required. Some hospitals require that a consent form be signed by the patient for surgical procedures but not for certain equally risky interventions. If a signed consent form is not required, and the treatment carries risk, clinicians should seriously consider writing a note in the patient's chart to document that the consent process has been obtained.

When taking consent, the physician should consider issues of adequate disclosure, the patient's capacity, and the degree of voluntariness.

"Voluntariness" refers to a patient's right to make health care choices free of any undue influence. However, a patient's freedom to make choices can be compromised by internal factors such as pain and by external factors such as force, coercion and manipulation. In exceptional circumstances -- for example, involuntary admission to

hospital -- patients may be denied their freedom of choice; in such circumstances the least restrictive means possible of managing the patient should always be preferred.

Special circumstances affecting the consent process are listed below

The Unconscious Patient

Consent may be implied or assumed on the grounds that if the patient were conscious they would consent to their life being saved.

The Violent Patient

A doctor asked to examine a violent patient is under no obligation to put him/herself in danger but should attempt to persuade the person concerned to permit an assessment as to whether any therapy is required.

The mentally ill

If the RMDP is in any doubt as to the patient's capacity to consent it is advisable to seek specialist opinion as well as discussing the matter with parents, guardians, or relatives.

The Mentally Handicapped

The RMDP should attempt to obtain consent but, depending on the degree of handicap, may have to consult with the patient's parents or guardians, and, in particularly difficult cases may have to obtain a second opinion.

Children

Children are entitled to considerate and careful medical care as are adults. If the doctor feels that a child will understand a proposed medical procedure, information or advice, this should be explained fully to the child. Where the consent of parents or guardians is normally required in respect of a child for whom they are responsible, due regard must be given to the wishes of the child. Also, the doctor must never assume that it is safe to ignore the parental/guardian interest.

7. Confidentiality-good practice in handling patient information:

7.1. Ethical and legal issues of confidentiality:

- Trust is an essential part of the doctor-patient relationship and confidentiality is central to this. Patients may avoid seeking medical help, or may under-report symptoms, if they think their personal information will be disclosed by doctors.
- The physician has a right to and should withhold disclosure of information received in a confidential context, whether this be from a patient, or as a result of being involved in the management of the patient, or review of a paper, except in

certain specific circumstances where s/he may carefully and selectively disclose information where health, safety and life of other individual/s may be involved.

- Doctors are under both ethical and legal duties to protect patients' personal information from improper disclosure. But appropriate information sharing is an essential part of the provision of safe and effective care. Patients may be put at risk if those who are providing their care do not have access to relevant, accurate and up-to-date information about them.
- The professional medical record of a patient should not be handed over to any person without the consent of the patient or his/her legal representative. Generally speaking, the state has no right to demand information from the doctor about his patient, save when some notification is required by statute such as in the case of communicable diseases. When in doubt, a legal advisor should be consulted.
- Doctors, like everyone else, must comply with the law when using, accessing or disclosing personal information.
- A presiding judge, may, despite the physician claiming the knowledge and communication is confidential overrule this contention and order or direct the witness to supply the required information. The doctor has no option but to comply unless willing to accept imprisonment for contempt of court.

7.2. Ending professional relationship with a patient:

- In rare circumstances, the trust between RMDP and a patient may break down, and he/she may find it necessary to end the professional relationship. For example, this may occur if a patient has been violent to the practitioner or a colleague, has stolen from the premises, or has persistently acted inconsiderately or unreasonably. As a RMDP, one should not end a relationship with a patient solely because of a complaint the patient has made about him/her or his/her team, or because of the resource implications of the patient's care or treatment.
- Before ending a professional relationship with a patient, RMDP must be satisfied that his/her decision is fair. RMDP should inform the patient of his/her decision and reasons for ending the professional relationship, wherever practical in writing.
- RMDP must take steps to ensure that arrangements are made promptly for the continuing care of the patient, and he/she must pass on the patient's records without delay.

8. Writing reports and CVs, giving evidence and signing documents

- An RMDP must be honest and trustworthy when writing reports, and when completing or signing forms, reports and other documents.
- He/she must always be honest about their experience, qualifications and position, particularly when applying for posts.
- He/she must do their best to make sure that any documents they write or sign are not false or misleading. This means that RMDP must take reasonable steps to verify the information in the documents, and that he/she must not deliberately leave out relevant information.
- If as an RMDP, he/she has agreed to prepare a report, complete or sign a document or provide evidence, it must be done without unreasonable delay.
- If RMDP is asked to give evidence or act as a witness in litigation or formal inquiries, he/she must be honest in all spoken and written statements. He/she must make clear the limits of his/her knowledge or competence.
- An RMDP must co-operate fully with any formal inquiry into the treatment of a patient and with any complaints procedure that applies to their work. He/she must disclose to anyone entitled to ask for it any information relevant to an investigation into his/her own or a colleague's conduct, performance or health. In doing so, he/she must follow the guidance in Confidentiality.
- If RMDPs are involved in designing, organizing or carrying out research, they must:
 - Put the protection of the participants' interest's first
 - Act with honesty and integrity
 - Follow the appropriate national research governance guidelines and the guidance in Research: The role and responsibilities of doctors.

9. Financial and commercial dealings

- RMDP must be honest and open in any financial arrangements with patients. In particular:
 - RMDP must inform patients about his/her fees and charges, wherever possible before asking for their consent to treatment;
 - RMDP must not exploit patients' vulnerability or lack of medical knowledge when making charges for treatment or services;
 - RMDP must not encourage patients to give, lend or bequeath money or gifts that will directly or indirectly benefit them;
 - RMDP must not put pressure on patients or their families to make donations to other people or organizations;
 - RMDP must not put pressure on patients to accept private treatment;
 - if RMDP charge fees, they must tell patients if any part of the fee goes to another healthcare professional.
- **Commercial Dealings:** An RMDP must be honest in financial and commercial dealings with employers, insurers and other organizations or individuals.

In particular:

(a) Before taking part in discussions about buying or selling goods or services, they must declare any relevant financial or commercial interest that they or their family might have in the transaction;

(b) If an RMDP manages finances, he/she must make sure the funds are used for the purpose for which they were intended and are kept in a separate account from their personal finances.

- **Conflicts of interest:** If the RMDP has financial or commercial interests in organizations providing healthcare or in pharmaceutical or other biomedical companies, these interests must not affect the way you prescribe for, treat or refer patients.
- If RMDP has a financial or commercial interest in an organization to which they plan to refer a patient for treatment or investigation, he/she must tell the patient about his/her interest.

Section 5

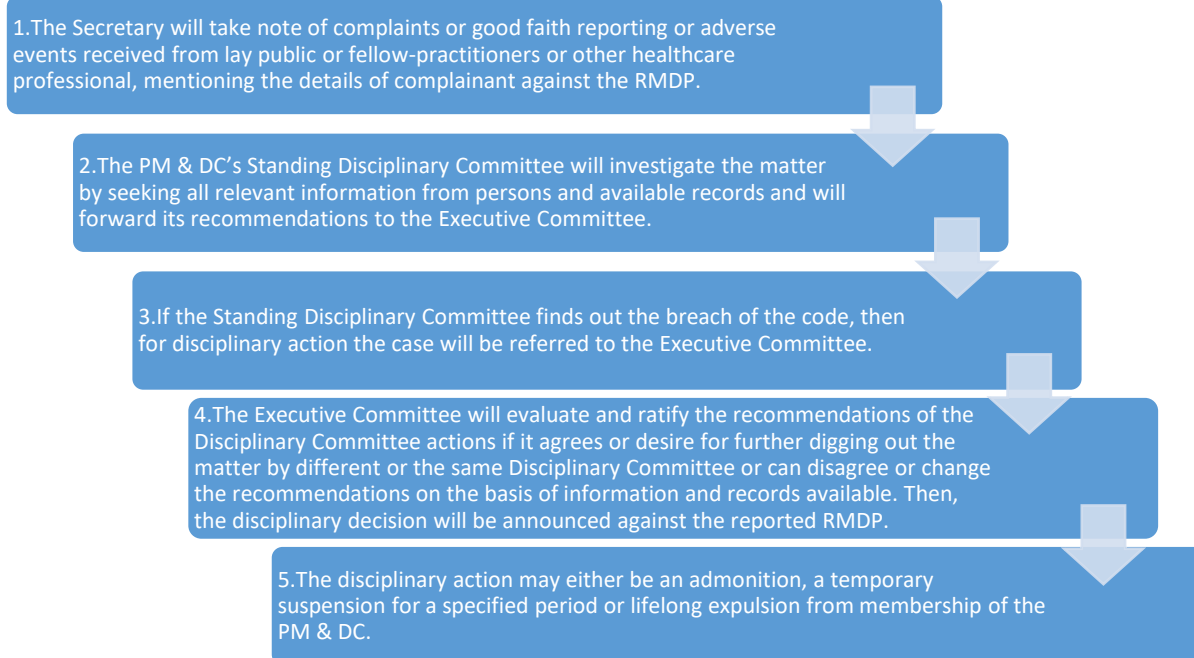
Disciplinary Issues and Working with other health care Professionals and Community

This section deals with the disciplinary issues and their management processes. It also gives the guidelines for working with other health care professionals and community members.

1. Disciplinary Issues and Its Management Process

1.1. Introduction to PM&DC disciplinary committee

Disciplinary issues will be faced by RMDP in their daily practices and during interactions with the patients, families and other health care professionals. Any issue i.e. adverse events, good faith reporting and complaints by patients or attendants if reported to PM&DC, the PM&DC may take disciplinary action (on the basis of recommendations of disciplinary committee) against members who violate the code. The following steps will be taken to tackle the disciplinary issues.



Complaint Management Process Summary

1.2. Adverse Events:

During practice when adverse events will occur, it is obligatory for RMDP to be open and honest in communication with the patient or their family members. Then, the practitioner will find out the root cause of the event in order to safeguard the patients in future. When some adverse event will occur, following steps needs to be taken by RMDP:

- Identify what has happened.
- Take prompt actions to rectify the adverse event.

- Provide appropriate support to patient.
- Comply with reporting requirements of the adverse event.
- Report adverse events.

1.3 Good Faith Reporting of Suspected Wrongdoing

- **“Good faith report”** means a report of conduct that can be defined as wrongdoing, where the reporting person thinks that report is true and where the reporting is made without malevolence.
- **“Wrongdoing”** means a breach of code of ethics or an apprehension in respect to any future improprieties.
- All the Good Faith Reports, investigations or inquiries and results will be kept strictly confidential unless disclosure is ordered by a court or regulatory agency. No action will be taken against the person who is reporting any wrongdoings in good faith. The colleagues, other physicians and health professionals like nurses, pharmacists and allied health professionals can do good faith reporting.

1.4 Complaints by the Patients or families:

Patients or families who will be dissatisfied regarding RMDP practices, care, attitude or conduct have right to complaint. The action will be taken as per PM&DC rules and regulations.

1.5 Process for Initiating Complaints:

The Secretary will take note of complaints or good faith reporting or adverse events received from lay public or fellow-practitioners or other healthcare professional, mentioning the details of complainant against the RMDP.

1.6 Disciplinary Action:

The disciplinary action that can be taken either be a warning, suspension for a particular time or lifelong expulsion from the PM&DC membership. The disciplinary action may either be an admonition, a temporary suspension for a specified period or lifelong expulsion from membership of the PM&DC. The PM&DC will take all decisions keeping in view the public interest and patients’ safety.

1.7 Constitution of the Disciplinary Committee:

This committee will be constituted as per regulations of PM&DC.

- No excuse of RMDP regarding PM&DC regulations ignorance will be acceptable. The information will be available on the website.

- The name of practitioners who have been expelled from the PM&DC register, will be displayed in PM&DC Gazette and the concerned regional health authorities will be informed.

2. Advertisement and Social Media

2.1 Introduction:

“**Social Media**” defines the mobile tools, websites and online applications that people use to share variety of information, experiences, opinions, videos, images, and sound clips. These media sources are used for social networking and linkages.

Whether an online activity is restricted to specific group of people or open to the public, the doctors must maintain the professional standards of confidentiality and keep in mind the consequences of their actions in all circumstances.

2.2 Advertisement:

When publishing the info, the RMDP should neither make claims about the quality of services’ nor make comparison with other doctors. The RMDP must neither provide guarantee of cure nor take advantage of patient’s medical knowledge deficiency. The RMDP will not advertise any information about services that pressurize the patients in any way to utilize those services.

The doctors can publicize their change of address and practicing hours in the local newspaper either once in three different newspapers or three times in the same newspaper, on three successive days. The RMDP may fix their nameplates at the residence where they are practicing, but the name plates must not be showy.

2.3 Photography:

The photography or making of videos for any purpose by medical or dental students or RMDP shall require permission. These photographs and videos must not show the identity of the patients to anyone else. If the patient is recognizable in photos or videos, he or she must be taken consent in written form Any kind of information for any type of purpose that can breach the patient’s confidentiality or any of his/her right shall not be shared on any kind of media, otherwise, the patient or family members can file complaint against the doctor or medical student.

3. Self-Regulation of the Profession

3.1 Introduction:

When RMDPs provide care to the patient, they enter into the complex system of private and public professional regulations, which define the working scope, restrict the practitioner who can perform what tasks and set different standards of

qualifications and continuous educational programs standards. Due to pervasive nature of professional regulations' system and their role in defining and implementing standards of professional conduct, it is very crucial for young RMDPs to understand the nature of their working along with the hurdles they will face. Self-regulation is the vital component in the field of medicine and during their career the RMDP will be involved in setting and implementing the professional standards in a variety of ways. The RMDPs must, therefore, comply with the regulation requirements of the PM&DC. These self-regulations among RMDPs will be ensured at individual and collective levels.

3.2 Individual Obligation:

The individual obligations can be fulfilled through following ways by:

- Maintaining competence
- Supporting professional associations and regulatory bodies
- Ensuring their integrity

3.3 Collective Obligation:

The collective obligations of self-regulation can be demonstrated by:

- Practicing morality and virtue
- Being open and transparent
- Being governed by an institutional code

4. Working within Health Care System

4.1 Introduction:

All RMDPs have a duty and responsibility of contributing towards the efficiency and effectiveness of health care system of Pakistan.

4.2. Prudent Use of Health Care Resources:

- All RMDPs shall wisely use the available health care resources. The RMDP shall: -
- Ensure that all the provided services are necessary and beneficial for patient
- Protect the right of the patients in order to gain access to the required level of health care and helping the patients wherever possible.
- Provide transparent and equitable distribution of health care resources.

4.3 Health Advocacy:

The numerous health disparities prevail in the health status of different Pakistani communities. These result from numerous social, geographic, cultural and other factors. In general, the Pakistani people are suffering from the burden of health inequity. RMDPs will, therefore, use best of their skills to protect the health and well-being of all patients and communities through health advocacy.

4.4 Public Health:

RMDPs will promote the health of the community through working in the areas of disease prevention and control. The practitioners will also participate in the efforts that will gear towards health education, health promotion, disease prevention, screening and reporting of notifiable diseases.

Section 6

The Ethical Issues relating to Research

This section deals with the ethical, clinical and regulatory issues of medical research conducted, participated and supervised by Registered Medical and Dental Practitioners. Moreover, this section highlights the established International guidelines on research ethics.

1. Medical Research

1.1. Scope/Over review

Medical research involves experimentation in a wide range of fields, including human tissue samples, medicine, biology, chemistry, pharmacology, toxicology, diagnostics and health information with the goal of developing new medicines or medical procedures or improving the application of those already available. It can be preclinical research (in cellular systems and animal models) and clinical research (clinical trials).

The commitment to research involves ethics (autonomy, non-maleficence, beneficence, justice, and fidelity), communication and compliance with pre-defined and written protocols as per International Conference on Harmonization (ICH), /Good Clinical Practices (GCP), the declaration of Helsinki and Belmont report guidelines.

Those who conduct research (i.e. clinical or non-clinical) should follow the above mentioned guidelines while conducting research on humans, regardless of who or what entity sponsors the research. Study subjects or their specimen should only be included in study after the subject have understood the potential risk and benefits of the study and has been informed in detail before giving and signing informed consent.

Only qualified and relevant competent RMDP should be involved in conducting research or their training must be ensured beforehand.

1.2. Approval from Institutional Review Board & Ethics Committee/National Bio

Ethics Committee

The RMDP must ensure the submission and approval of any kind of personal or collaborative clinical research from both i.e. Institutional Review Board and Ethics Committee (IRB&EC). In case the study is going to be conducted in that specific institute or in absence of such body, the National Bioethics Committee (NBC), approval should be sought before starting the test trials.

1.3. Research Ethics

Being involved in designing, organizing, conducting or reporting of health research which involves human beings, there are particular responsibilities for RMDPs, which include:

- Providing to participants the respect and protection that is due to them.

- Acting with honesty and integrity.
- Ensuring that any protocol for human research has been approved by the relevant review board and ethics committee (IRB&EC) or national bioethics research committee (NBC).
- Disclosing the sources and amounts of funding for research to the IRB/NBC.
- Disclosing any potential or actual conflicts of interest to the IRB/NBC.
- Ensuring that human participation is voluntary and based on an adequate understanding of sufficient information about the purpose, methods, demands, risks and potential benefits of the research by obtaining informed consent.
- Ensuring that any dependent relationship between RMDPs and their patients is taken into account in the recruitment of patients as research participants.
- Seeking advice when research involves children or adults who are not able to give informed consent, to ensure that there are appropriate safeguards in place. This includes ensuring that a person empowered to make decisions on the patient's behalf, has given informed consent. (For further detail please see General/inform Consent, section).
- Adhering to the approved research protocol. In case of changes, approval of changed protocol must be obtained by relevant IRB&EC.
- Monitoring the progress of the research and promptly reporting adverse events or unexpected outcomes to the institute and regulatory authority in case of any analytical/experimental studies.
- Respecting the entitlement of research participants to withdraw from any research at any time and without giving reasons.
- Adhering to the guidelines regarding publication of findings, authorship and peer review.
- Reporting possible fraud or misconduct in research.

1.4 ICH/GCP Compliance

The approved study/clinical research should be compliant with the latest ICH-GCP guidelines.

1.5 Registration of research (Trials.gov, DRAP)

Every registered RMDP must register his or her trial/study/research at www.trials.gov and DRAP/regulatory body after getting IRB&EC approval and before starting the recruiting process.

1.6 Informed Consent Elements

As per ICH-GCP eight elements of informed consent are essential. RMDP must clearly describe the eight elements, starting from description of study/research and its potential risks, discomforts and benefits, alternative procedure/treatments,

confidentiality of records, compensation and treatment for injury, contact information, voluntary participation in their local languages and should give appropriate time to decide with one copy of informed consent for their record. Also he/she must comply with ICH-GCP defined elements of informed consent (where applicable).

1.6.1 Complete Elements of Informed Consent

Described below are the twenty elements of informed consent, which increases the credibility of the research. However, RMDP must comply with the eight essential elements of informed consent as mentioned in section 1.6.

- That the trial involves research.
- The purpose of the trial.
- The trial treatment(s) and the probability for random assignment to each treatment.
- The trial procedures to be followed, including all invasive procedures.
- The subject's responsibilities.
- Those aspects of the trial that are experimental.
- The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant.
- The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
- The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks.
- The compensation and/or treatment available to the subject in the event of trial-related injury.
- The anticipated prorated payment, if any, to the subject for participating in the trial.
- The anticipated expenses, if any, to the subject for participating in the trial.
- That the subject's participation in the trial is voluntary and that the subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled.
- That the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority (ies) will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access.
- That records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject's identity will remain confidential.

- That the subject or the subject's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the subject's willingness to continue participation in the trial.
- The person(s) to contact for further information regarding the trial and the rights of trial subjects, and whom to contact in the event of trial-related injury.
- The foreseeable circumstances and/or reasons under which the subject's participation in the trial may be terminated.
- The expected duration of the subject's participation in the trial.
- The approximate number of subjects involved in the trial.

1.6.2 “Waiver”:

As per the guideline [45CFR46.116\(d\)](#)

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

1.7 Insurance/Indemnity

To protect the research participant from unforeseen circumstances due to active research/study, insurance/indemnity fund must be ensured by the RMDP in case of active participation of human subjects in experimental/interventional/analytical study. This clause is exempted where the study/research does not involve active human subjects.

2. Research Vulnerabilities

2.1 Research on Infant/children/teenager/adult

- Children/teenagers and adults should be involved as much as possible in discussions about their healthcare. When talking to a child/teenager or adult, it is important to give them information in an age-appropriate manner, listen to their views and treat them with respect.

- Refusal of treatment by a patient who is equal to 18 years, which is against medical advice and parental wishes, is of uncertain legal validity. In this event, consider seeking legal advice before acting on such a decision.
- Where the patient is under the age of 18 years, it is usual that the parents will be asked to give their consent to medical treatment/research participation on the patient's behalf.
- When a clinical trial/study (therapeutic or non-therapeutic) includes subjects who can only be enrolled in the trial with the consent of the subject's legally acceptable representative (e.g., minors, or patients with severe dementia), the subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

2.2 Research on Pregnant Women

The pregnant women should be excluded from clinical trials where the drug is not intended for use in pregnancy. If a patient becomes pregnant during administration of the drug, treatment should generally be discontinued if this can be done safely. Follow-up evaluation of the pregnancy, fetus, and child is very important. Similarly, for clinical trials that include pregnant women because the medicinal product is intended for use during pregnancy, follow-up of the pregnancy, fetus, and child is very important.

2.3 Vulnerable Population

The RMDP must protect the vulnerable individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, and patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

3. Research Funding

RMDP must disclose the direct, indirect, national, international funding source for the study with details of amount and service to the regulatory bodies, National Bioethics Committee and IRB&EC. This information should be available in the researcher study investigator file during and after one-year completion of the study.

3.1 Sponsored Research

Studies with the amount of 100,000/- or more should be readily available for audit purposes with a notice of 48 hours.

3.2 Non Sponsored Research

In case of self-sponsoring the researcher must disclose the financial details of the study.

4. Regulatory Issues

In any form of research either observational or analytical, RMDP must seek IRB&EC or National Bioethics Committee approval. For more information, these include;

4.1 Observational Studies

Case studies, Case series, Cross-Sectional, Case-Control, Prospective Cohort, Retrospective Cohort, health trends, Prevalence/incidence studies, Marketing surveillance studies or equivalent with same objectives.

4.2 Experimental/Analytical Studies

Quasi Experimental, Randomized control trial/studies, interventional trials/studies, gene therapies, or equivalent with same objectives.

5. Research Misconduct

5.1 Fraud

RMDP must not only hold himself/herself accountable under oath but also discourage others (colleagues) for that unethical and immoral activities and if observed, refer to sponsors/institute and copy to regulatory body.

5.2 Biasness

It leads to unwanted and compromised results therefore biasness towards patients, colleagues, family, friends should be avoided conducting studies and if observed.

5.3 Kick back

It is considered as a form of negotiated bribery in which commission/benefit is paid to the bribe-taker in exchange for services rendered. The remuneration could be in the form of money, goods, and/or services. He/she must avoid any form of benefit mentioned above and if observed must report to regulatory agencies.

5.4 Bribery

In any form should be avoided and if observed should be reported to regulatory agencies.

7. Research Medium

7.1 Clinics (Personal, Combined, Private)

RMDP who is part of the sponsored studies conducted in any form at personal clinics should be notified individually or collaboratively to relevant regulatory agencies at every six months with complete progress report.

7.2 THQ, DHQ, Poly Clinics/Equivalent

RMDP who is part of sponsored studies in any form conducting at Tehsil Headquarters (THQ), District Headquarters (DHQ), polyclinics or equivalent should notify regulatory/relevant agencies.

7.3 Hospital Clinics

RMDPs working at government and private hospitals and conducting research must notify annual research study progress report to regulatory/relevant agencies in case of long duration, more than one year studies and biannually in case of one year or less duration studies.

7.4 Telemedicine/Using Electronic medium (any)

- The practice of medicine through web-based telemedicine sites or other telecommunication methods requires clear adherence to principles of confidentiality and data protection. If a practice is conducted by such means, there must be adherence to strong security measures to protect the privacy of patient information. Web-based telemedicine sites must make their information policies clear to users. If telemedicine or other telecommunication services are provided to patients within the country, you must be registered with the PM&DC.
- It must be ensured that the transfer of any personal patient information to other jurisdictions complies with data protection principles and any sort of patient confidentiality information shared without informed consent will be considered as violation.
- To help patients understand telemedicine, they must be explained that there may be aspects of telemedicine that are different to traditional medical practice, for example a consultation involving physical examination.
- The qualified doctor must be registered under PM&DC for practicing and prescribing using any medium.

8. Disclosure of Research Information

Confidentiality is a fundamental principle of medical ethics and is central to the trust between patients and RMDP. Patients are entitled to expect that information about them will be held in confidence.

8.1. Legal/regulatory agencies

In certain limited circumstances, disclosure of patient information may be required by law. These circumstances are not limited to but may include: when ordered by a judge in a court of law, or by a tribunal or body established by an Act of the regulatory agency. In these instances, there must be information dissemination to the patients about the disclosure and the reasons for it.

8.2. Outbreak of communicable disease

While conducting research if there is any case of threat to outbreak or infectious disease it is mandatory to notify the relevant authorities and also notify the patient regarding disclosure of the patient confidential information.

8.3. Patients families, colleagues

While the concern of the patient's relatives and close friends is understandable, information should not be disclosed to anyone without the patient's consent. If the patient does not consent to disclosure, then it should be respected, except where failure to disclose would put others at risk of serious harm.

If the patient is considered to be incapable of giving or withholding consent to disclosure, it should be considered whether disclosing the information to family and carers is in the best interests of the patient.

8.4. Hospital/health care Professionals

Most people understand and accept that information must be shared within the healthcare team to provide safe and effective care. If disclosure of a patient's information is necessary as part of their care and treatment, reasonable steps should be taken to ensure that such a disclosure is done to an appropriate person who understands that the information must be kept confidential.

Clinical audit and quality assurance systems are essential to the provision of good care and must be supported by access to high quality reliable data. When patient information is to be used as part of clinical audit and quality assurance systems, it should be made anonymous as far as possible. Where making someone anonymous is not possible or appropriate, it should be clarified to the patients that their identifiable information may be disclosed for such purposes. They should have the opportunity to object to disclosure of their information and any such objection must be respected.

Education and training of health professionals is essential to the provision of safe and effective healthcare. When patient information is to be used for education and training purposes, it should be made anonymous as far as possible. Where making someone anonymous is not possible or appropriate, it should be clarified to the patients that their identifiable information may be disclosed for such purposes. They should have the opportunity to object to disclosure of their information and any such objection must be respected.

8.5. Sponsors/Other Competent Authority

In case of clinical study participants, no personal patient identification information should be shared with the sponsor. This information should be coded and must be secured. Laboratory reports and patient progress could be shared with Contract research organization (CRO's) and sponsors only for study/research progress. Complete patient confidential information will be provided under supervision of site investigator (or nominated team) on site for only source document verification process.

