



Institutional Ethical Committee

CODE OF ETHICAL PRACTICE FOR RESEARCH

Chhattisgarh Dental college & Research Institute
Sundra, Rajnandgaon – 491441 (C.G.)

CODE OF ETHICAL PRACTICE FOR RESEARCH

INTRODUCTION

Institutional Ethical Committee (IEC), CDCRI expects that all research carried out at or on behalf of the University, by staff and students, is conducted to the highest level of ethical standards and in accordance with current legislation and policy requirements.

The purpose of this policy is to protect the dignity, rights, safety and well-being of research participants; the safety and reputation of researchers; the reputation of college & the University, to ensure research carried out in connection with the University is lawful; to manage and mitigate the risks arising from research; and to ensure ethical awareness is embedded across all faculties & students.

The policy sets out the required standards of researcher integrity and requirements for ethical review of research projects that must be complied with for all projects undertaken by staff and students of CDCRI.

RESEARCH REQUIRING ETHICAL REVIEW

All research involving human participants, their tissue or data must undergo ethical review before initiation. This includes studies such as questionnaires and internet research where the researcher may not have direct contact with participants; and also studies involving combination of anonymous data where there is a possibility that individuals could be identified by combination of the data with another dataset or other information that is already in the public domain.

For funded research it is generally accepted that ethical approval need not be sought until funding is confirmed, but IEC can advise on methodological ethical queries that arise on funding applications, where necessary.

BENEFICENCE AND NONMALEFICENCE

All the staffs and students shall respect and safeguard the welfare and rights of all individuals with whom they interact professionally, including but not limited to research participants. All the staffs and students shall act in the best interest of research participants and society. When designing, reviewing or conducting research, staffs & students shall ensure that potential risks to research participants prior to and throughout the research are minimized, and that those risks are outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained. Steps taken to uphold this ethical principle include, but are not limited to:

- a. Design and conduct studies where a state of clinical equipoise exists, that is, to test hypotheses that have not yet been adequately tested through current or previous reported research results, to avoid unnecessary risks or inconveniences to participants of redundant research and to maximize often scarce research resources.
- b. Design and conduct research studies with scientific value.
- c. Ensure clinical research is conducted in accordance with currently accepted ethical guidelines and standards.
- d. Never use coercion or undue influence when recruiting research participant Seek autonomous informed and appropriately documented consent from participants or, where applicable, their legally acceptable representatives prior to the instigation of any research procedure.
- e. Never coerce, or attempt to coerce or induce individuals, such as staff members, vendors, contractors, investigators, or regulators, to act in an unethical manner in any respect.
- f. Avoid using substances, such as alcohol or drugs, while performing professional duties that may impair professional judgment or performance.

- g. Perform only those duties for which one is appropriately qualified and trained to perform.
- h. Where an individual is a member of a professional organization with its own licensing requirements and/or code of ethical or professional conduct, operate within the scope of practice and professional standards outlined within those professional guidelines, codes or licenses.
- i. Report any acts that appear to be unethical or illegal to appropriate organizational, institutional or legal authorities, so long as supported by reasonable evidence.

1. INTEGRITY

- a. Staffs & Students shall educate themselves, and where applicable, their students and their colleagues, about responsible research practices.
- b. Staffs & Students shall apply sound ethical values, scientific principles and judgment in the design, conduct and analysis of clinical studies, and in interpretation of their results.
- c. Staffs & Students shall report research findings accurately and shall not misrepresent, fabricate or falsify results.
- d. Staffs & Students shall conduct research in accordance with an approved research protocol/plan.
- e. Staffs & Students shall make all research data available to authorized persons for verification in accordance with established standards of the clinical research profession.
- f. Within their scope of authority, Staffs & Students shall ensure the dissemination of scientifically sound information from clinical trials and other investigations, and shall not withhold information relevant to full evaluation of the safety, efficacy or utility of

clinical interventions, agents or devices under investigation for the benefit of medicine, patients, science and society regardless of the research outcome.

2. CONFLICTS OF INTEREST

It is recognized that real, potential and apparent conflicts of interest naturally occur from time to time. Conflicts of interest arise when personal, professional, business, political and/or financial influences have the potential to significantly impair professional judgment, and hence lead to consequent acts of research misconduct. It is essential that Staffs & Students recognize when they may have a conflict of interest, and disclose such conflict as soon as the potential conflict is recognized. If participation in any research-related activity that poses a potential conflict of interest situation is unavoidable, Staffs & Students must ensure that steps are taken to appropriately manage any such conflicts to safeguard quality and credibility of their professional judgment from inappropriate influence so that research participants' rights and safety are fully protected. Staffs & Students shall not, under any circumstance, unduly exploit any professional relationship to further personal, political or business interest at the expense of others. Where Staffs & Students are part of an organization with a Conflict of Interest Policy, they are expected to respect and adhere to that Policy. Steps taken to uphold this ethical principle include but are not limited to:

- a. Publicly disclose relationships and potential conflicts of interest in publications, speaking engagements, Advisory Boards and any other venue or activity in which the Staff & Student is perceived as providing subject matter expertise.
- b. Retain documentation and use factual quantitative measures to conduct one's own professional duties and procurement of vendor services.
- c. Avoid dual relationships that could impair professional judgment or increase the risk of harm to others.

- d. Avoid performing services for direct competitors without the express knowledge and documented agreement of each party.

PRIVACY AND CONFIDENTIALITY

Privacy refers to the legal rights of individuals to limit public scrutiny; to limit access to their private acts and their personal information; and to limit disclosure of such personal information. Confidentiality refers to the obligation to protect private information about an individual or organization from unauthorized disclosure. Clinical research professionals have access to confidential information, whether it is intellectual property of a company or personal health information of research participants, and have the responsibility to maintain this confidentiality. Staff and students must maintain the privacy and confidentiality of research participants and of any confidential information received in connection with the Staff and students research to the extent required by applicable law(s) and/or signed contractual agreements. Steps taken to uphold this ethical principle include but are not limited to:

- a. Store written and/or electronic records in secure locations with access provided only to authorized individuals.
- b. Collect and transmit only the minimum essential information required to accomplish the task at hand.
- c. Apply standards of confidentiality to retrospective, current and prospective data collection and protected personal information.
- d. Ensure that all aspects of the privacy of research participants and their families is respected prior to, during, and following, any clinical research project

DUTIES TO SOCIETY AND COMPLIANCE WITH THE LAW

By the very nature of their work, Staffs and students are engaged in professional endeavors that enhance knowledge, skill, judgment and intellectual development that strives to contribute to improving the human condition. As such, clinical research professionals must be both aware and conscious of their duty to society and the clinical research arena. Staffs & students shall uphold the profession's responsibility to society by promoting ethical and professional practice standards, and be willing to be held professionally accountable for upholding those standards. Staffs & students shall not participate in criminal, fraudulent, or other illegal activities.

If a Staff & student is faced with a conflict between abiding by a law or regulation and following an ethical principle, except in extraordinary circumstances such as an emergency, Staffs & students shall consult with experienced, respected professional colleagues and seek their guidance. Staffs & students shall not advocate, sanction, participate in, or condone any act that is prohibited by this Code, unless failure to do so would be seriously detrimental to the rights and well-being of others.

DUTIES TO PROFESSIONAL DISCIPLINE AND BENEFICIARIES OF PRACTICE

Staffs & students shall be personally committed, and encourage others, to engage in safe, sound research practices consistent with the relevant ethical and scientific standards and the requirements of their professional discipline. Staffs & students shall uphold standards of equality and non-discrimination in all professional interactions, and shall cooperate with other professionals as appropriate and ethical. Staffs & students have a duty to assist colleagues entering the profession by sharing knowledge and understanding of the ethics, responsibilities and needed competencies of their chosen area of research and practice. Where Staffs & students seek to acquire or maintain a medical or other professional license,

additional laws and ethical standards of conduct that are not pertinent to clinical research may apply. Staffs & students shall, in addition to adhering to this Code of Ethics and Professional Conduct, abide by their respective discipline's laws and ethical standards of conduct. Additionally, Staffs & students who are also involved in the clinical care of patients shall take steps to avoid contributing to therapeutic misconception of research participants, and to ensure that the roles and responsibilities of physicians and other health care professionals acting as investigators and care providers remain clear. Staffs & students shall also ensure that all contributory information provided to research participants, their legal representatives and other health care providers not involved with the research is fair, balanced, accurate, understandable and sufficiently comprehensive to enable well-informed decisions about the use of pharmaceuticals, medical devices or other clinical services or interventions.

GROUND FOR DISCIPLINARY ACTION

A Staff & student shall be subject to disciplinary action if the actions of such Staff & student are determined, in accordance with the Discipline and Complaints Policy, to constitute one or more of the following:

- a. Gross negligence or willful misconduct in the performance of services, or other unethical or unprofessional conduct based upon demonstrable or serious violations of this Code of Ethics and Professional Conduct.
- b. Conviction of a Staff & student of a felony or other crime of moral turpitude under federal or state law in a matter related to the conduct of the profession.

COMPLAINTS

To file a complaint against a Staff & student, please contact IEC, CDCRI, Rajnandgaon. Complaints will be addressed according to the Discipline and Complaints Policy, available here, developed by the IEC, CDCRI Rajnandgaon.


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