

Research Policy Manual



St. John's Research Institute
St. John's National Academy of Health
Sciences

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Introduction

St. John's National Academy of Health Sciences (SJNAHS) aims to improve the health of the community and patient through research in lifestyle diseases, infectious diseases, and cancer and to develop models of cost-effective healthcare systems. SJNAHS and St. John's Research Institute (SJRI) is a Center for Excellence for medical research in India. The Institute considers research, creation of new evidence and the pursuit of knowledge to be one of its vital functions. It is committed to ensuring that all research activities is done in accordance with the highest standards of professional and ethical conducts.

It is the responsibility of researchers and investigators, with the guidance of their mentors, to observe the relevant academic conventions and requirements appropriate to their field, including acknowledgement of the intellectual property of others, and to avoid all forms of research misconduct.

Purpose of these Policies:

The purpose of these policies is to provide guidance to Principal Investigators (PI's), Co-Investigators (Co-I's), Faculty, and personnel of St. John's National Academy of Health Sciences regarding the policies related to research conducted within the Academy. It includes guidance and policies that are necessary for managing and administering research grants and all aspects of research pertaining to sponsored research, investigator-initiated research and academic research in accordance with SJNAHS rules, statutory compliances or other Institutional and sponsor requirements.

The research policies of the Academy aspires to support and create a culture of research amongst the faculty, staff and students and intends to leverage it for enriching and enhancing the professional competence of the faculty members and students. It also aims to fulfill the research mission of the Academy.

Scope of these Policies

These policies are applicable to all academic and administrative departments, divisions, units and personnel of St. John's National Academy of Health Sciences (SJNAHS) involved in any form of research activity and administering sponsored awards, investigator-initiated research and academic research studies.

The scope of these policies will be applicable to all the following administrative units of the Academy:

1. St. John's Medical College
2. St. John's Medical College Hospital
3. St. John's College of Nursing
4. St. John's Institute of Allied Health Sciences
5. St. John's Research Institute

These policies will be applicable to:

- a. All staff, temporary and permanent, who are active in teaching, research, administration and provision of any form of support to the core functions of the Academy.
- b. All students who participate in research within SJNAHS
- c. All mentors, guides, external experts and sponsors associated with any of the research activities of the Academy.

General Research Guidelines

Administration of Research Grants

All research grants will be administered by St. John's Research Institute as per SJNAHS guidelines. The Grants office will coordinate and facilitate all contractual and legal processes to obtain and manage research grants. The Grants office will liaise with the Director's office and the Legal office of SJNAHS to facilitate this process.

Receipts and Payments from Grants

The receipts policy aims to provide guidance concerning the deposit of receipts of the Institute and project funds to ensure they are deposited in accordance with the rules and regulations of the Institute and to ensure accurate accounting. Receipts and Payments guideline deals with the kinds of receipts and the accounts into which they are deposited.

SJRI is a unit of The CBCI Society and shares a common PAN Number. Funds are received into two accounts.

- a) CBCI Society for Medical Education
- b) St. John's Research Institute.

The receipts are:

- i) Grants for research projects (including industry sponsored clinical trials)
- ii) Endowments
- iii) Philanthropic Grants

Research Projects Grants include National and International governmental and non-governmental Research grants. All receipts should support necessary documentation that includes Award letter, Agreements and regulatory approvals. The amounts from Indian Government projects, workshops, and trainings will be received at St. John's Research Institute's account directly either in the form of cheque / DD or RTGS/NEFT. All International Research grants receipts will be in the form of Wire transfer directly to FCRA account of CBCI.

Institutional Overheads

Institute deducts 15 % of the total grant as overhead charges for all the research projects and 20% for Industry sponsored Research except Government Grants/ Specific Federal Funded Grants (where the overhead will be the maximum permissible by the funding agencies). The management reserves the right to revise the Institutional overheads from time to time and based on Institutional requirements.

Where the overheads do not meet the Institutional norms, the grant budget should incorporate direct costs in each grant budget to support the administrative activities of Research within SJNAHS.

Research Budget and Approval

Investigators are requested to submit their budgets for approval to the Budget and Accounts section for review prior to grant application and submission.

For all receipts a budget document with line items for all potential expenses should be submitted along with the Agreement. The budget has to be adhered to strictly. In case where funding agency

pays per patient, the Head of the Project/ Principal Investigator has to create and submit an internal budget for the same.

Purchases Guideline

All purchases for research projects will comply with the Purchase policy of SJNAHS. The main objective of the purchase guideline is to safeguard assets, prevent and detect error and fraud and optimize the uses of resources.

Assets Management Guideline

The Assets Management guideline covers all fixed and intangible Assets owned by the Institute and Project. All assets procured through research projects will be maintained in an asset management electronic register.

Travel Guideline

This guideline document aims to explain the travel related parameters that must be adhered to. SJNAHS adheres to Institute/Government/ Sponsors policies when processing travel reimbursement. Travel expenses must be reasonable and necessary, and travelers must always use the most cost-effective means of travel.

Purpose

- i. Workshop/Conference/Training/Meeting
- ii. Travel for Consultation
- iii. Travel for Deputation
- iv. Travel for Monitoring

Travel Advances

The purpose of the travel advance guideline is to allow Institute/project employees to receive advance funds to cover the cost of trip authorized by the Institute/project Official.

Exemptions

Travel performed as part of a project, which is sponsored by a grant, or Agreement is subject to such additional travel restrictions as may be imposed by the terms of the grant or Agreement. If Sponsor has more restrictive travel guideline, then the Sponsor guideline takes precedence.

Regulatory Approval Requirements:

SJNAHS is committed to meeting all regulatory approvals prior to the conduct of any research. This includes

1. Approval of Institutional Ethics Committee (IEC)
2. Approval of Drug Controller General of India in case of Clinical Trials and Medical Devices.(DCGI,CDSCO).
3. Approval of Health Ministry Screening Committee for all studies involving Indo –Foreign Collaboration
4. Approval of the Institute Bio-Safety Committee (IBSC) for any genetic and molecular studies.
5. Appropriate Material Transfer Agreement for the transfer of any biological Material outside the country
6. Registration prior to enrollment of all clinical trials in the national Clinical Trial Registry-India.
7. Any other regulatory procedures as required by the sponsor or regulatory authorities.

Research Integrity Policy

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

SJNAHS is committed to the conduct of research in an ethical manner fulfilling all ethical responsibilities related to

1. Procedures and processes as laid down by the Institutional Ethics Committee, SJNAHS
2. Compliance with existing ethical policies
 - i. Indian Council of Medical Research ethical policies for bio medical research on human participants
 - ii. Declaration of Helsinki
 - iii. Guidelines of the Catholic Church
 - iv. The Concordat – to support Research Integrity, UK
3. Ethical practices of investigators with regard to
 - i. Ethical oversight of the studies for which they are responsible
 - ii. Fair and ethical publication procedure

All research studies have to be mandatorily approved by the Independent Institutional Ethics Committee (IEC). In case of animal studies, review and approval by the Institute Animal Ethics Committee (IAEC) is required.

The respective committees have guidelines that are update periodically and shared with all investigators.

Policy Statement and Commitments:

1. SJNAHS is committed to maintaining the highest standards of rigor and integrity in all aspects of research.
2. SJNAHS is committed to ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards.
3. SJNAHS is committed to supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice, and support for the development of researchers.
4. SJNAHS is committed to using transparent, robust, and fair processes to deal with allegations of research misconduct should they arise.
5. SJNAHS is committed to working together to strengthen the integrity of research and to reviewing progress regularly and openly.

The complete document of Research Integrity developed by the Concordat Working Group is in the link below:

https://teams.microsoft.com/l/file/E3234F98-0457-40D1-80CB-D48588A242F5?tenantId=fd6a8a4c-d7f8-4fbd-8eb3-c80cf0019796&fileType=pdf&objectUrl=https%3A%2F%2Fsjmch.sharepoint.com%2Fsites%2FDocuments%2FShared%20Documents%2FGeneral%2Fthe-concordat-to-support-research-integrity.pdf&baseUrl=https%3A%2F%2Fsjmch.sharepoint.com%2Fsites%2FDocuments&serviceName=teams&threadId=19:YPu9D6bb1B60orUtvv_Y9fKyP8HDarkeHcX6if05F2Q1@thread.tacv2&groupId=13af27c0-85c7-49b0-afec-61bed9c9ea83

The ICMR Policy on Research Integrity and Publication Ethics is a reference document that guides our researchers

https://teams.microsoft.com/l/file/B74AF297-2FD8-4282-A7A2-075AAC3D29E3?tenantId=fd6a8a4c-d7f8-4fbd-8eb3-c80cf0019796&fileType=pdf&objectUrl=https%3A%2F%2Fsjmch.sharepoint.com%2Fsites%2FDocuments%2FShared%20Documents%2FGeneral%2FICMR_policy_RPE%202019.pdf&baseUrl=https%3A%2F%2Fsjmch.sharepoint.com%2Fsites%2FDocuments&serviceName=teams&threadId=19:YPu9D6bb1B60orUtvv_Y9fKyP8HDarkeHcX6if05F2Q1@thread.tacv2&groupId=13af27c0-85c7-49b0-afec-61bed9c9ea83

Research Misconduct

Research misconduct is characterized as behaviour or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. It is a problem because it can cause harm (for example to patients, the public and the environment), damages the credibility of research, undermines the research record, and wastes resources.

SJNAHS based on the concordat recognizes that academic freedom is fundamental to the production of excellent research. This means that responsibility for ensuring that no misconduct occurs rests primarily with individual researchers. However, both employers of researchers and funders of research have an active role to play in sustaining research integrity. For example, failing to deal with allegations of misconduct appropriately and refusing to publish negative research findings would be equally harmful to the reputation and quality of research, and to the research record.

Research misconduct can take many forms, including:

- o **fabrication:** making up results or other outputs (eg, artefacts) and presenting them as if they were real.
- o **falsification:** manipulating research processes or changing or omitting data without good cause
- o **plagiarism:** using other people's material without giving proper credit
- o **failure to meet ethical, legal and professional obligations:** for example failure to declare competing interests; misrepresentation of involvement or authorship; misrepresentation of

interests; breach of confidentiality; lack of informed consent; misuse of personal data; and abuse of research subjects or materials.

- o **improper dealing with allegations of misconduct:** failing to address possible infringements such as attempts to cover up misconduct and reprisals against whistleblowers.

This list is not intended to be exhaustive. Honest errors and differences in, for example, research methodology and interpretations are not examples of research misconduct.

It is imperative that when an allegation of research misconduct arises suitable procedures are in place to deal with it effectively and fairly. Employers have a duty of care to the researchers they employ, and there needs to be appropriate protection for the rights and interests of all parties. There must be accountability when things go wrong and, where concerns are upheld, appropriate action must be taken.

Managing Allegations of Research Misconduct

1. **Employers of researchers** have the primary responsibility for investigating allegations of research misconduct. It is the responsibility of employers to ensure that any person involved in investigating such allegations has the appropriate knowledge, skills, experience and authority to do so.

Employers of researchers are also responsible for taking appropriate steps to remedy any situations arising from an investigation. This can include imposing sanctions, correcting the research record and reporting any action to regulatory and statutory bodies, research participants, funders or other professional bodies as circumstances, contractual obligations and statutory requirements dictate. Employers should also be mindful that minor infractions, where there is no evident intention to deceive, may often be addressed informally through mentoring, education and guidance.

2. **Researchers will:**
 - o act in good faith with regard to allegations of research misconduct, whether in making allegations or in being required to participate in an investigation
 - o handle potential instances of research misconduct in an appropriate manner; this includes reporting misconduct to employers, funders and professional, statutory and regulatory bodies as circumstances require.

As part of existing mechanisms and conditions of grant, employers of researchers should already:

- o have clear, well-articulated and confidential mechanisms for reporting allegations of research misconduct
- o have robust, transparent and fair processes for dealing with allegations of misconduct that reflect best practice
- o ensure that all researchers are made aware of the relevant contacts and procedures for making allegations
- o act with no detriment to whistleblowers making allegations of misconduct in good faith

- provide information on investigations of research misconduct to funders of research and professional and/or statutory bodies as required by their conditions of grant and other legal, professional and statutory obligations
- support their researchers in providing appropriate information to professional and/or statutory bodies.

Funders of research will:

- have clear expectations of what constitutes research misconduct
- ensure that recipients of funding are aware of requirements regarding the investigation and reporting of research misconduct, and that these are openly stated.

Other organizations may be able to offer advice, guidance and practical assistance to all those involved with handling allegations of research misconduct. identifies some resources that can help organizations ensure that systems for handling allegations of misconduct are effective.

Whistleblower Policy

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

'Whistleblowing' is a term used to describe a disclosure alleging corruption, malpractice or wrongdoing on the part of another person within an organization. A whistle-blower is a person who exposes this.

Whistleblowing, however, tends to relate to matters concerning the organization, such as:

- o A criminal offence
- o An individual is failing to comply with their legal obligations
- o A departure from agreed procedures relating to statutory or other requirements
- o The health or safety of an individual has been, is being, or is likely to be endangered
- o The environment has been, is being, or is likely to be damaged
- o Research misconduct
- o Any of the above has been, is being, or is likely to be deliberately concealed

SJNAHS recognizes that academic freedom is the fundamental to the production of excellent research outcomes. The responsibility to ensure that no misconduct occurs lie within the individual researchers. However, both the employers, employees and sponsors of the research have an active role to play in sustaining research integrity.

Scope:

The Whistleblowing policy concerning with research conduct is applicable to all employees of all the units of this Academy, namely,

1. St. John's Medical College
2. St. John's Medical College Hospital
3. St. John's College of Nursing
4. St. John's Research Institute
5. St John's Institute of Allied Health Sciences

This policy applies to all categories of employees of the Academy involved in research, it includes permanent, temporary and contractual employees. This policy also applies to all students, researchers including visiting researchers, persons with honorary positions, conducting research within, or on behalf of, the SJNAHS.

Commitment

SJNAHS is committed to ensuring that all corruption, malpractice or wrongdoing on the part of another person within an organization including research misconduct are investigated thoroughly, fairly and expeditiously, and with care and sensitivity. To this end, the procedure for handling allegations of misconduct is separated into two stages.

- i. Firstly, an initial assessment to determine whether there is a legally required presumption case for an investigation, and

- ii. Secondly a formal investigation to examine and evaluate all the relevant facts, and to determine whether research misconduct has been committed.

Definitions:

- I. Whistleblowing**
Whistleblowing is an act wherein a person exposes secretive information or activity within a private or public organization that is deemed illegal, unethical, or not correct.
- II. Whistle-blower**
A person who exposes to whistleblowing
- III. Respondent/s**
An employee or employees against whom the whistle-blower has made a complaint.
- IV. Employer**
SJNAHS or a Sponsored Research Project
- V. Employee**
Any employee, faculty or non-faculty, working for the organization, part-time or full-time or working for a specific research project who may be:
 - Permanent
 - Temporary
 - Contractual
 - Consultants
 - Advisers
 - Research Students
 - Honorary positions
 - Visiting Researchers
- VI. Misconduct**
Any allegations, corruption, malpractice or wrongdoing on the part of another person within an organization including research malpractices.
- VII. Research Misconduct**
Research misconduct is characterized as behaviour or actions that short of the standard ethics and research standard required that the integrity of the research is upheld. This includes fabrication, falsification, and plagiarism, failure to meet ethical legal and professional standards.
- VIII. Dean's Office, St. John's Research Institute**
The Dean's office includes the Office of the Dean of the St. John's Research Institute (SJRI) who administers and oversees the research activities/projects at SJNAHS. It also includes the Office of the Vice-Dean of SJRI.
- IX. Associate Director – College and Research Institute**
The Associate Director – College and Research Institute oversees the administration of St. John's Research Institute in addition to the medical college.

Reporting

What could be reported?

An exhaustive list of misconduct or non-compliance matters may be reported, such as: -

- i. Corruption
- ii. Financial fraud
- iii. Conflict of interest
- iv. Misuse of research funds
- v. Health and safety issues
- vi. Anti-competitive strategies
- vii. Unethical research conduct
- viii. Breaching confidentiality of subject information
- ix. Harassment or discrimination
- x. Workplace violence
- xi. Any other practice which may be illegal or unlawful

Procedure:

1. Initial Allegation of misconduct

- o Any member of SJNAHS who believes that an act of misconduct has occurred or is occurring in relation to a research study or a research implementation or a research project should notify their respective Head of the Division or Department. Where this is not possible because of the personal involvement of the Head of the Division /Department, the matter should be raised directly with the Dean's Office, St. John's Research Institute (SJRI) or Dean, St. John's Medical College as required
- o The recipient of the report (Head of the Division or the Dean's Office) should undertake a preliminary assessment of the allegation received. Where he or she considers the matter to be of sufficient seriousness, the matter should be reported/forwarded as soon as possible to the Dean's Office, SJRI or SJMC. Where the individual raising the matter is dissatisfied with the conclusion reached by the Head of the Division, he or she may raise the matter directly with the Dean's Office, SJRI or SJMC.
- o Such complaints received in writing should mention the identity of the individual making the allegation and should be signed by the same.
- o Complaints will be handled as per the applicable regulations/statutes of India and as per the Institutional policies.
- o All possible steps will be taken by the Institution to ensure the anonymity of the individual reporting suspected misconduct until such time as it is decided that a formal investigation is warranted.
- o Where a sponsor requires SJNAHS to notify it of allegations of misconduct at the stage that it is decided to undertake an 'informal inquiry' or 'preliminary investigation', the Head of the Department or Division should inform the Dean's Office, SJRI or SJMC that an initial assessment is being undertaken along with the name of the individual, the link to the funder and the nature of the allegation(s).

2. Assessment of whether a formal Investigation is required.

The Dean's Office, SJRI or SJMC shall assess whether the allegation should result in instant suspension or dismissal in accordance with the Institutional procedures, whether the matter can be resolved informally, or whether a formal investigation is warranted. Wherever necessary, the Dean's Office, SJRI or SJMC will consult senior faculty in this regard, in confidence, where it is determined that formal investigation is required.

The Dean's Office, SJRI or SJMC shall also ask the person making the allegation to submit in writing a detailed statement in support of the allegation, along with evidence/s and statements

where required. The respondent shall be entitled to seek appropriate advice before responding. The Dean's Office, SJRI or SJMC may also, at his or her discretion, choose to evaluate anonymous allegations, depending on the seriousness of the issues, the credibility, and the feasibility of confirming the allegation with credible sources.

3. Formal Investigation.

- o If the allegation is subject to the law or would be subject to instant dismissal or suspension under the Institutional procedures, it should be dealt with through the appropriate mechanism. Otherwise, the Dean's Office, SJRI or SJMC shall request the ***Institute Ethics Committee*** to setup an independent inquiry and formal investigation into the allegation.
- o The purpose of the formal investigation is to examine and evaluate all relevant facts related to the misconduct, and to determine whether the misconduct has been committed, and if so, the responsible person(s) and the seriousness of the misconduct.
- o Where the Dean's Office, SJRI or SJMC has determined that a formal investigation is required, he or she shall notify appropriate persons including the Executive members and the Head of the Division/Department that the Investigation is taking place. However, it is also essential to limit circulation of details of the allegation strictly to those who have a genuine interest, and to protect the identity of the whistle-blower and other individuals involved.
- o The individual against whom the allegation is made (the respondent) shall be informed in writing by the IEC Committee, of the allegations, and be invited to respond in writing and to produce further written statements or evidence in his or her defense.
- o The IEC may: (a) examine the statements of the person making the allegation and the respondent (b) interview the respondent and any other parties it chooses (c) require the respondent - and if it judges it necessary, other members of the Academy - to produce files, notebooks and other records; (d) widen the scope of its investigation if it considers that necessary; (e) seek evidence from other parties.
- o Where possible, the IEC shall complete its work within 60 days of its establishment and submit a report to the Dean's Office, SJRI.
- o The respondent shall be given copies of the report and evidence considered by the IEC. Care shall be taken to maintain the anonymity of the whistle-blower and key witnesses.

4. Appeal

The respondent and the whistle-blower shall have the right of appeal against the findings of the IEC for a final review. Any appeal must be addressed to the convenor of the IEC, SJNAHS and normally lodged within 14 calendar days of the findings being made available to the respondent/whistle-blower for making the appeal. The appeal will be referred to 2 independent SJNAHS faculty who have not previously had a role in the case, and these individuals may take such action as deemed necessary. The IEC, will notify the respondent in writing of the outcome of the appeal to the Respondent, Whistle-blower, the IEC and to the Sponsor (if applicable). The decision of the Dean's Office shall be final.

5. Subsequent Action

If the IEC has found the allegation proven, in whole or in part, or proven to be false, and any appeal has not been upheld, the findings of the Committee shall be reported to the Director, who shall finalize the final outcome.

6. Confidentiality

All members of the IEC and those assigned for record keeping, as well as any staff member questioned in relation to an issue at hand, are bound by the duty of confidentiality at all times and hold in confidence, all documentation and information exchanged in the process.

7. Amendment

SJNAHS may amend/modify this policy in whole or part from time to time, with the approval of the Executive Committee Members, based on changes with the regulations or institutional policies

8. Retention of Documents

All the documents and testimonials in relation to complaint received and gathered during investigations shall be stored by the Dean's Office for a minimum period of five years.

9. Auditing

An annual internal audit will be conducted by a separate Audit Committee to prepare a report on the number of complaints received, results of the investigations and the action taken.

Human Research Protection Policy

Purpose and Scope

This policy will cover all types of research activities involving Human subjects, both funded and non-funded by members of the Academy and will also include undergraduate student projects, post graduate dissertations and postdoctoral thesis works.

The Research at SJNAHS is extensive and broad in the scope and nature of its activities, including biomedical, behavioral, social science, and epidemiological research, as well as studies in the area of health services. Subjects may include healthy volunteers as well as patients and other individuals who may be considered vulnerable due to medical, cognitive, emotional, economical, educational, age, or other factors. Although much of the research is conducted in the Bangalore City area and on SJNAHS, faculty members may also actively mentor research at other sites both domestic and international. Furthermore, many SJNAHS faculty members collaborate on projects with investigators at other institutions. Throughout these written procedures, “human subjects research” (HSR) is defined as those activities that meet the criteria articulated in applicable U.S. DHHS regulations to be considered as both research” and as involving “human subjects”.

Definition of research:

CDSCO defines a clinical trial as follows;

A systematic study of pharmaceutical products on human subjects – (whether patients or non-patient volunteers) – in order to discover or verify the clinical, pharmacological (including pharmacodynamics / pharmacokinetics), and / or adverse effects, with the object of determining their safety and / or efficacy.

The IEC of SJNAHS also reviews Quality assurance and public health projects although the reference quoted does not consider it as “research”. Classroom projects that have the sole purpose to teach research methods to students are not reviewed by the IEC. Case studies of single patients do not fit the definition of a systematic investigation and therefore, do not require review by the IEC.

Definition of human subjects:

CDSCO defines a study subject as follows:

A Study Subject may be a healthy person volunteering in a trial or a person with a medical condition that is unrelated to the use of the Investigational Product or a person whose medical condition is relevant to the use of the Investigational Product.

Under the ICMR regulations (2006), human subjects are defined as living individual(s) about whom an investigator conducting research obtains:

- (1) Data through intervention or interaction with the individual; or
- (2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for

specific purposes by an individual and which can reasonably expect will not be made public (e.g., medical record information.) Since the definition of a human subject is a living individual, research involving autopsy materials or cadavers is not considered human subjects research and is not reviewed by the HRPP although it may come under the purview of IEC.

Definition of an investigational product:

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.(1.33 ICH GCP).

Responsibilities of the Institute Ethics Committee (IEC) regarding Human Subjects

The IEC at St. John's National Academy of Health Science has been setup as an independent Ethics review committee and has the responsibilities listed below:

- Responsible for implementation/supervision/evaluation of the Human Research protection policy
- Providing inputs for review of existing policies and procedures under the program and suggest modifications.
- The IEC will regularly interact with various entities which will assist it in promoting human protection, dissemination of ethical principles and education of both researchers and research participants.
- It will be responsible for addressing complaints, non-compliance, undue influence etc and is entrusted with carrying out an enquiry, audit or investigation to address the issue and communicate it to the researcher.
- It will address issues arising out of "Conflict Of Interest" as disclosed in submissions to IEC or if subsequently develops. It has the authority to suspend or terminate a trial if a gross misconduct is found. It has the authority to censure the investigator and bar him from conducting research studies for a period of time.
- Research involving Human subjects which does not need IEC approval will be periodically reviewed by the IEC to ensure protection to Human subjects as this group needs additional protection.
- It will follow up implementation of any suggestions or directives given to researchers by constant communication to ensure compliance.
- The IEC will be available to address any concerns, questions and complaints of both researchers and research participants through written communication via e-mail or printed or written letters.

Human Subject in Research Policy Statement

In order to safeguard the rights and welfare of Human Subjects in Research, St. John's National Academy of Health Sciences follows the ethical principles of the Belmont Report and adheres to all applicable federal or state law or regulations, and Academy policies and guidelines governing the participation and protection of Human Subjects in Research.

The IEC of St. John's National Academy of Health Sciences holds a current Federal wide Assurance (FWA) filed with the Department of Health and Human Services Office of Human Research

Protection (OHRP) for the protection of Human Subjects, USA. This assurance applies to all Research with Human Subjects in which the Academy is engaged and that is funded or supported by any funding agency that has adopted the Common Rule, regardless of the site of the activity.

The Academy's commitment to protecting Human Subjects applies to all Human Subjects Research in which it is engaged, regardless of funding source or the institution that provided the IEC review.

Investigator Responsibilities:

All faculty and staff who are conducting Research involving Human Subjects within the course and scope of their Academic duties, as well as students who are conducting Research involving Human Subjects within the course and scope of their academic course and studies, regardless of whether the Research is funded and regardless of the source of funding, must submit Human Subject Research protocols to the IEC for approval or follow IEC policies and/or procedures for obtaining an exempt determination prior to commencing Research. Investigators must maintain IEC approval for the lifespan of the project, submit continuing review documents to the IEC as necessary to maintain the approval, and follow all IEC and Academy policies for the protection of human subjects in the conduct of the project.

Training Requirements

For all sponsored studies involving human subjects research, SJNAHS investigators and all key personnel must fulfill the protection of human subjects education and certification requirement. This can be achieved by completing the training hosted by the Office of Human Research Protection's Human Research Protection Training.

Website: <https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/index.html>

Data Sharing Policy for Access and Use of Healthcare Data for Research, Scientific and Statistical Purposes

This will provide the means of sharing of sensitive and non-sensitive healthcare data that has been collected at various units or projects of St. John's National Academy of Health Sciences, Bangalore (SJNAHS). Access will be provided to parties on a case-by-case basis based on the assessment of the nature of data for which access is sought, purpose of such sharing, ethical issues involved, consent from the concerned authorities, etc.

Purpose

This Data Sharing Policy for access and use and sharing of healthcare data for research, scientific and statistical purposes will apply to both sensitive data (containing identifiers) and non-sensitive data generated at SJNAHS. This policy document is designed to promote data sharing and access of non-sensitive data. Data collected can be shared as per the applicable laws, regulations, policies. Some of the laws that need to be considered include:

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1. Article 19 and 21 of the Constitution of India (Right to Privacy)
2. Information Technology (IT) Act, 2000 and the IT (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011
3. International Standard IS/ISO/IEC 27001 on "Information Technology-Security Techniques – Information Security Management System- Requirements".
4. Ethical Guidelines for Biomedical Research on Human Subjects 2000
5. Indian Medical Council Regulations, 2002
6. Medical termination of pregnancy (MTP) Act 1971 and MTP Rules, 2003
7. Epidemic Disease Act 1897
8. Consumer Protection Act, 1987
9. Mental Health Act 1987
10. Pre-Natal Diagnostic Techniques Act, 1994
11. UIDAI Act, 2010
12. Right to Information Act
13. The Personal Data (Protection) Bill, 2013
14. Digital Information Security in Healthcare Act (DISHA), 2018 (as applicable prospectively)
15. Any other act, policy, ethical guideline, quality standard or international commitment that may be applicable

It is important to note that, both within and outside St. John's, should be approved in advance by the St. John's Institutional Ethical Committee.

Data access for Research Purposes

1. **Data access of participants for primary research purposes**

If the data is collected for primary research purposes, then a consent process involving a consent form should be developed. The data access process and parties (individuals) having access should be mentioned. Additionally, if data is shared for secondary research (like a building a repository), the same should be informed to the subject during the consent process. The plan to remove all the identifiers should be explained in the consent form (de-identification and encoding process). The subject should also be given the flexibility of withdrawing consent whenever they require, and in such cases, their data also deleted from that point of time onwards. There should be a data sharing agreement between SJNAHS and the research collaborators having access to the data, including the party receiving the data should be bound by a Non-Disclosure Agreement for a period as long as they hold the data. This agreement should define the means by which the data will be shared, confidentiality clauses, IP and other protocols linked with data sharing. Only anonymized data can be shared and sharing of any identifiers or any data that may identify the subject is not permitted.

2. **Data access for Secondary Research purposes**

In such cases the data has to be shared in a fair, ethical manner with authorized recipients only. There should be a data sharing agreement between the PI of St. John's National Academy of Health Sciences and the other party, including the party receiving the data should be bound by a Non-Disclosure Agreement for a period as long as they hold the data. This agreement should define the means by which the data will be shared, confidentiality clauses, IP and other protocols linked with data sharing. It is important to note that sensitive data generated including the patient or subject identifiers should NOT be shared and any document containing such identifiers will NOT be provided to anyone except the primary in-charge (may be the Principal investigator or a research study, Treating Department HOD, etc). The sharing of such documents should be done only if the identifiers have been removed and the data has been encoded.

For secondary research, data can be shared based on the type of data involved: -

1. If identifiable data is shared of subjects: It is not authorized to share any data of subjects that have the identifiers included. Such data should be stored in an area within the premises of St. John's National Academy of health sciences with access and responsibility only with the PI/HOD for the security and storage of such data.
2. If identifiable data is removed and encoded: Such a situation may be permitted if the St. John's Institutional Ethics Committee find that the purpose and other aspects of the study meets with the ethical guidelines.

3. If unlinked data is to be shared: Such a situation may be permitted if the St. John's IEC determines that there are no ethical issues involved in sharing such data.

Data sharing within St. John's National Academy of health sciences (Intra-mural projects)

The IEC should provide permission for data sharing between the various departments of St. John's National Academy of health Sciences. It is also important that the transfer of such data is recorded, and appropriate permissions are documented from the relevant authorities within St. John's National Academy of health sciences is taken. However, such data collected and shared within entities within SJNAHS should be stored within the premises of SJNAHS, in full control and responsibility with the PI/HOD.

Data Sharing with Repositories outside SJNAHS

The PI/HOD may deposit required data with secure depositories and for non-profit purposes, as long as permitted by the law (such as the notifiable disease act). It is important to understand the purpose and the type of authority collecting such data and if permitted by law (such as a notifiable disease law). An agreement should be signed between SJNAHS and the authority collecting data where the purpose, model, permissions, confidentiality, security and analysis plans of data collected is clearly outlined. It is important that the St. John's IEC provides permission in advance for collection of data on such repositories involving SJNAHS.

Ownership of data

The respective primary owner of the data will include: -

The Patient or Subject whose data has been collected.

The custodians of the data will include:

Principal investigator of a research study

Co-Investigator of a research study, data from the respective department has contributed to the performance and analysis the study

Head of the respective department from where data has contributed towards a study.

In all circumstances, the permission of the primary owner will be required in writing and acknowledgment of such contribution should be mentioned in the paper arising out of the research study.

Data Sharing Plan (DSP)

All activities that are undertaking research and sharing of data, will have to create and describe the DSP and include the following aspects: -

1. Data to be produced for the research
2. Principle of data sharing
3. Manner in which subject confidentiality and privacy is maintained

- a. Confidentiality clause should extend for a duration beyond the study
4. Manner in which identifiers will be removed and data encoded
5. IPR issues that will preclude sharing of data and secondary research information
6. Timeline for sharing the data
7. Costs and resources required to support the DSP
8. Data formats - Data is to be shared in an open format that can be machine-readable such as by Statistical Software like SPSS and R (like CSV, XLS, ODS, XML, RDF, KML, GML, RSS).

Research Publication Policy

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

SJNAHS produces high quality research across many disciplines. SJNAHS is committed to ensuring that the outputs of research are freely accessible and disseminated so that the potential for economic, social and cultural impact can be maximized. Some researchers and many outside the academic community do not have access to the outputs of SJNAHS research because of the restrictions placed by publishers on access to subscription-based scholarly journals. We share the ambition to allow access to research outputs to the widest possible community.

Policy Statement:

1. SJNAHS Research Publications Policy requires that:
 - o Authors record bibliographic details of all research outputs in SJNAHS publications database, no later than three months after the date of acceptance for publication.
 - o Authors deposit full text copies of research outputs, i.e. final accepted peer-reviewed journal articles and conference papers (and where appropriate, monographs) in the institutional repository no later than three months after the date of acceptance for publication.
2. Where publisher's copyright permissions allow and there are no confidentiality or commercial constraints, the research outputs in the institutional repository must be made 'open access', i.e. freely accessible over the internet.
3. Where outputs are not embargoed for any period they must be made open access within one month of deposit. After an embargo period, outputs must be made open access immediately after the last day of the embargo period.
4. Authors must comply with the funders' policies relating to open access and research data management.
5. Authors must use a standardized institutional affiliation "St. John's Medical College" along with their respective Institutional affiliation such as St. John's Research Institute, in all research outputs to ensure clear affiliation with the St. John's
6. Authors must acknowledge the source of grant funding associated with a research output in the publication itself. Information about the grant should also be linked, by the author, to the record of the publication in the SJNAHS Publications Database.
7. Authors should register for an individual ORCID2 identifier and should include it on a personal webpage, when submitting publications, when applying for grants, and in any research workflow to ensure that the individual is credited for their work and that the correct institutional affiliation is achieved.
8. The policy applies to all research outputs, including those published by PhD students. Where copyright permits, monographs may also be deposited. Other forms of published outputs, e.g. articles or letters published in the press, may also be added to the institutional repository. These often contribute to the impact of the researchers' work and provide valuable permanent accounts of our research activities.
9. SJNAHS will comply with the International Committee of Medical Journal Editors (ICMJE) guidelines for publishing research manuscripts.

International Committee of Medical Journal Editors (ICMJE) guidelines

1. Defining the Role of Authors and Contributors

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

2. Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest.

[http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsib%60lities--conflicts-of-interest.html](http://www.icmje.org/recommendations/browse/roles-and-responsibilities/author-responsibilities--conflicts-of-interest.html)

3. Responsibilities in the Submission and Peer-Review Process

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/responsibilities-in-the-submission-and-peer-peview-process.html>

4. Journal Owners and Editorial Freedom

<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/journal-owners-and-editorial-freedom.html>

Policy on Plagiarism

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

This policy aims to describe the steps instituted by SJNAHS to curb academic dishonesty and research misconduct specifically plagiarism.

Definition

Plagiarism is defined as presenting someone else's work as one's own work. This may include copying or reproducing a matter without the acknowledgement of the source. Plagiarism involves copying of: phrases, clauses, sentences, paragraphs or longer extracts from or longer extracts from either published or unpublished work even from the legitimate cooperation without acknowledgment of the source.

Types of Plagiarism

Plagiarism may be of several types:

- (i) The researcher may quote invalid sources which may be incorrect or nonexistent attempting to increase the list of references and to hide inadequate research.
- (ii) Sometimes the researcher may use a secondary source taking the primary source within the secondary one. This may provide a false sense of the amount of review that went into the research.
- (iii) Self plagiarism involves reusing one's own previous research and research papers.
- (iv) Paraphrasing is intellectual theft which includes taking another person's writing and changing the words, making it appear as original idea or piece of research. Paraphrasing ranges from sample rephrasing to completely rewriting the content while maintaining the original idea or concept.
- (v) Repetitive research is a type of self-plagiarism which includes repeating of data or text from a similar study with a similar methodology in a new study without proper attribution.
- (vi) Replication in submission of a paper to multiple publications which results in the publication of the same paper more than once.
- (vii) Inaccurate authorship is a type of plagiarism where authors are denied credit for partial or significant contributions made to a research work or the reverse, that is, authors are cited in a paper who have not made any contribution.
- (viii) Unethical collaborative research work using written work, outcomes, and ideas without citing

the nature of collaboration and the participants involved is considered unethical.

(ix) Verbatim plagiarism is copying another person's words and works without giving proper attribution.

(x) Complete plagiarism includes resubmitting in one's own name, a study, a manuscript or other work from another research.

Policy Statement and Commitments

Evaluation of academic and research work of scholars and students and also faculty members leading to the partial fulfillment for the award of degrees at Master's and research level in the form of thesis, dissertation and publication of research papers, chapters in books, full-fledged books and any other similar work, reflects the extent to which elements of academic integrity and originality are observed in various relevant processes adopted by the Institute.

The Institute makes it compulsory for all faculty, researchers and students to adhere to the policy of academic malpractice and plagiarism and strives to use best tools and practices to identify and detect academic malpractice and plagiarism.

Responsibility of the Research Scholar

1. A research scholar should get proper awareness about responsible conduct of research, thesis, dissertation, promotion of academic integrity and prevention of misconduct including plagiarism in academic writing.
2. The scholar should know thoroughly about the impact of plagiarism and the penalties of the act.
3. It is an utmost important duty of any scholar to see that she does not attempt any misconduct during the research work either during experimental data collection or data analysis or report writing or publication of research articles, research journals or presentation of scientific findings in conferences.
4. It is very essential for the research scholar to submit her manuscripts to plagiarism detection mechanisms available in her institution and detect the percentage of plagiarized matter and revise the script to minimize it.

Responsibility of the Mentor

1. Proper awareness on plagiarism in research should be imparted by the research supervisors to the scholars right from identifying the research problem, formulating and executing the research design, interpretation and presentation of the reports.
2. The mentor is expected to subject any manuscript of research work either of her own work or the work of her scholars to proper detection mechanisms available in the Institution and revise or redo for minimum similarities.
3. The mentor has to issue a certificate to the scholar in case of reuse of earlier published research data and papers by the same scholar to avoid self-plagiarism. Only these articles should be excluded from check.

4. Consent letter from co-author(s) have to be obtained by the supervisor, if the research work has been co authored by others.

Institutional Guidelines for the Prevention of Plagiarism

Plagiarism detection is the process of locating instances of plagiarism in a research work or research document. The widespread use of computers and the advent of the internet have made it easier to plagiarize the work of others. It is the prime responsibility of an Institute or individual to distinguish original content from plagiarized work.

The postgraduate, doctoral and post-doctoral students / scholars are required to submit a signed statement that they are aware of the plagiarism policy of the Institute and no part of their work, be it a project report or thesis or dissertation is copied in any form and it is their own creation.

The Institute provides plagiarism detector software to detect the similar textual content already published in various information sources. The Institute gets access to anti-plagiarism software (iThenticate software) which is available for all faculty and students.

UGC Guidelines on Plagiarism

University Grants Commission (Promotion of Academic Integrity and Prevention of Plagiarism In Higher Educational Institutions) Regulations, 2018 is an act that specifies the guidelines for higher educational institutes (HEI)

SJNAHS's Plagiarism policy is based on these guidelines and the act below:

https://teams.microsoft.com/l/file/78A3ACC1-4219-4113-A08D-360FB2EE5AC1?tenantId=fd6a8a4c-d7f8-4fbd-8eb3-c80cf0019796&fileType=pdf&objectUrl=https%3A%2F%2Fsjmch.sharepoint.com%2Fsites%2FDocuments%2FShared%20Documents%2FGeneral%2FUGC_academic-integrity-plagiarism-Regulation2018.pdf&baseUrl=https%3A%2F%2Fsjmch.sharepoint.com%2Fsites%2FDocuments&serviceName=teams&threadId=19:YPu9D6bbIB60orUtvv_Y9fKyP8HDarkeHcX6if05F2Q1@thread.tacv2&groupId=13af27c0-85c7-49b0-afec-61bed9c9ea83

Financial Conflict of Interest Policy

The faculty and members of the academia at SJNAHS are encouraged to apply for funding to carry out research work in accordance with the applicable ethical codes, and in compliance with the applicable regulations.

Purpose

SJNAHS has a responsibility to manage conflicts of interest that arise in the course of research activities being conducted. The objective of this policy and the applicable regulations on which it is based is to promote "objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded will be biased by any conflicting financial interest of an Investigator". Further, the policy protects the credibility and integrity of the Institution's faculty and staff so that public trust and confidence in the Institution's sponsored activities is ensured.

Policy

SJNAHS requires that Investigators disclose Significant Financial Interests when applying for external grant funding as well as during the award period. Each Investigator doing funded research must complete the Institution's Financial Conflict of Interest (FCOI) training.

Applicability

This policy applies to all investigators undertaking research work at the SJNAHS involving human subjects. The Dean of St. John's Research Institute (SJRI) is the designated Institutional official responsible for ensuring implementation of this policy and may suspend all relevant activities until the financial conflict of interest is resolved or other action deemed appropriate by the institutional authority is implemented. Violation of any part of these policies may also constitute cause for disciplinary or other administrative action pursuant to Institutional policy.

This policy is predicated on the expectation that investigators should conduct their affairs so as to avoid or minimize conflicts of interest and must respond appropriately when conflicts of interest arise. To that end, this policy informs investigators about situations that generate conflicts of interest related to research, provides mechanisms for investigators and institutions to manage those conflicts of interest that rise, and describes situations that are prohibited. Every investigator has an obligation to become familiar with, and abide by, the provisions of this policy. If a situation raising questions of conflict of interest arises, an investigator should discuss the situation with Institutional official.

Disclosure of Financial Interests

All Investigators are required to disclose their outside financial interests as defined above to the institution on an annual and on ad hoc basis, as described below. The institutional official is responsible for the distribution, receipt, processing, review and retention of disclosure forms.

Annual Disclosures

All investigators must disclose their Significant Financial Interests that are related to the investigator's institutional responsibilities to the institution, through the institutional official, on an annual basis. All forms should be submitted to the institutional official by March 31st for the previous calendar year.

Adhoc Disclosures

In addition to annual disclosure, certain situations require ad hoc disclosure. All investigators must disclose their Significant Financial Interests to the Institution, through the Institutional official, within 30 days of their initial appointment or employment.

Prior to entering into research projects or applications for sponsored projects, where the investigator has a significant Financial Interest, the investigator must affirm the currency of the annual disclosure or submit to the institutional office an ad hoc updated disclosure of his or her significant financial interests with the outside entity. The institution will not submit a research proposal unless the Investigator (s) have submitted such ad hoc disclosures.

In addition, all investigators must submit to the institutional official an ad hoc disclosure of any significant financial interest they acquire or discover during the course of the year within (30) days of discovering or acquiring the Significant Financial Interest.

Travel

Investigators must also disclose reimbursed or sponsored travel related to their institutional responsibilities, as defined above in the definition of Financial Interest and Significant Financial Interest. Such disclosures must include, at a minimum, the purpose of the trip, the identity of the sponsor/ organizer, the destination, the duration, and if known, the monetary value. The Institutional Official will determine if additional information is needed to determine whether the travel constitutes a Financial Conflict of Interest with the Investigator's research.

Review and Decision of the Institutional Official

If the disclosure form reveals a Significant Financial Interest, it will be reviewed promptly by the Institutional Official for a determination of whether it constitutes a financial conflict of interest. If a Financial Conflict of Interest exists, the Institutional Official will take action to manage the financial conflict of interest including the reduction or elimination of the conflict, as appropriate. If the institutional official determines that there is a financial conflict of interest that can be managed, he or she must develop and implement a written management plan. The affected investigator must formally agree to the proposed management strategies and sign the written management plan before any related sponsored research goes forward.

Clinical Trials

Clinical Trials involve particularly sensitive issues if the investigator has a financial interest related to the clinical trial or the Industry sponsoring the clinical trial.

a) Certification that no financial arrangements with an investigator has been made where study outcome could affect compensation, investigator has any proprietary interest in the tested product, any significant equity interest in the sponsors of the covered study and that the investigator has not received any significant payments of other sorts and or

b) Disclosure of specified financial arrangements and reports taken to minimize the potential for bias.

Disclosable Financial arrangements

A) Compensation made to the investigator in which the value of compensation could be affected by study outcome.

B) A proprietary interest in the tested product including but not limited to a patent, trademark and copyright.

C) Any equity interest in the sponsor of a covered study-ownership, interest, stock options

D) Significant payments of other sorts, which are payments that have a cumulative monetary value or more made by the sponsor of a covered study to the investigator or to the investigator institution to support activities of the investigator exclusive of the costs of conducting the clinical study or other clinical studies during the time the clinical investigator is conducting the study.

In the event of non-compliance with reporting and /or management of a financial conflict of interest involving a sponsored clinical research whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment as required by this policy, the investigator must disclose the financial conflicts of interest in each public presentation of the results of the affected sponsored research and request an addendum to previously published presentations.

A. Reporting

The institutional official will report financial conflicts of interest or non-compliance to the granting agency in accordance with the regulations. If the funding for the research is made available from a prime awardee, such reports shall be made to the prime awardee prior to the expenditure of any funds and within 60 days of any subsequently identified financial conflict of interest such that the prime awardee may fulfil their reporting obligations.

B. Investigator Non-Compliance

Disciplinary Action

In the event of an investigator's failure to comply with this policy, the institutional official may suspend all relevant activities or other action deemed appropriate by the institutional official is implemented. This decision will be described in a written explanation. The institution will promptly notify the granting agency of the action taken or to be taken. If the funding for the research is made available from a prime awardee, such notification shall be made promptly to the prime awardee for reporting.

Retrospective Review

In addition, if the institutional official determines that a financial conflict of interest was not identified or managed in a timely manner the institutional official will complete a retrospective review of the investigator's activities and the sponsored research project to determine whether the research conducted during the period of non-compliance was biased in the design, conduct or reporting of the research. If bias is found, the institution will promptly notify the granting agency and submit a mitigation report.

C. Training

Each investigator must complete training on this policy, the investigator's responsibilities regarding disclosure prior to engaging in research, and at least every four years thereafter. It is also required in case SJNAHS reviews its COI policy, or in case a new investigator joins the Institute or in case the investigator has found not to be in compliance with the SJNAHS COI Policy.

A suggested tutorial on FCOI is available at this link:

https://grants.nih.gov/grants/policy/coi/fcoi_web-based_tutorial.pdf

D. Record Retention

The institutional official will retain all disclosure forms and related documents for a period of 3 years from the date the final expenditure report is submitted to the sponsoring agency or to the prime awardee.

E. Confidentiality

To the extent permitted by law all disclosure forms and related information will be confidential. However, the institution may be required to make such information available to the primary entity who made the funding available to the institution if requested or required.

F. Public Accessibility

Prior to the expenditure of funds, the institution will respond to any requestor within fifteen business days of the request, information concerning any Significant Financial Interest that meets the following criteria:

- a) The significant financial interest was disclosed and is still held by the senior key personnel.
- b) Determination has been made that the significant financial interest is related to the sponsored research; and
- c) A determination has been made that the significant financial interest is a financial conflict of interest.

Anti-Money Laundering Policy

Purpose and Scope

This policy aims to maintain the appropriate standards of conduct, by preventing criminal activity through money laundering, and has been adopted to introduce safeguards in the system to help identify and report on instances where money laundering is suspected. SJRI works with entities such as academic institutions, universities, funding agencies, industry partners, UN organizations, governmental organizations, companies and individuals in research, development and innovation in connection with various research endeavors, which may be known as a 'Collaborator'.

Policy Statement

As per the Section 3 of the Prevention of Money Laundering Act (PMLA), 2002, "whosoever directly or indirectly attempts to indulge or knowingly assists or knowingly is a party or is actually involved in any process or activity connected with the proceeds of crime and projecting it as untainted property shall be guilty of offence of money laundering".

SJNAHS responsibilities

1. Use the fund provided for the specific purpose such fund has been issued for,
2. Take reasonable steps to identify any person for whom it is proposed to provide any services where applicable,
3. Retain identification and transactional documentation as defined in the legislation in the jurisdiction in which we operate,
4. Provide initial and ongoing training to ensure all relevant staff are aware of their personal responsibilities and the anti-money laundering procedures in respect of identifying collaborators, monitoring, record-keeping, vigilance and reporting suspicious transactions,
5. Ensure our Policy is developed and maintained in line with evolving and applicable statutory and regulatory obligations from enforcement agencies,
6. Ensure that staff do not indulge in activities of money laundering, and hold internal procedures if such activities are suspected, and
7. Report to the relevant authority where there are reasonable grounds to suspect that a money laundering offence has been committed.

Due Diligence Processes

1. Obtaining all Know your Collaborator (KYC) documentation, in advance
2. Verification of the KYC before opening any account
3. Maintaining all KYC documentation for a sufficient duration of time as required by the law
4. Identification of risks and vulnerabilities involved
5. Appropriate training of employees in dealing with new collaborators and identifying the risks
6. Conduct background check of individuals, potentially to be hired for previous instances of fraud
7. Identify and implement appropriate counter measures to handle the 3 steps of money laundering including: -
 - a. Placement
 - b. Layering
 - c. Integration
8. Monitoring every transaction or attempted transactions for the source, nature, bonafide purpose and other such details

9. Providing required documentation to the authorities
10. Conducting frequent audits and checks in the system
11. Reporting and appropriate handling of any violations
12. Take appropriate corrective action in compliance with the regulations

Anti-Corruption and Anti-Bribery Policy

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. It is SJNAHS's policy to ensure that our Institution and its employees are committed to complying with appropriate legislation (including the Prevention of Corruption Act, 1988, and other international prescriptions), regulations and appropriate guidelines designed to combat bribery and corruption in the jurisdictions in which we operate.

SJNAHS will always ensure it follows a fair, honest and transparent system, and ensures that no employee indulges in acts of bribery or corruption with any other person, party or government official. These are also in line with the objective of SJNAHS, working towards the wellbeing of the society.

Purpose

This Anti-Corruption & Bribery (ACB) Policy applies to all directors, members, managers, faculty, staff, consultants, interns, students and part-time staff (referred to as 'employees'). Third party refers to individuals, organizations, collaborators or governmental agencies, who may encounter the employee during the employee's engagement with SJNAHS. The implementation of the ACB Policy for all research projects conducted in SJNAHS will be headed by the SJRI Dean's office in coordination with the SJRI Accounts office and the SJRI Personnel Office (referred to as 'internal authority').

The ACB Policy sets out the responsibilities to comply with regulations against bribery and corruption and provides guidance of how to recognize and deal with corruption. SJNAHS follows a **zero-tolerance** approach to any act of bribery or corruption, giving or receiving, by any employee who is acting on behalf of SJNAHS. Any breach noted, will be regarded as a serious matter, and subject to inquiry and necessary disciplinary action.

Policy Statement

What constitutes bribery or corruption?

Bribery includes the following unreasonable or uncompensated benefits: -

- a) giving or offering money, a gift, a complimentary, or something else of unreasonable value to a third party related an undue advantage
- b) induce or reward a third party for acting improperly or where it would be improper for the recipient to accept the benefit
- c) offer or giving of a bribe to a third party made by or through an agent, representative or intermediary
- d) providing or receiving entertainment, travel, foreign visits or conference expenses from third parties with no reason
- e) giving or accepting loans, guarantees or extensions of credit, with undue benefits
- f) uncompensated use of facilities or resources
- g) providing or receiving a job or an internship to/from a third party (paid or unpaid), without following due procedures
- h) awarding a contract or an order to a party in connection with the main contract, without following due procedures
- i) offering or receiving donations or charity amounts, without due procedures and with the intention for undue influence
- j) making donations or providing benefits to a political party with the intention of undue benefits

- k) induce another individual or employee to indulge in acts of corruption
- l) threaten another employee who has refused to commit a bribery offence, ignore/ overlook violations, or raise concerns under this Policy
- m) engagement in any activity/truncation that may lead to breach of this Policy

Due Diligence procedures

The following may be concerned as due diligences mandated by the regulations. In case the employee needs any clarification, the internal authority needs to be contacted: -

1. Any invitation received from a third party should be justified and clearly demonstrated there is no undue advantage to any of the party
2. Any expenditure to be borne should be reasonable, fair and budgeted under the respective project's or ledger expenditure
3. Any payment does not provide any unreasonable personal benefits to the employee
4. Any consultation/advisory service to a third party must be with prior permission obtained from the Head of the Institution. The Consultancy policy of the Academy provides guidance for external consultancies. Further, a Conflict-of-Interest form needs to be submitted.
5. Any hospitality or gift to be received or given, must be approved in advance, and demonstrated not to cause undue influence.
6. All research faculty and staff recruited should be as per the Institutional policy in coordination with the HR department and advertised on the website. Records of the HR procedures and details of selection is to be maintained.
7. Items required for the project should be procured as per the Institute's purchase policy.
8. In case of provision of services/consumables frequently, a rate/service contract arrangement needs to be done in prior as per the Institutional Policy, with approval of the Head of the Institution as per the purchase policy of SJNAHS
9. All records of payments and any expenditure incurred on third party should be maintained in a separate book of account, ensuring accuracy and completeness. There should be no records maintained 'off-book' for payments.

The ACB Policy may be updated from time-to-time based on regulatory requirements. Training of all staff on this Policy will be done during their induction. Any clarification or reporting under this Policy can be brought to the notice of the Internal authority.

Policy for Prevention of Financial Fraud

Purpose

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by CBCI Society for Medical Education. This policy is to ensure that our Institution (SJNAHS) and its employees are committed to work in an environment free of fraudulent activities and in compliance with the regulations (including the RBI Fraud Classification and Reporting Guidelines, 2003).

This Policy for Prevention of Financial Fraud (PFF) has been developed to oversee the practices for prevention of financial fraud. For all Research activities, the implementation of the PFF Policy will be headed by the SJRI Dean's office in coordination with the SJRI Accounts office and the SJRI Personnel Office (referred to as 'internal authority').

Objectives

This policy will ensure and provide for the following: -

- i. establishing procedures for preventing fraud and/or detecting fraud when it occurs
- ii. provide a clear guidance to employees and others dealing with SJNAHS, forbidding them from involvement in any fraudulent activity and initiate action where they suspect any fraudulent activity related to research activities.
- iii. conduct investigations into fraudulent activities.
- iv. provide assurances that all suspected fraudulent activity will be fully investigated.

Application

This Policy applies to any fraud, or suspected fraud, involving employees as well as consultants, vendors, contractors and third parties working with SJNAHS. Fraud refers to "All instances wherein Banks have been put to loss through misrepresentation of books of accounts, fraudulent encashment of instruments like cheques, drafts and bills of exchange, unauthorized handling of securities charged to banks, misfeasance, embezzlement, theft, misappropriation of funds, conversion of property, cheating, shortages, irregularities etc" (RBI Frauds Classification and Reporting, 2003). If "a person is said to have done thing fraudulently if he did that thing with intent to defraud but not otherwise." (Section 25, Indian Penal Court). Hence fraud can be interpreted as "an act of criminal deception carried out singly or in collusion with others with a view to deriving gains to which one is not legally entitled".

Actions constituting fraud

The following may be considered as fraudulent activity (illustrative and not exhaustive): -

- i. Forgery or alteration of any document or account
- ii. Forgery or alteration of cheque, bank draft or any other financial instrument etc.
- iii. Misappropriation of funds, securities, supplies or other assets by using fraudulent means
- iv. Falsifying records such as pay-rolls, removing the documents from files and /or replacing it by a fraudulent note
- v. Willful suppression of facts in matters of appointment, placements, submission of reports, tenders, etc, because of which a wrongful gain(s) is made to one and wrongful loss(s) is caused to the others.
- vi. Utilizing project funds for personal purposes without reason or authorization.
- vii. Authorizing or receiving payments for goods not supplied or services not rendered.

- viii. Destruction, disposition, removal of records or any other assets of research projects with an ulterior motive to manipulate and misrepresent the facts to cause suppression because of which assessment cannot be done
- ix. Any other act that falls under the gamut of fraudulent activity.
- x. Any other aspects related to fraud including conduct of such employees will be handled as per the Institutional HR Policy, additionally.

Responsibility for fraud prevention

- i. Every employee, representative consultants, vendors, contractors and third parties working with SJNAHS, is expected and shall be responsible to ensure that there is no fraudulent act being committed in their areas of responsibility. As soon as it is learnt that a fraud or suspected fraud has taken or is likely to take place they should immediately apprise the same to the internal authority.
- ii. The SJRI Accounts and Personnel Department shall ensure implementation of this policy by educating and familiarizing the employees during induction on various aspects of this policy
- iii. In agreements with third parties, adherence to the SJNAHS's PFF Policy should be mentioned and agreed by the third party
- iv. Any clarification or reporting under this Policy

Handling cases of Fraud

- i. Cases of fraud or suspected fraud reported or made known to the internal authority, will be investigated with due procedures, keeping in mind confidentiality.
- ii. An internal officer will be designated to handle the complaint of fraud and can view the internal records and interrogate employees to gather more evidence.
- iii. An internal report will be submitted, and necessary corrective action will be taken.

Risk Management Policy

Purpose and Scope

St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education (a registered Society), headed by the Dean and engaged in health research and innovation. All research activities carried out by Researchers may involve of a few internal and external risks. Risks refers to the effect of uncertainty (uncertain event) on the objectives and involves the consequences of likelihood of such uncertain events. SJNAHS' risk management policy involves identification, assessment and prioritization of risks to minimize the impact of these uncertain events. It includes a strategic focus, using management approaches, balancing the costs of risk management against anticipated benefits, mitigating risks and contingency planning. It also enables compliance with the regulations and assuring financial stability of the institution.



Application

The need for effective risk management arises from several regulatory commitments. The Risk management policy concerns all areas of SJNAHS' functioning more specifically to Research activities and projects.

Risks Factors

A. External Risks

- o Political environment
- o National and international policies
- o Market conditions and economy
- o Revenue concentration and liquidity of assets
- o Inflation

- o Obsolesce of technology
- o Legal environment
- o Fluctuation of foreign currency
- o Relationships with patients
- o Relationship with collaborators and funding agencies
- o Litigation and professional liabilities
- o Permission from various external agencies
- o Ethical standards

B. Internal Risks

- o Efficient execution of projects
- o Contractual compliance
- o Operational efficiency
- o Hurdles affecting optimum use of resources
- o Quality standards and assurance
- o Environmental management
- o Effective HR management
- o Organizational culture and values
- o Internal approvals

Responsibilities

Risk management involves assigning responsibilities at various levels in the Institution: -

1. The CBCI Society for Medical Education Governing Board in coordination with the SJNAHS Executive Committee and the Secretary, CBCI Society for Medical Education will be responsible for the Organizational Risk Governance including defining governance structures and assignment of roles and responsibilities
2. The SJRI Dean's office will be responsible for the risk management at SJRI for research projects and activities, in coordination with the SJRI's Grant's office, Personnel office and Account's Office.
3. The Head of the Department/Division will be responsible at the Departmental/ Divisional level to identify and address the risks involved concerning the Departmental research projects and activities.
4. Every Principal Investigator concerned with a research project will be responsible for the risk management of the various risks concerning that project. They will be responsible for identifying the risks and developing strategies to mitigate the risks.
5. It is mandatory that all the Research agreements signed with funding agencies or collaborators should acknowledge and mention the risks involved and the means of addressing the risk. Any budgetary implications for risks management need to be covered by the respective funding agency. The PI of the research project will ensure that this is met.

Risk Reporting

Risk Reporting will include the following: -

1. An incident report to be filled for every incident occurring in the Institution, Department or Research project, along with necessary documents enclosed
2. Adverse Event (AE) and Serious Adverse Event (SAE) format filled up and submitted to the necessary authorities including the St. John's Institutional Ethics Committee, Sponsors patient's rights groups, governmental and non-governmental authorities, and regulatory

authorities, as necessary. The IEC's Standard operating procedures will be adhered to with respect to all such risk reporting.

3. The project report done following completion of the project should specify and include details of the risks encountered during the project and necessary steps taken to mitigate the risks.

Anti-Slavery Statement and Policy

Purpose and Scope

St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean. It is SJNAHS' policy to ensure that our Institution and its employees are committed to complying with appropriate Indian legislations (including the Indian Slavery Act, 1843, Indian Constitution, 1950, Minimum Wages Act, 1948 and Bonded Labour System (Abolition) Act, 1976) and international guidelines designed to combat human trafficking, servitude and child labour. SJNAHS is dedicated to ensuring that no modern slavery or trafficking is present in its system. These are in line with the objectives of St. John's towards working for the wellbeing of the society.

Due Diligence processes

1. All work is carried out in authorized premises or remote centres and closely monitored
2. Vendors and partners are screened before engagement, and are advised of the expected business behavior
3. All research studies are being reviewed for fulfilling the ethical guidelines (including informed consent & confidentiality) by the Institutional Ethical Committee (IEC)
4. All Principal investigators and research staff are trained in ethics and good clinical practices (GCP) wherever required.
5. The IEC may audit any research study to determine if it meets with the international and national ethical guidelines
6. All staff are employed with proper screening and in accordance with the Institutional policy
7. Employees are educated of this Policy during induction
8. Reporting of any issue under this Policy may be informed to the Dean's office, which will handle such cases in coordination with the SJNAHS HR Department.

Reference:

Wipro (2017). WIPRO'S ANTI SLAVERY AND ANTI HUMAN TRAFFICKING POLICY STATEMENT 2017. <https://www.wipro.com/content/dam/nexus/en/investor/corporate-governance/policies-and-guidelines/ethical-guidelines/modern-slavery-statement-august-2017.pdf>

Biomedical Waste Management Statement and Policy

Scope and Purpose

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by CBCI Society for Medical Education. It is SJNAHS' commitment to handle bio-medical waste in any form in an appropriate manner as per the guidelines published by the Government and the regulatory authorities.

Bio-medical Waste (Management & Handling) Rules, 1998 were notified by the Ministry of Environment & Forests (MoEF) under the Environment (Protection) Act, 1986. In exercise of the powers conferred by Section 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), and in supersession of the Bio-Medical Waste (Management and Handling) Rules, 1998 and further amendments made thereof, the Central Government vide G.S.R. 343(E) dated 28 th March, 2016 published the *Bio-medical Waste Management Rules, 2016* and the *Bio-Medical Waste Management (Amendment) Rules, 2018* dated 16 March 2018.

Policy Statement

This Policy Statement affirms that St. John's National Academy of Health Sciences and all its administrative units will comply with the *Biomedical Waste Management Rules, 2016*, the *Bio-Medical Waste Management (Amendment) Rules, 2018* and the regulations and notifications issued by the respective authorities of the Government of India, Government of Karnataka and other regulatory authorities.

This policy statement affirms that all research laboratories generating biomedical waste in SJNAHS will comply with the SJNAHS standard operating procedures for biomedical waste management based on the *Biomedical Waste Management Rules, 2016* and the *Bio-Medical Waste Management (Amendment) Rules, 2018*

The St. John's Biomedical waste management unit comprising of committee members will oversee the activities under this Policy. The members of Bio Medical Waste Management Unit at SJNAHS include

1. Medical Superintendent (Chairperson)
2. Microbiology Faculty
3. Community Medicine Faculty
4. Hospital Infection Control Nurse/ Officer
5. Facilities Manager
6. Nursing Superintendent
7. Senior Faculty (Surgery)
8. Senior Faculty (Emergency)
9. Senior Faculty (Gynaecology & Obstetrics)
10. OT Nurse / Technician/ Assistant
11. Senior Faculty-Laboratory Services
12. Blood Bank/ Storage Unit Technician
13. Housekeeping In charge
14. Pharmacist
15. Health Inspector
16. Central Waste Storage Area incharge
17. Infection Control Nurses (at least three)

Policy Guideline References

Compliances towards the Biomedical Waste Management Regulations, and measures adopted are available the following link on the St. John's Website:

http://www.stjohns.in/biomedical_wastemanagement

Biomedical Waste Management Rules, 2016

https://dhr.gov.in/sites/default/files/Bio-medical_Waste_Management_Rules_2016.pdf

Bio-Medical Waste Management (Amendment) Rules, 2018

[https://pcb.ap.gov.in/APPCBDOCS/Tenders_Noti//WasteManagement//Bio%20medical%20waste%20management%20\(amendment\)%20Rules%202018.pdf](https://pcb.ap.gov.in/APPCBDOCS/Tenders_Noti//WasteManagement//Bio%20medical%20waste%20management%20(amendment)%20Rules%202018.pdf)

Guidelines for Management of Healthcare Waste as per Biomedical Waste Management Rules, 2016

<https://tspcb.cgg.gov.in/Shared%20Documents/Guidelines%20for%20Management%20of%20Healthcare%20Waste%20Waste%20Management%20Rules,%202016%20by%20Health%20Care%20Facilities.pdf>

Environmental Policy

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

It is SJNAHS' commitment to reduce the impact of its activities on the environment and promote environmental protection by focusing the impact of environmental issues on health and wellbeing. SJNAHS will also promote environmental-friendly practices. This policy is in line with the applicable laws and regulation and international guidelines. The objectives of this policy are in line with the objectives of St. John's towards, working for the wellbeing of the society and aligning with the United Nations sustainable developmental goals.

Objectives of this Policy

1. To ensure that all activities are conducted within the campus are in an environmentally conscious manner, with an intention to reduce any negative impact on the environment.
2. To promote change and enable a transformation towards promotion of environment protection and practices for the good of the communities to improve health and wellbeing.
3. To educate and engage students, faculty and employees on environmental concerns and sustainability.
4. To recognize and appreciate the efforts of students, faculty and employees towards environment conservation and sustainable development.
5. To promote and encourage innovations and startups for sustainable development.
6. To encourage initiative on afforestation, landscape and ecosystem restoration, waste water conservation, water quality maintenance, waste management, clean energy sources and climate change mitigation.

Policy Statement and Commitments

1. Wherever feasible SJNAHS and SJRI will ensure that its activities have minimal impact on the environment through several measures implemented including: -
2. Investment in clean energy wherever feasible, and smart technology with an intention of reducing the carbon footprint
3. All researchers and particularly Principal Investigators of all research studies will assess the environment risks and impact for each project and reduce any impact on the environment and promote environment protection.
4. Training, educating and creating awareness for the staff of the environmental issues and promoting environmental protection.

5. Efficient management of waste generated with an intention to reduce, re-use and recycle using a color-coded waste disposal system.
6. Strict compliance with management biomedical wastes. A separate Biomedical waste disposable policy is available for SJNAHS based on the Biomedical Waste management rules 2016 and 2018 (Refer page: 28 in this document).
7. Providing leadership and implementation for environment and health programs that are advocated by the Institution such air pollution and health, river water quality monitoring system, etc.
8. Encouraging office activities which focus on the environment.
9. Work with other organizations and collaborators on environment safety and the impact of environment on health.
10. Setup a system for wastewater purification and recycling on campus.
11. Make necessary recommendations to the government, policy-makers and international authorities regarding the necessary steps required to promote environmental protection and reducing the impact of air and water pollution on human health.
12. Fostering research and development of new technologies and process that impact climate change, environment, and health, etc.
13. Reviewing the environmental policy, activities and programs and taking necessary steps to optimize environmental protection.
14. To help build up a society that has a conservation-oriented attitude and exists in harmony with nature.

References

1. Making Peace with Nature A scientific blueprint to tackle the climate, biodiversity and pollution emergencies (2021), United Nations Environment Program
<https://sdgs.un.org/publications/publication-making-peace-nature-scientific-blueprint-tackle-climate-biodiversity-and>
2. United Nations- Sustainable Development Goals : <https://sdgs.un.org/goals>
Goal 6 – Clean water and sanitation
Goal 7- Affordable and clean energy
Goal 11 – Sustainable cities and communities
Goal 12 – Responsible consumption and production
Goal 13 – Climate action
Goal 14 – Life below water
Goal 15 – Life on Land
3. PWC- Environment Policy: <https://www.pwc.in/assets/pdfs/aboutus/environment-policy.pdf>
4. AICTE environmental policy: <https://www.aicte-india.org/sites/default/files/Environment%20Policy%20Final.pdf>

Child Protection and Safeguarding Policy

Purpose and scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

The purpose of this policy is to protect people, particularly children, children who volunteer to participate in research studies, and at-risk adults from any harm that may be caused due to their coming into contact with SJNAHS. This includes harm arising from:

- o The conduct of staff or any personnel associated with SJNAHS
- o The design and implementation of SJNAHS services and activities

The policy lays out the commitments made by SJNAHS and informs staff and associated personnel of their responsibilities in relation to safeguarding.

This policy does not cover:

- o Sexual harassment in the workplace – this is dealt with separately under the SJNAHS Internal Complaints Committee and Policy
- o Safeguarding concerns in the wider community not perpetrated by SJNAHS or associated personnel

This policy applies to anyone working on behalf of SJNAHS or working in any Research Project administered by St. John's Research Institute (SJRI), including executives, faculty, staff, senior managers, board of trustees, paid staff, contractual research project staff and volunteers, workers, contracting agency staff and students.

Definition of Safeguarding:

Safeguarding means taking all reasonable steps to prevent harm, particularly sexual exploitation, abuse and harassment from occurring; to protect people, especially children and vulnerable adults, from that harm; and to respond appropriately when harm does occur. In the context of SJNAHS, we often use this to apply to the safety and welfare of people involved in the delivery of health services and public engagement activities and research activities.

Policy Statement

SJNAHS believes that all individuals who come into contact with the organization, either in person or through digital channels, regardless of age, gender, disability or ethnic origin has the right to be protected from all forms of harm, abuse, neglect and exploitation. SJNAHS will not tolerate abuse and exploitation by staff or associated personnel.

This policy will address the following areas of safeguarding: child safeguarding, adult safeguarding, and protection from sexual exploitation and abuse. These key areas of safeguarding may have different policies and procedures associated with them (see Associated Policies).

SJNAHS is committed to addressing safeguarding throughout its engagements and work, using three key approaches of prevention, reporting and response.

Prevention:

SJNAHS' responsibilities

- o Ensure all employees, staff, students have access to, are familiar with, and know their responsibilities within this policy
- o Design and undertake all its services, activities and research in a way that protects people from any risk of harm that may arise from their coming into contact with SJNAHS either in person or through our digital channels.
- o Ensure all staff understand and sign up to SJNAHS Safeguarding Code of Conduct.
- o Follow up on reports of safeguarding concerns promptly and according to due process.

Staff responsibilities

Child safeguarding

SJNAHS employees, staff and students and associated personnel must not:

- o Engage in sexual activity with anyone under the age of 18
- o Sexually abuse or exploit children
- o Exchange money, employment, goods or services for sexual activity. This includes any exchange of assistance that is due to beneficiaries of service or research volunteers – either in person or on-line
- o Subject a child to physical, emotional or psychological abuse, or neglect – either in person or on line
- o Engage in any commercially exploitative activities with children including child labour or trafficking

Adult safeguarding

SJNAHS employees, staff and students and associated personnel must not:

- o Sexually abuse or exploit at-risk adults
- o Subject an at-risk adult to physical, emotional or psychological abuse, or neglect – either in person or on-line

SJNAHS employees, staff and students and associated personnel are obliged to:

- o Contribute to creating and maintaining an environment that prevents safeguarding violations and promotes the implementation of the Safeguarding Policy.
- o Report any concerns or suspicions regarding safeguarding violations by an SJNAHS employee, staff member, student or associated personnel to the appropriate authority.

Reporting

SJNAHS will ensure that safe, appropriate, accessible means of reporting safeguarding concerns are made available to staff and the populations we work with.

Any personnel reporting concerns or complaints will be protected by SJNAHS Whistleblowing Policy.

SJNAHS will also accept complaints from external sources such as patients, research volunteers, collaborators and other official bodies.

Procedure for reporting a safeguarding concern:

Employees, Staff members or Students who have a complaint or concern relating to safeguarding should report it immediately to their respective reporting authority such as the Head of Department, Vice Dean (Undergraduate or Postgraduate). If the staff member or student does not feel comfortable reporting to their respective reporting authority (for example if they feel that the report

will not be taken seriously, or if that person is implicated in the concern) they may report to any other appropriate authority such as the Dean, Medical College, Chief of Medical Services, Hospital, Chief of Nursing Services, Hospital, Dean of Research Institute, Associate Directors (Hospital or College and Research Institute).

Response

SJNAHS will follow up safeguarding reports and concerns according to policy and procedure.

SJNAHS will apply appropriate disciplinary measures to employees, staff or students if found in breach of policy.

SJNAHS will offer support to survivors of harm caused by an employee, staff, student or associated personnel, regardless of whether a formal internal response is carried out (such as an internal investigation). Decisions regarding support will be led by the survivor.

Definitions

Child

A person below the age of 18.

Harm

Psychological, physical and any other infringement of an individual's rights.

Psychological harm

Emotional or psychological abuse, including (but not limited to) humiliating and degrading treatment such as bad name calling, constant criticism, belittling, persistent shaming, solitary confinement and isolation.

Protection from Sexual Exploitation and Abuse (PSEA)

The term used by the humanitarian and development community to refer to the prevention of sexual exploitation and abuse of affected populations by staff or associated personnel. The term derives from the United Nations Secretary General's Bulletin on Special Measures for Protection from Sexual Exploitation and Abuse (ST/SGB/2003/13).

Safeguarding

Safeguarding means taking all reasonable steps to prevent harm, particularly sexual exploitation, abuse and harassment from occurring; to protect people, especially vulnerable adults and children, from that harm; and to respond appropriately when harm does occur. In our sector, we often use this to apply to the safety and welfare of people involved in the delivery or receipt of humanitarian aid and development assistance.

Sexual abuse

The term 'sexual abuse' means the actual or threatened physical intrusion of a sexual nature, whether by force or under unequal or coercive conditions.

Sexual exploitation

The term 'sexual exploitation' means any actual or attempted abuse of a position of vulnerability, differential power, or trust, for sexual purposes, including, but not limited to, profiting monetarily, socially or politically from the sexual exploitation of another.

Survivor

The person who has been abused or exploited. The term 'survivor' is often used in preference to 'victim' as it implies strength, resilience and the capacity to survive, however it is the individual's choice how they wish to identify themselves.

At-risk adult

Sometimes also referred to as vulnerable adult. A person who is or may be in need of care by reason of mental or other disability, gender, sexual orientation, age or illness; and who is or may be unable to take care of him or herself, or unable to protect him or herself against significant harm or exploitation.

References:

This safeguarding policy was written up and derived from the safeguarding policy of Avert, a UK based Charity.

1. Safeguarding Policy – Avert, 2019
<https://www.avert.org/safeguarding-policy>
2. NSPCC Learning – 2019 –“Example of a Safeguarding Policy”
<https://learning.nspcc.org.uk/media/1601/safeguarding-policy-statement-example.pdf>
3. National Child Protection Policy, 2018. Ministry of Women and Child Development
https://wcd.nic.in/sites/default/files/Download%20File_1.pdf

Child Labour Policy

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

Children are a valuable asset for any society. They constitute a very large segment of our population. As per 2011 Census, the persons below the age of 14 years account for 29% of the total population while persons between the age group 14-18 years account for another 10% of the total population. The child's natural place is at school and the playground. However, many children are unfortunately denied these basic development opportunities in childhood. They instead get burdened with work because of poverty, irregular income streams for the family, economic shocks, ignorance, lack of access to social security, education, health facilities and food security.

Government of India enacted legislation (1986) and prepared the national policy on child labour (1987) to tackle the problem with a multi-pronged approach and to prohibit the engagement of children in certain employments and to regulate the conditions of work of children in certain other employments.

The purpose of the SJNAHS child labour policy is to align with the national policy on Child labour and ensure that children are not employed or engages in work at the organization.

Policy Statement:

1. SJNAHS will not employ any child below the age of 18 years and will be compliant to the Child Labour (Prohibition & Regulation) Act of 1986.
2. The Human resource department of SJNAHS will verify all government recognized or provided age-proof documents prior to any employment as per Institutional procedure.
3. If any child approaches SJNAHS for employment, he/she will be counselled and referred to a Government rehabilitation facility under the National Child Labour Project Scheme (NCLP).
4. All faculty, employees and staff of SJNAHS will be made aware of this policy to ensure compliance with the policy and the Act.

References:

1. Child Labour Policies, Ministry of Labour and Employment. Govt. of India.
<https://labour.gov.in/childlabour/child-labour-policies>
<https://labour.gov.in/sites/default/files/PolicyofGovernmenontheissueofChildLabour.pdf>
2. The Child Labour (Prohibition and Regulation) Act, 1986. Govt. of India.
https://labour.gov.in/sites/default/files/act_3.pdf

Accessibility and Disability Policy

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

It is being increasingly realized that people with disabilities can make valuable contribution to businesses and to the national economy. Studies have shown that disabled people are capable, reliable employees, who often stay in the job longer than other employees. They contribute to productivity, to staff morale and to team spirit in the workplace as a whole. Employers are playing a more central role than ever before in promoting opportunities for job seekers with disabilities, in retaining workers who acquire a disability while in employment and developing return-to-work strategies for those who have left the active labour force.

SJNAHS ensures that its employees, staff and students are committed to complying with appropriate Indian legislations and international guidelines designed to provide equal opportunities for all individuals including individuals with special needs and people with disability by providing them with a conducive environment, friendly to their functioning and personal wellbeing. These are in line with the objectives of St. John's towards working for the wellbeing of the society.

Definition of Disability:

Disability is defined to include 19 conditions such as: autism; low vision and blindness; cerebral palsy; deaf blindness; haemophilia; hearing impairment; leprosy; intellectual disability; mental illness; muscular dystrophy; multiple sclerosis; learning disability; speech and language disability; sickle cell disease; thalassemia; chronic neurological conditions; and multiple disability.

Person with disability means a person with long term physical, mental, intellectual or sensory impairment which, in interaction with barriers, hinders his full and effective participation in society equally with others.

Persons with benchmark disabilities are defined as those with at least 40 per cent of any of the above specified disabilities.

Policy Statement:

- o Each candidate (student, faculty or staff) who applies to us, their applications are reviewed based on their aptitudes, abilities and qualifications, and all are given equal opportunity based on the equal opportunities policy.
- o Providing persons with disability or special needs an inclusive, easily accessible and safe facilities and environment, to support their special requirements in SJNAHSI, as reasonably possible.
- o SJNAHS will ensure for all persons with disabilities employed, respect for inherent dignity, individual autonomy including the freedom to make one's own choices, and independence of persons.
- o Providing support and information to persons with disability and special needs.
- o Learning, teaching and training strategies adopted at SJNAHS enable inclusion of persons with disability as reasonably possible.

- o SJNAHS will ensure the prohibition of illegitimate discrimination against persons with disability within the workplace.
- o SJNAHS will maintain a record of all employees with disabilities.
- o No person with disability shall be a subject of any research without,
 - i. his or her free and informed consent obtained through accessible modes, means and formats of communication; and
 - ii. prior permission of a Committee for Research on Disability constituted in the prescribed manner for the purpose by the appropriate Government in which not less than half of the Members shall themselves be either persons with disabilities or Members of the registered organization as defined under clause (z) of section 2 of *The Rights of Persons with Disabilities Act, 2016*.

Implementation

- o During recruitment of faculty, staff or admission of students, efforts will be made that the process provides equal opportunity for all, and applications will be reviewed based on the individual's aptitudes, abilities and qualifications.
- o The respective reporting authority or liaison officer of the person with disability will ensure such individuals are provided a safe environment for working, and adaptations and aides necessary are provided. A personal plan will be prepared for staff, faculty and students with special needs by the respective reporting authority and will also include an emergency plan.
- o Creating awareness amongst the staff, faculty and students with an intention to accommodate and help persons with disabilities at SJNAHS.
- o Implementation of improved measures, wherever feasible, to promote and support employment of persons with disability
- o Wherever feasible, ensure that persons with disability are placed in jobs that are matched to their skills and abilities, and are not disadvantaged by their special needs.
- o Based on individual's special requirements of employees and students, access to specific laboratories and infrastructure may be modified to meet with the specific requirement of persons with disability to improve accessibility.

References:

1. The Rights of Persons with Disabilities Act, 2016, Govt. of India
https://legislative.gov.in/sites/default/files/A2016-49_1.pdf
2. Adapt: Code of Policy and Practice for People with Disabilities
<http://www.adaptssi.org/img/brochure/copp.pdf>

Equality, Diversity, and Inclusivity Policy

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

SJNAHS is committed to encouraging equality, diversity and inclusion among our workforce, and eliminating unlawful discrimination.

The aim is for our workforce to be truly representative of all sections of society and our clients and collaborators, and for each employee to feel respected and able to give their best.

The organization - in providing services, research activities and/or facilities - is also committed against unlawful discrimination of clients, collaborators or the public.

The policy's purpose is to:

- o provide equality, fairness and respect for all in our employment, whether temporary, part-time or full-time.
- o not unlawfully discriminate because of caste, race, ethnicity, descent, colour, sex, sexual orientation, gender identity, gender expression, tribe, nationality, disability, marital status, pregnancy, health (including HIV / AIDS status), occupation, political opinion and belief, linguistic identity, place of birth, age, migration, religion, refugee status, socio-economic disadvantage, food preference or any combination of these characteristics.
- o oppose and avoid all forms of unlawful discrimination. This includes in pay and benefits, terms and conditions of employment, dealing with grievances and discipline, dismissal, redundancy, leave for parents, requests for flexible working, and selection for employment, promotion, training or other developmental opportunities.

Policy Statement and Commitments:

SJNAHS commits to:

- o Encourage equality, diversity and inclusion in the workplace as they are good practice and make business sense.
- o Create a working environment free of bullying, harassment, victimization and unlawful discrimination, promoting dignity and respect for all, and where individual differences and the contributions of all staff are recognized and valued.
- o This commitment includes training leaders, managers and all other employees about their rights and responsibilities under the equality, diversity and inclusion policy. Responsibilities include staff conducting themselves to help the organization provide equal opportunities in employment, and prevent bullying, harassment, victimization and unlawful discrimination.
- o All staff should understand they, as well as their employer, can be held liable for acts of bullying, harassment, victimization and unlawful discrimination, in the course of their employment, against fellow employees, clients, collaborators, suppliers and the public
- o Take seriously complaints of bullying, harassment, victimization and unlawful discrimination by fellow employees, customers, suppliers, visitors, the public and any others in the course of the organization's work activities.

- o Such acts will be dealt with as misconduct under the organization's grievance and/or disciplinary procedures, and appropriate action will be taken. Particularly serious complaints could amount to gross misconduct and lead to dismissal without notice.
- o Make opportunities for training, development, and progress available to all staff, who will be helped and encouraged to develop their full potential, so their talents and resources can be fully utilized to maximize the efficiency of the organization.
- o Decisions concerning staff being based on merit
- o Review employment practices and procedures when necessary to ensure fairness, and also update them and the policy to take account of changes in the law.
- o Monitor the make-up of the workforce regarding information such as age, sex, ethnic background, sexual orientation, religion or belief, and disability in encouraging equality, diversity and inclusion, and in meeting the aims and commitments set out in the equality, diversity and inclusion policy.
- o Monitoring will also include assessing how the equality, diversity and inclusion policy, and any supporting action plan, are working in practice, reviewing them annually, and considering and taking action to address any issues.

The equality, diversity and inclusion policy is fully supported by the senior management of SJNAHS.

Details of the SJNAHS' grievance and disciplinary policies and procedures in the next chapter. This includes with whom an employee should raise a grievance.

References:

1. The Draft Equality (Prohibition of Discrimination) Bill, 2021 – Centre for Law and Policy Research
<https://clpr.org.in/wp-content/uploads/2020/01/Equality-Bill-2021-8th-January-2021.pdf>
2. Equality Rights – Article 14-18, Govt. of India.
<https://iitr.ac.in/internalcomplaintscommittee/annexure.pdf>

Grievance Redressal policy

Purpose and Scope

St. John's National Academy of Health Sciences (SJNAHS) is owned and operated by the CBCI Society for Medical Education. St. John's Research Institute (SJRI) is a unit of CBCI Society for Medical Education, headed by the Dean, SJRI and co-administered by the Associate Director of Research and Medical College.

The Governing Board of St. John's National Academy of Health Sciences (SJNAHS) approved the new Grievance redressal policy on 14th March 2019. This new policy replaces Section 25 on "redressal of grievances" in the service rules of St. John's Medical College and St. John's Medical College Hospital.

Purpose

The Grievance Redressal Policy of St. John's National Academy of Health Sciences (SJNAHS) is intended to provide a platform for all its employees to voice and redress their grievances related to employee-employee relationships, employee-employer relationships and the work environment in SJNAHS. The Grievance redressal policy seeks to create a healthy work environment that enables SJNAHS employees to pursue professional growth with equal opportunity and contribute to the mission of the Institution to the best of their abilities without fear or favour.

Scope:

The policy is applicable to employees in all the administrative units of the Academy, namely:

1. St. John's Medical College
2. St. John's Medical College and Hospital
3. St. John's College of Nursing
4. St. John's Research Institute
5. St. John's Institute of Allied Health Sciences

Policy Statement and Commitments

The complete policy document is available in the link below:

https://teams.microsoft.com/l/file/A30ADDD0-3F78-40C9-8F91-708B2353377E?tenantId=fd6a8a4c-d7f8-4fbd-8eb3-c80cf0019796&fileType=pdf&objectUrl=https%3A%2F%2Fsjmch.sharepoint.com%2Fsites%2FDocuments%2FShared%20Documents%2FGeneral%2FNew%20Grievance%20Redressal%20Policy.pdf&base%20Url=https%3A%2F%2Fsjmch.sharepoint.com%2Fsites%2FDocuments&serviceName=teams&threadId=19:YPu9D6bblB60orUtvv_Y9fKyP8HDarkeHcX6if05F2Q1@thread.tacv2&groupId=13af27c0-85c7-49b0-afec-61bed9c9ea83

