Summer Internship Project Report

Topic – CONSENT FORM AUDIT

AT

Fortis Memorial Research Institute, Gurugram

(April 4th to June 18th 2022)

Submitted by-

Dr Pankaj Joshi

Post-graduate Diploma in Hospital and Health Management

2021-2023

International Institute of health Management Research,New Delhi

ACKNOWLEDGEMENT

With immense pleasure, I express my heartfelt gratitude to **Dr. Sutapa Bandyopadhyay Neogi** (Director, IIHMR Delhi) and placement and training team of IIHMR, Delhi for giving me this opportunity to undergo training at **Fortis Memorial Research Institute, Gurugram.**

I am extremely indebted to all the professionals at **Fortis Hospital** for generously sharing their knowledge and precious time which inspired me to do my best during the summer training.

I am sincerely grateful to **Dr. Nisha Sharma,** for being my mentor throughout the training, and for giving me incredible opportunities to gain knowledge about management of a healthcare organization by arranging required exposure of other departments of the hospital. Her dynamic thinking, her broad and profound knowledge, her critical thinking has given me constant encouragement to achieve the task allotted and perform better. I am also indebted to her for sharing her valuable experiences and giving her truthful and illuminating views on a number of issues related to management.

I am also grateful to all the department heads and staffs; without their active co-operation the study would have not been completed.

Special thanks to my college mentor **Dr. Nikita Sabherwal** for her constant supervision and support in completing the project.

Place: Gurugram, Haryana
(122001)

Date: 17/06/2022 **Name: Dr Pankaj Joshi**

Certification of Approval

The Summer Internship Project Titled "**CONSENT FORM AUDIT**" at **FORTIS MEMORIAL RESEARCH INSTITUTE, GURUGRAM**, is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed, or conclusion drawn there in but approve the report only for the it is submitted

Dr. Nikita Saberwal

Associate Dean (Training)

Associate Professor (Hospital Administration)

IIHMR-Delhi

FEEDBACK FORM

(Organization Supervisor)

Name of the Student: Dr. Pankaj Joshi

Summer Internship Institution: Fortis Memorial Research Institute, Gurugram

Area of Summer Internship: Medical Administration

Attendance: Regular

Objectives met: Completed Assigned Tasks on - Tracer Audit, consent forms Audits, And MRD

Deliverables: - Did Project work on consent forms Audit
- Did Administration Tasks
- Work in IPD's

Strengths: Flexible, Patience, Polite

Suggestions for Improvement: Practice, Orientation and Determination.

Assistant Medical Superintendent
Fortis Memorial Research Institute
Sector-44, Gurugram-Faridabad Road, Haryana

Signature of the Officer-in-Charge (Internship)

Date: 16-June-2022
Place: Gurugram

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RESEARCH INSTITUTE
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June 17, 2022

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Dr. Pankaj Joshi** has undergone an internship in the **"Department of Medical Administration"** from **April 04, 2022 to June 17, 2022** at **Fortis Memorial Research Institute, Gurgaon.**

During this period, he exhibited a high level of professionalism and a tremendous zest for learning.

We wish **Dr. Pankaj Joshi** all the best in his future endeavors.

With Best Wishes,

Shivani Dhir
SBU Head-Learning & Development

Fortis Hospitals Ltd. Gurgaon

Head of Department

Medical Superintendent
Fortis Memorial Research Institute
Sector - 44, Gurgaon - 122002
Haryana (India)

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FORTIS MEMORIAL RESEARCH INSTITUTE

INTRODUCTION

About The Hospital

One of the top hospitals in Gurgaon is the multi-super specialty, quaternary care Fortis Memorial Research Institute (FMRI). Fortis Hospital, Gurgaon has dedicated to consistently meeting strict international standards and has undertaken a thorough on-site examination of the quality and safety of the care being given. Fortis Hospital, Gurgaon has solidified its position as one of the top hospitals in Gurgaon by using cutting-edge technology and top clinicians to provide the best possible healthcare. Unmatched in the fields of Neurosciences, Oncology, Renal Sciences, Orthopedics, Cardiac Sciences, and Obstetrics and Gynecology. One of the biggest healthcare organizations in the nation, Fortis Healthcare, operates the main hospital, Fortis Memorial Research Institute. Currently, Fortis hospitals throughout the nation treat more than 3.5 lakh patients annually, relying on the pulse of the people we serve, ranging from customized preventive health checks to quaternary care from super specialized clinicians conducting rare and complicated operations It was "patient first" back then, and it still is. Because Fortis will always put you first.

Fortis Memorial Research Institute beat out many other top-notch medical facilities worldwide to be ranked No. 2 among the 30 most technologically advanced hospitals in the world by topmastersinhealthcare.com

VISION

To serve as the "Mecca of Medicine" for healthcare.

MISSION

To deliver quaternary care in a caring, honorable, and distinctive way to the community

AFFILIATIONS AND ACCREDIATIONS

The accreditation of hospital programmers and divisions, in FMRI's opinion, is yet another significant accomplishment that strengthens the institute's position in the healthcare industry and will further its exceptional quality medical services.

The National Accreditation Board for Hospitals & Healthcare Providers (NABH) has granted accreditation to Fortis Memorial Research Institute, which abides by its principles in order to meet patients' requirements and establish standards of excellence for the healthcare sector.

On the other hand, the FMRI blood bank has considerable service delivery in the relevant domain, earning it accreditation from NABH. Additionally, the National Accreditation Board for Testing and Calibration Laboratories (NABL), whose goal is to offer the government, regulators, and industry a programme of laboratory accreditation, has granted us accreditation for our laboratory services.

DRIVE TOWARDS CONTINUOUS IMPROVEMENT

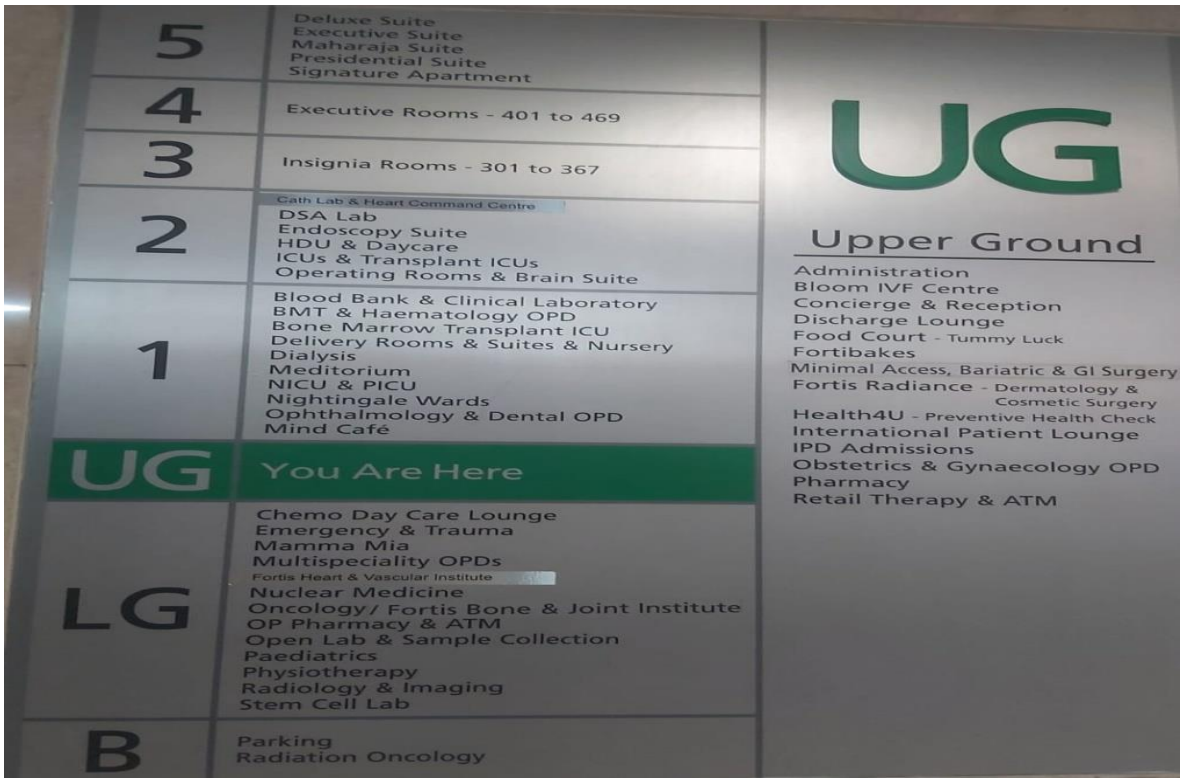
The leadership of FORTIS adheres to the quality cycle of planning, designing, checking, and applying the learning to constantly enhance the services, with the collective understanding that the simplest solutions are frequently the most effective. Every important procedure has been given a set of quality indicators, which are tracked to ensure ongoing quality improvement. More significantly, there are frequent contacts between management and employees, ensuring that everyone in the organization shares the commitment to ongoing learning and improvement

Hospital acreditado por Joint Commission International

FLOOR	DEPARTMENTS
5	Deluxe Suite Executive Suite Maharaja Suite Presidential Suite Signature Apartment
4	Executive Rooms-401 to 469
3	Insignia Rooms-301 to 367
2	**Cath Lab and Heart Command Centre** DSA Lab Endoscopy Suite HDU and Daycare ICUs and Transplant ICUs Operating Rooms and Brain Suite

1	Blood Bank and Clinical Laboratory BMT and Hematology OPD Bone Marrow Transplant ICU Delivery Rooms and Suites and Nursery Dialysis Meditorium NICU AND PICU Nightingale Wards Ophthalmology and Dental OPD Mind Café
UG	Administration Bloom IVF Centre Concierge and Reception Discharge Lounge Food Court Fortibakes **Minimal Access, Bariatric and GI Surgery** Fortis Radiance-Dermatology and Cosmetic Surgery Health4U-Preventive Health Check International Patient Lounge IPD Admissions Obstetrics and Gynecology OPD Pharmacy Retail Therapy and ATM
LG	Chemo Day Care Lounge Emergency and Trauma

	Mamma Mia Multispecialty OPDs **Fortis Heart and Vascular Institute** Nuclear Medicine Oncology/Fortis Bone and Joint Institute OP Pharmacy and ATM Pediatrics Physiotherapy Radiology and Imaging Stem Cell Lab
B	Parking Radiation Oncology



CENTRE OF EXCELLENCE

FOTIS BONE AND JOINT INSTITUTE

FORTIS CANCER INSTITUTE

FORTIS HEART AND EXCELLENCE INSTITUTE

INSTITUTE BLOOD DISORDERS AND BONE MARROW TRANSPLANT

MINIMAL ACCESS, BARIATRIC AND GI SURGERY

NEUROSCIENCES

PAEDIATRICS

RENAL SCIENCES

ROBOTIC SURGERY

SPECIALITY

ANAESTHESIOLOGY

COSMETIC, RECONSTRUCTIVE AND PLASTIC SURGERY

CRITICAL CARE

DENTAL SCIENCES

DERMATOLOGY

DIABETIES, ENDOCRINOLOGY AND METABOLIC DISORDERS

EMERGENCY MEDICINE AND TRAUMA

FORTIS BONE AND JOINT INSTITUTE

GENERAL SURGERY

GERIATIC MEDICINE

HAEMATOLOGY

HEPATO-PANCREATED-BILIARY SURGERY

INFECTIOUS DISEASES

INSTITUTE BLOOD DISORDERS AND BONE MARROW TRANSPLANT

INTERNAL MEDICINE

INTERVENTIONAL RADIOLOGY

IVF AND INFERTILITY

MINIMAL ACCESS, BARIATRIC AND GI SURGERY

MOTHER AND CHILD

NEUROSCIENCES

NUCLEAR MEDICINE

OPTHAMOLOGY

OTPRHINOLARYNGOLOGY

PAEDIATRICS

PAIN MEDICINE

PULMONOLOGY, PULMONARY CRITICAL CARE AND SLEEP

RHEUMATOLOGY AND CLINICAL IMMUNOLOGY

ROBOTIC SURGERY

STEM CELL THERAPY

SUPPORT SERVICES

SURGICAL ONCOLOGY

THORACIC SURGERY

TRANSFUSION MEDICINE

TRANSPLANT MEDICINE

URO-ONCOLOGY AND ROBOTIC SURGERY

Observational learning

1.1. Introduction:

Fortis Memorial Research Institute (FMRI) is a multi-super-speciality, quaternary care hospital with an enviable international faculty, reputed clinicians, including super-sub-specialists and speciality nurses, supported by cutting edge technology. Set on a spacious 11-acre campus with 1000 beds, this Next Generation Hospital is built on the foundation of Trust and rests on four strong pillars: Talent, Technology, Service and Infrastructure.

- ✓ FORTIS Healthcare Limited: Fortis Healthcare Limited is a leading integrated healthcare delivery service provider in India. In a global study of the 30 most technologically advanced hospitals in the world, its flagship, the FMRI', was ranked No.2, by 'topmastersinhealthcare.com, and placed ahead of many other outstanding medical institutions in the world.
- ✓ Vision: To be the ultimate healthcare destination - "Mecca of Medicine"
- ✓ Mission: To provide quaternary care to the community in a compassionate, dignified, and a distinctive manner
- ✓ Affiliations and Accreditations: FMRI Accredited from NABH and NABL and follow their all policies. Standard by ISO
- ✓ Speciality Clinics: Some specialities are:
  1-Paediatric 2-Oncology 3-Dental 4-Nephrology 5-Pulmonology 6-ENT
  7-Neurology 8- Cardiac 10-Gynae 11-Endocrinology 12-Orthopaedic 13-Eye
- ✓ Milestones: 2013-2014- FMRI was established in year 2008, in year 2013-14 so many memorable things was happening like - 1st Bone Marrow Transplant (BMT) was performed, Multiple surgeries for largest head circumference (Hydrophalus), Little Hearts Programme launched, surgery done for Lumber Spine Disc Prolapse, One of the best Fortis Hospital in India to be certified in Water Birth and Kangaroo care, NABH accreditation for Blood Bank

a) March 2014- 1st TCR alpha-beta depleted Haploidentical BMT was performed- 1st centre in India

b) April 2014- inauguration of new Ultrasound Facility- IU22- best features like 3D and 4D imaging

1.2. Method of data collection:

During the summer training worked in Vaccination, MRD, OPD, IPD, OT, PCS etc. Also worked in Medical file auditing and treasure audit. Learn about discharge process.

1.3. General findings on learning:

- ✓ Vaccination – Vaccination drive was started from May 1st, where Covaxin drive was started first but after the shortage of Covaxin, Covishield was stated. It was started in Meditorium which is located in first floor. Meditorium is an Auditorium where hospitals conferences were held.
  - ➢ Vaccination drive started in hospital for healthy or non-covid patients, in which 2 vaccines are given (1) COVAXIN (1250/-), (2) COVISHIED (850/-). Both vaccination centres are separated, which will help the person to find their vaccination centre and both centres are organized in a same way. There are certain steps for the vaccination:
    - Step 1: Patient early scheduled for vaccine in Aarogya Setu app in CoWIN site, once a scheduled will be done the patient will come into the hospital with their reference ID,
    - Step 2: After that they will go for verification in verification counter
    - Step 3: After verification go for billing, once billing will be done patient have to submit their bill in the certificate to next counter
    - Step 4: After billing patient will go for vaccination and they will receive their receipt and certificate
    - Step 5: After vaccination patient will go to in the observation area in which patient's vitals are check and wait for 30 minutes in the observation area

- ✓ MRD- Medical Record Department
  - ➢ Located at the basement of the hospital.
  - ➢ MRD co-ordinate with all hospital departments.
  - ➢ Mainly filing work.
  - ➢ There are several filing colours – Blue, Pink, and Green etc.

- All death and discharge summaries are saved in digital way.
- Audit

✓ IPD- Inpatient department

- IPD is basically located in 3rd floor, 4th floor, 5th floor and *Nightingale ward which is located in 1st floor.*
- 5th floor is a suite wards.
- Worked alone with nursing department, floor manager, DEOs and summary file entry operator.

✓ ICU- Intensive Care Unit

- ICU is located in 2nd floor where total 9 ICUs are there.
- During pandemic 3ICUs means 7th, 8th and 9th are Covid ICUs

✓ RRT

- Rapid Responsive Team is very responsive in their work they take action immediately after take any call.
- RRT No. Is 7777
- We call RRT after they receive we say "RRT adult, floor no, Room no and treating Doctor Name" we say it for 3 times. They take immediate action

Floor Structure

Project Report

2.1. Introduction:

Patient consent procedures for medical treatments must be exact and transparent in order to achieve excellence in clinical practice and a high level of healthcare delivery. Patients who are having elective surgery in particular need to be well educated before giving their consent. The importance of the consenting process for doctors is emphasized in the General Medical Council's guidelines, which are titled Consent: Patients and Doctors Making Decisions Together. Almost always, the level of completion of the permission forms has an impact on how well the consenting process works. Additionally, if something goes wrong, physicians and the trust could be held accountable for medical-legal acts due to missing information on consent forms.

Purpose of consent forms

Informed consent has become the standard prototype for safeguarding patient's legal rights and directing the medical practice in an ethical direction. It may be used for different purposes in different contexts: legal, ethical or administrative. Although these purposes overlap, they are not identical, thus leading to different standards and criteria for what constitutes "adequate" informed consent.

Legal: Legally, Consent protects patients against assault in the form of unwanted medical interventions. The higher standard of informed consent further safeguards patients' rights to autonomy, self-determination and inviolability. It is important for the decision maker to understand the relevant information, he or she should also be able to appreciate the information's importance and use it to weigh treatment options in light of their values.

Ethical: It is morally correct to uphold patients' autonomy and their stated objectives. The ethical purpose of informed consent is somewhat more abstract and ideological, seeking to respect patient autonomy by ensuring that treatment is directed toward the ends desired and is chosen by the patient. In this context, informed consent is intended to shift the ethical prototype for decision-making away from physician-centered models to more patient-centered approaches. The ethics literature regarding informed consent also emphasizes that it is not an event, but a process that precedes the "signing" of the document and continues for as long as the choice remains relevant. Thus, the consent to undergo dialysis or continue with chemotherapy is continually re-evaluated (and may change). The consent form should not be confused with the consent process; the form merely documents that the process has occurred. Importantly, other parts of the patient record (e.g., clinic and/or operative notes) should corroborate details of the process.

Administrative: For the sake of compliance, the informed consent document serves the administrative purpose of a systems-level check to ensure that a consent process has occurred. Patients simply do not advance to the operating room, for example, without a signed consent form. Unfortunately, pressures for efficient workflow may shift the focus of the informed consent process from robust conversation to the mere requirement of getting a signature.

Stakeholders in the informed consent process agree on at least four basic elements for discussions of informed consent: decision makers must have the capacity to make decisions; the doctor must disclose enough details for the decision maker to make an informed choice; decision makers must demonstrate understanding of the information disclosed; and the decision maker must freely authorize the treatment plan.

In present clinical practice, these four factors translate into five components that must be included in the discussion in order to reach agreement: diagnosis, suggested treatment, and risks and benefits associated with the treatment. alternative treatments, their risks and benefits, and the risks and benefits of refusing treatment.

2.2 Aim and objectives: -

2.2.1 Aim: -

The aim of this prospective study was to audit the quality of consent forms in a multidisciplinary 1000 bedded hospital and to suggest measures for improvement of practice.

2.2.2. Objective: -

- This project's goal was to evaluate our consenting procedures and identify the area of improvement.
- To suggest relevant measures for optimal consent taking procedure in order to maintain best practices.

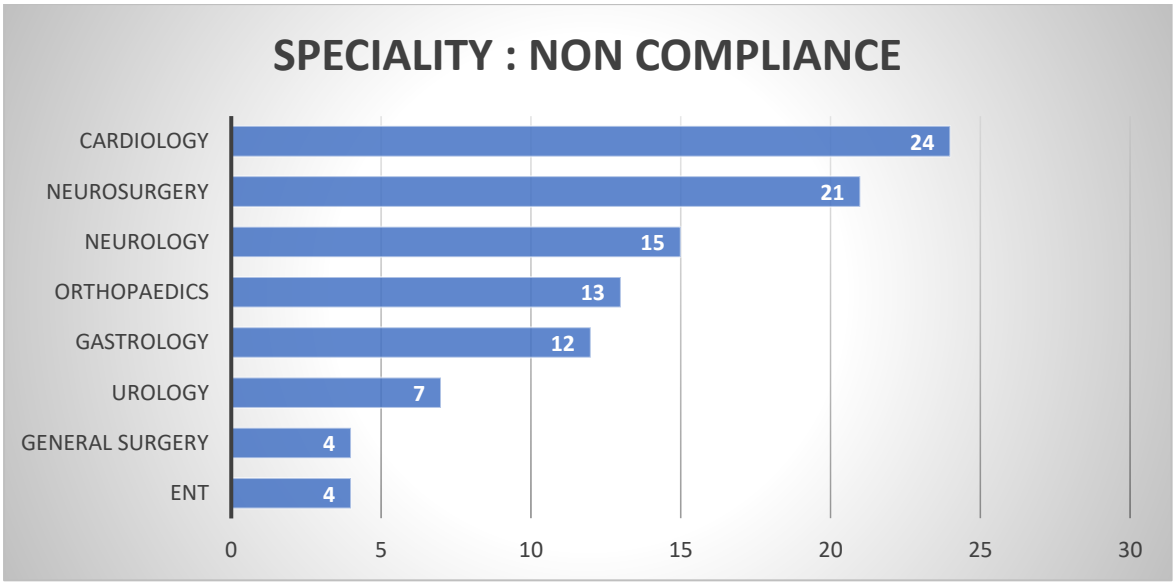
2.3 Methodology: -

- **Type of Study:** Qualitative Study.
- **Study Area:** Main OPD Area
- **Duration of Study: 6 weeks**
- **Type of Data**: Qualitative Data
- **Technique**: Direct observation
- **Sample size**: 200(N=200)

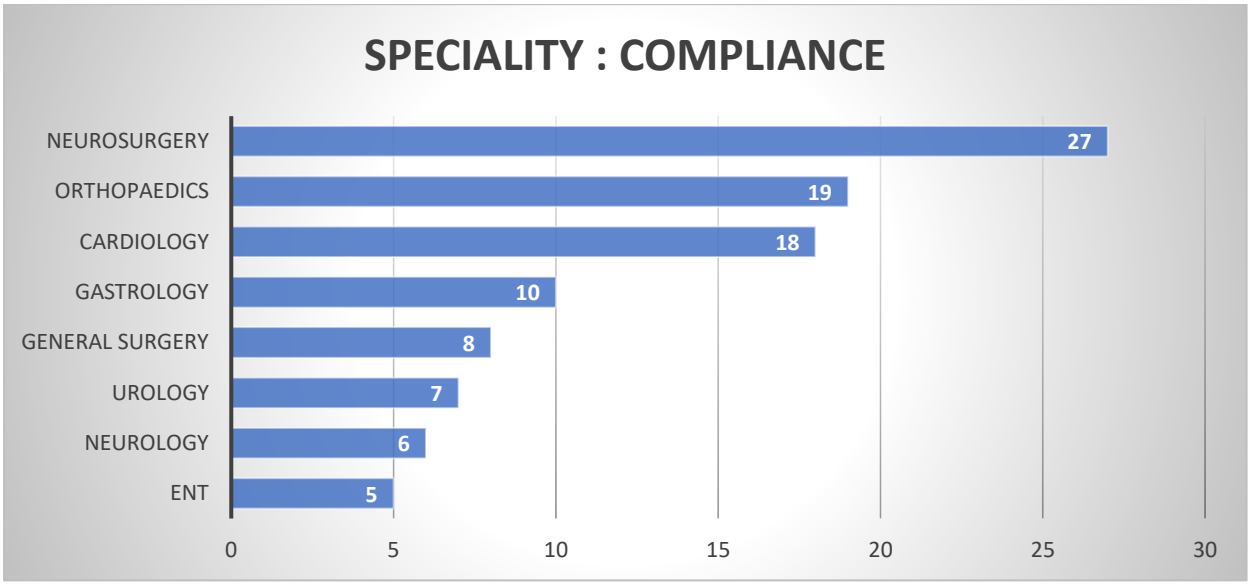
- **Sampling Technique**: Stratified Randomized selection was done.
- **Data Collection:** Primary and secondary.
  Primary data collection was done by auditing the patients' files in various IPDs to look for the completion of different types of consent forms.
  Secondary data was collected through internet by various data sources like PubMed, google scholar for review of literature.
- **The Methods of Ratings**: Here we give ratings to the findings,
  '0' Means the listed parameter is not documented in the form.
  '1' Means the listed parameter is documented in the form.
  '3' Means not applicable.
- **Data Analysis**: Using bar charts in Microsoft Excel

2.4 Data Analysis: -

SPECIALITY	COUNT OF 0	%
CARDIOLOGY	247	24
ENT	42	4
GASTROLOGY	121	12
GENERAL SURGERY	46	4
NEUROLOGY	155	15
NEUROSURGERY	220	21
ORTHOPAEDICS	139	13
UROLOGY	70	7



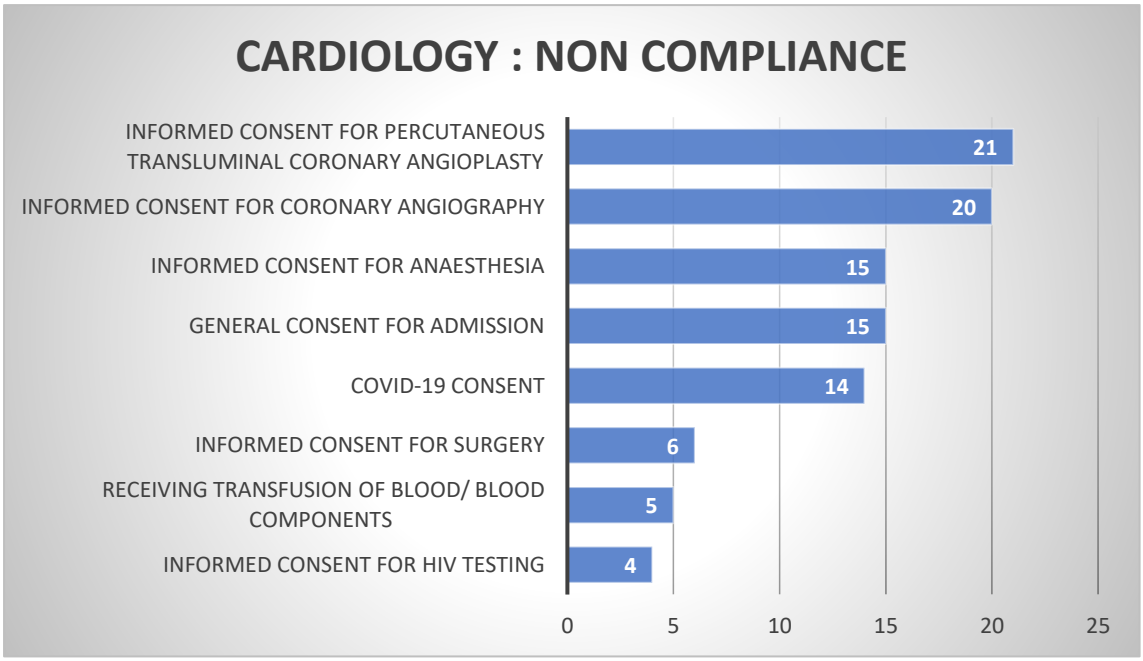
SPECIALITY	COUNT OF 1	%
CARDIOLOGY	396	18
ENT	103	5
GASTROLOGY	234	10
GENERAL SURGERY	188	8
NEUROLOGY	130	6
NEUROSURGERY	616	27
ORTHOPAEDICS	420	19
UROLOGY	162	7



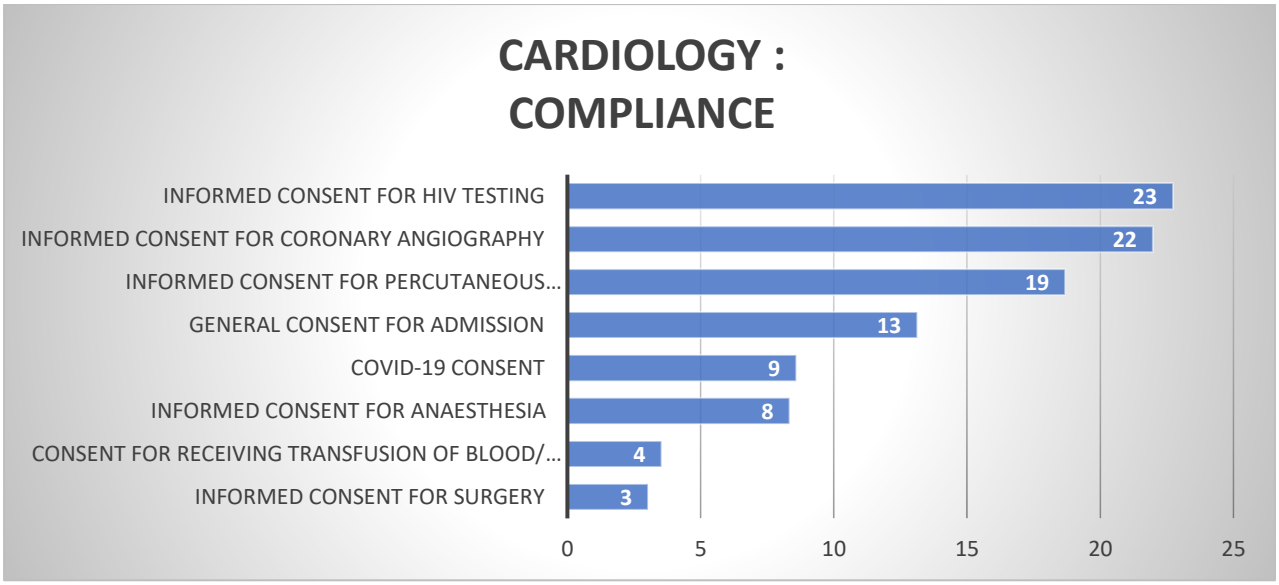
CARDIOLOGY

GRADE	COUNT OF GRADE
0	247
1	396

CARDIOLOGY CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE%
Receiving Transfusion of Blood/ Blood Components	12	5
Covid-19 consent	35	14
General Consent for Admission	38	15
Informed Consent for Anaesthesia	36	15
Informed Consent for Coronary Angiography	49	20
Informed consent for HIV Testing	11	4
Informed Consent for Percutaneous Transluminal Coronary Angioplasty	52	21
Informed consent for surgery	14	6



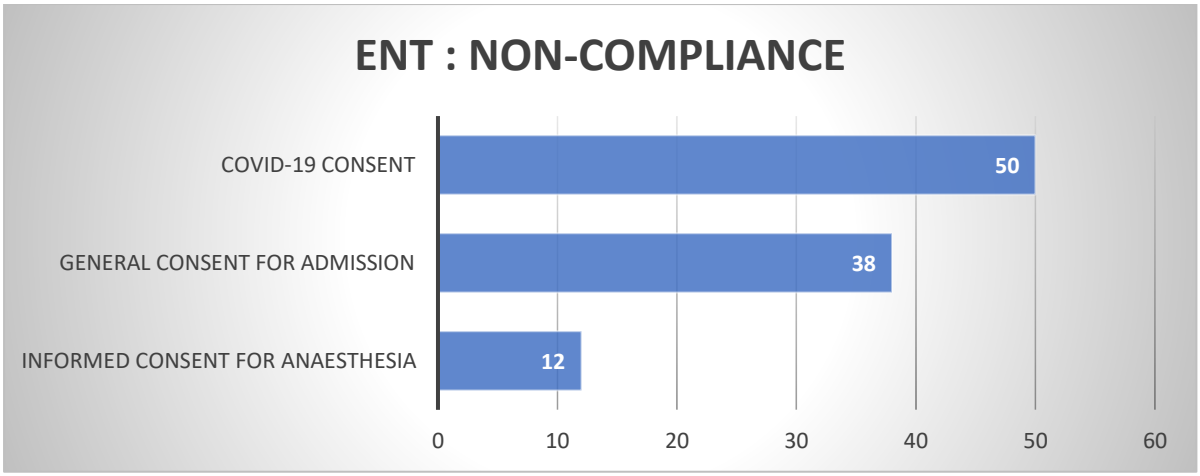
CARDIOLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Informed consent for surgery	12	3
Consent For Receiving Transfusion of Blood/ Blood Components	14	4
Informed Consent for Anaesthesia	33	8
Covid-19 consent	34	9
General Consent for Admission	52	13
Informed Consent for Percutaneous Transluminal Coronary Angioplasty	74	19
Informed Consent for Coronary Angiography	87	22
Informed consent for HIV Testing	90	23



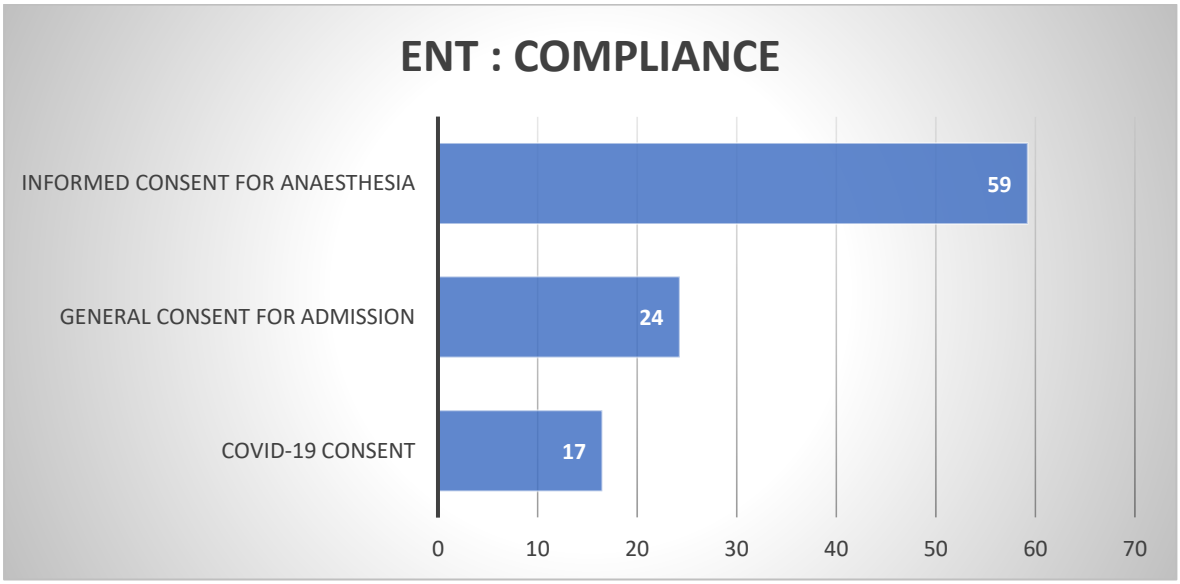
ENT

GRADE	COUNT OF GRADE
0	**42**
1	**103**

ENT CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE%
Covid-19 consent	21	50
General Consent for Admission	16	38
Informed Consent for Anaesthesia	5	12



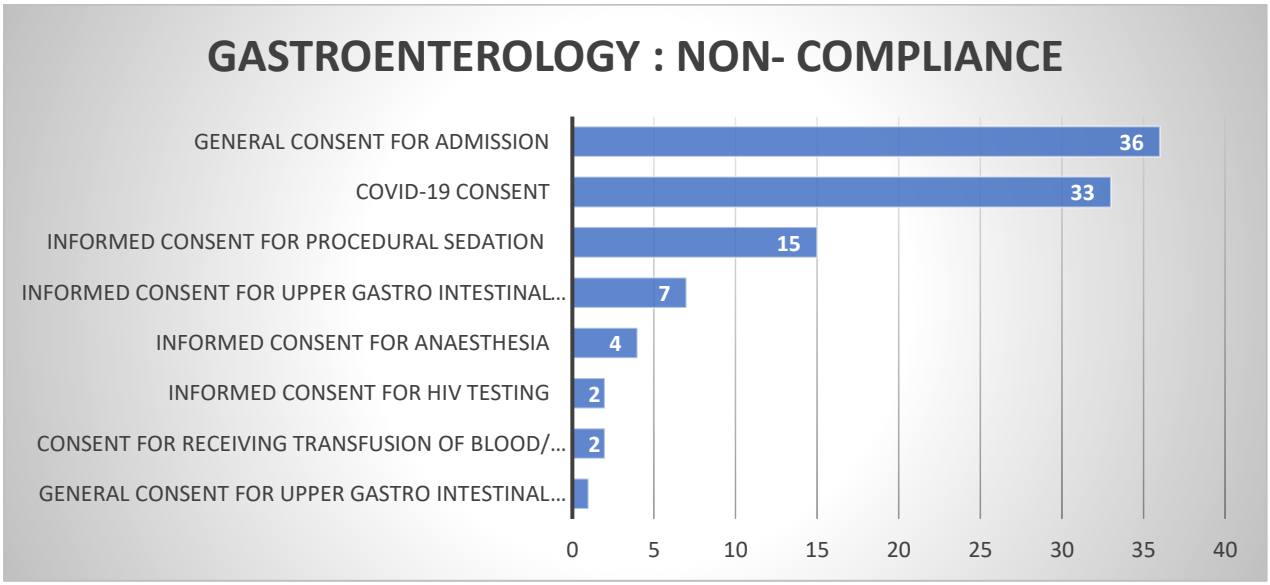
ENT CONSENT FORMS	COMPLIANCE	COMPLIANCE %
Covid-19 consent	17	17
General Consent for Admission	25	24
Informed Consent for Anaesthesia	61	59



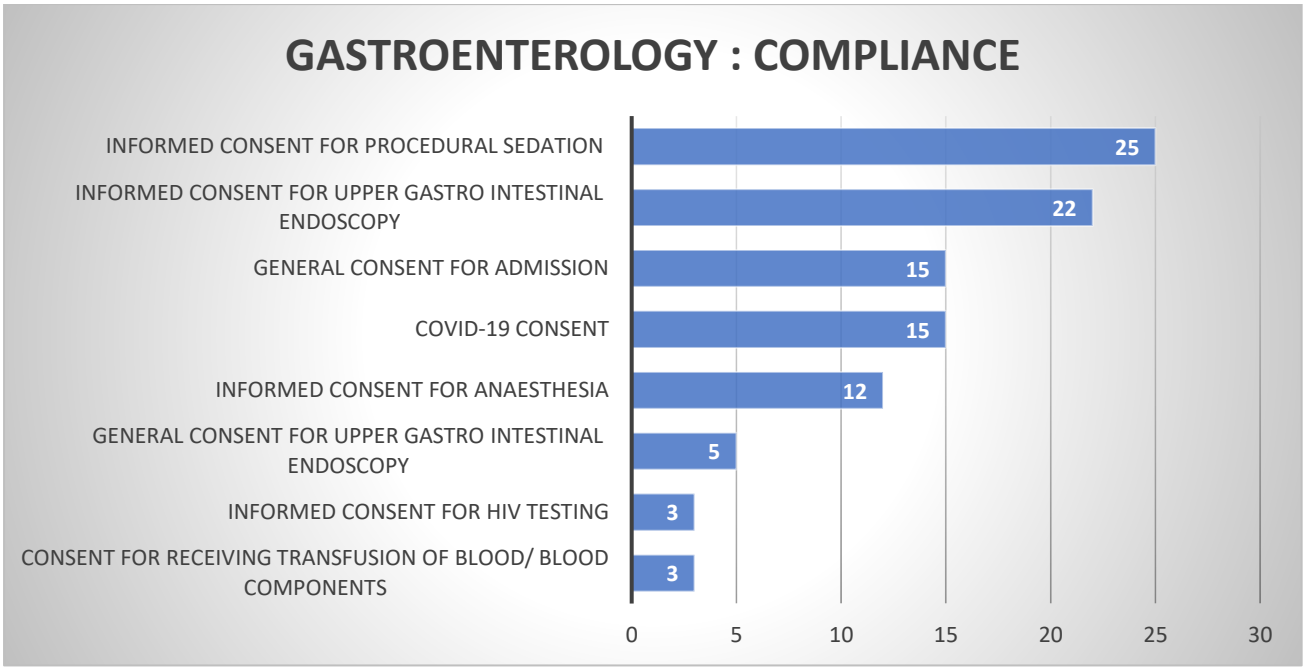
GASTROENTEROLOGY

GRADE	COUNT OF GRADE
0	121
1	234

GASTROENTEROLOGY CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	3	2
Covid-19 consent	40	33
General Consent for Admission	43	36
General Consent for Upper Gastro Intestinal Endoscopy	1	1
Informed Consent for Anaesthesia	5	4
Informed consent for HIV Testing	2	2
Informed Consent for Procedural Sedation	18	15
Informed Consent for Upper Gastro Intestinal Endoscopy	9	7



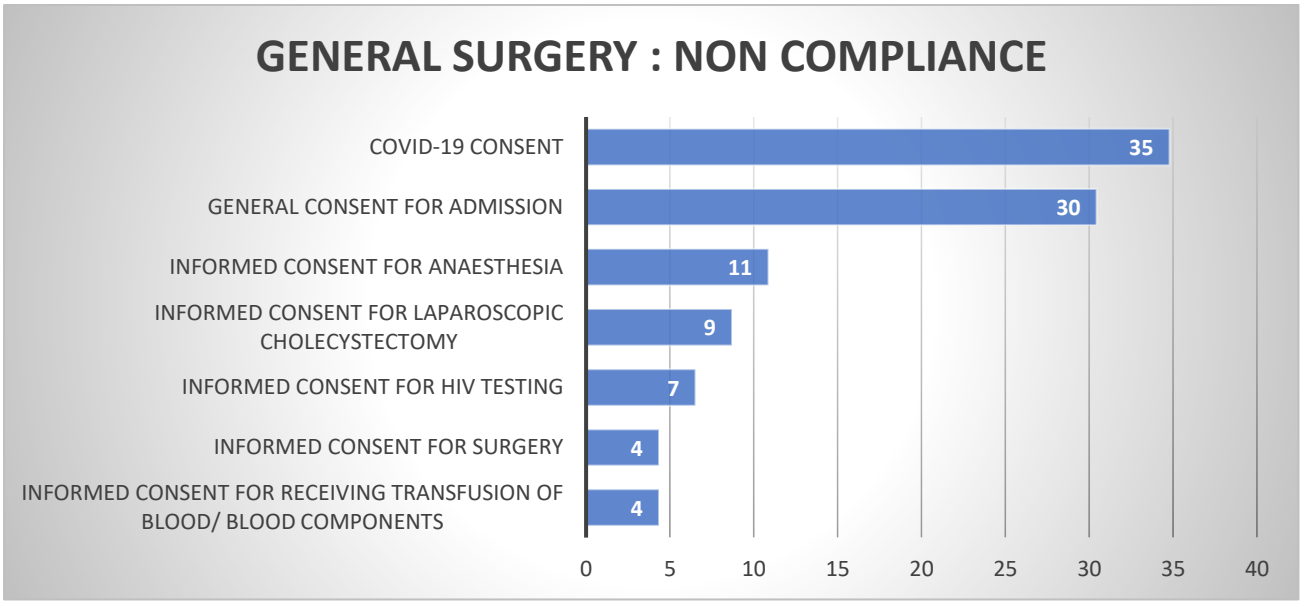
GASTROENTEROLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	8	3
Covid-19 consent	36	15
General Consent for Admission	35	15
General Consent for Upper Gastro Intestinal Endoscopy	12	5
Informed Consent for Anaesthesia	28	12
Informed consent for HIV Testing	7	3
Informed Consent for Procedural Sedation	58	25
Informed Consent for Upper Gastro Intestinal Endoscopy	51	22



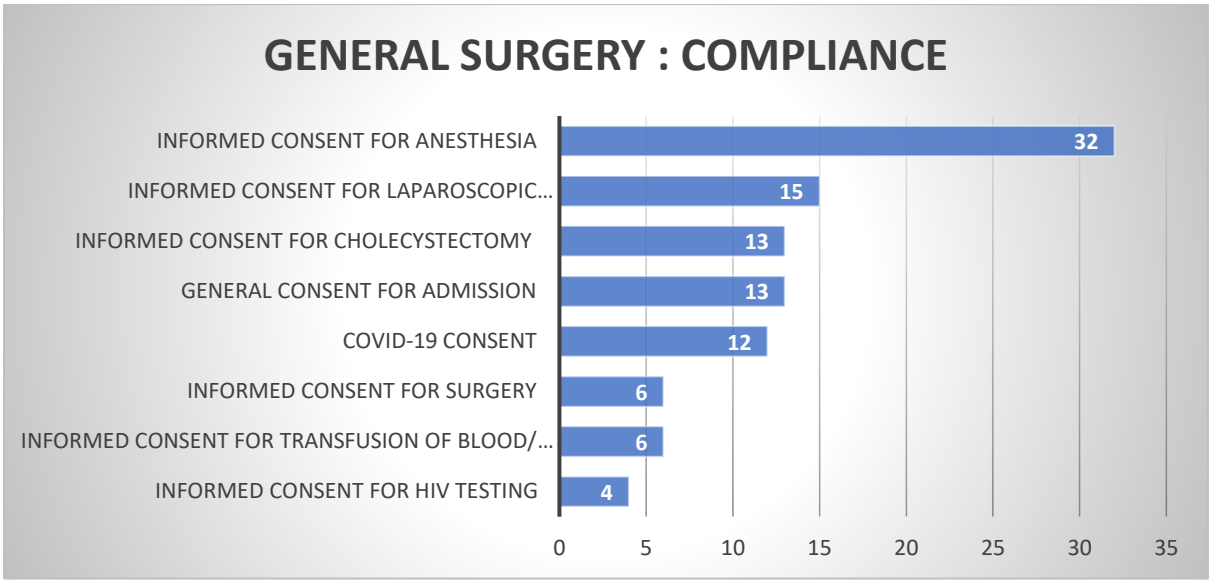
GENERAL SURGERY

GRADE	COUNT OF GRADE
0	46
1	188

CONSENT FORM OF GENERAL SURGERY	NON COMPLIANCE	NON COMPLIANCE%
Covid-19 consent	16	35
General Consent for Admission	14	30
Informed Consent for Anaesthesia	5	11
Informed consent for HIV Testing	3	7
Informed Consent for Laparoscopic Cholecystectomy	4	9
Informed Consent for Receiving Transfusion Of Blood/ Blood Components	2	4
Informed consent for surgery	2	4
Informed consent for surgery	2	11



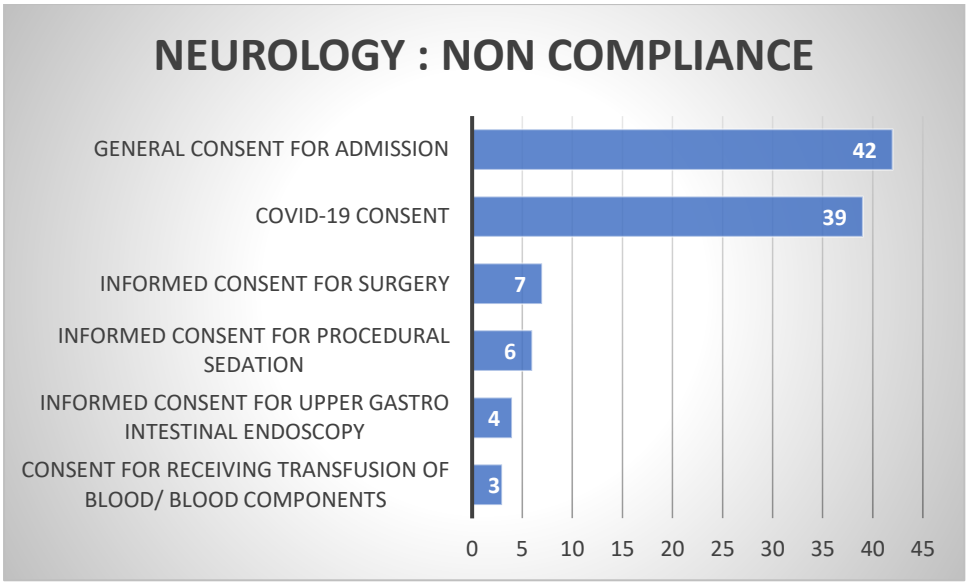
GENERAL SURGERY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Covid-19 consent	22	12
General Consent for Admission	24	13
Informed Consent for Anesthesia	60	32
Informed Consent For Cholecystectomy	24	13
Informed consent for HIV Testing	7	4
Informed Consent For Laparoscopic Cholecystectomy	29	15
Informed Consent For Transfusion Of Blood/ Blood Components	11	6
Informed consent for surgery	11	6



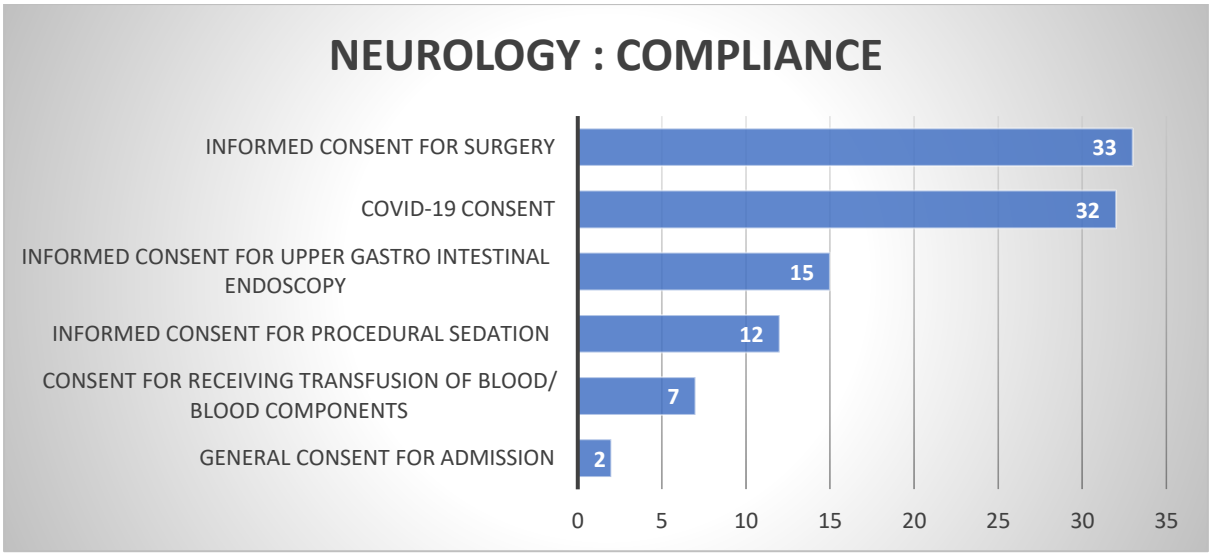
NEUROLOGY

GRADE	COUNT OF GRADE
0	**155**
1	**130**

NEUROLOGY CONSENT FORMS	NON COMPLAINCE	NON COMPLAINCE%
Consent For Receiving Transfusion of Blood/ Blood Components	4	3
Covid-19 consent	60	39
General Consent for Admission	65	42
Informed Consent for Procedural Sedation	9	6
Informed consent for surgery	11	7
Informed Consent for Upper Gastro Intestinal Endoscopy	6	4



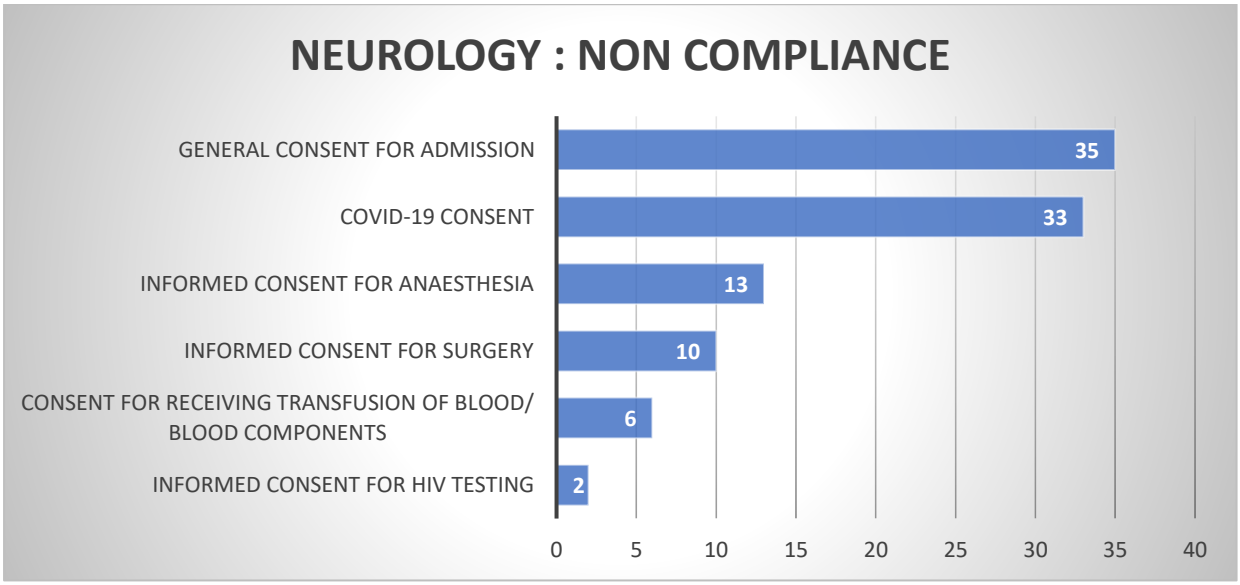
NEUROLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	9	7
Covid-19 consent	41	32
Informed Consent for Surgery	43	33
Informed Consent for Procedural Sedation	15	12
General consent for Admission	3	2
Informed Consent for Upper Gastro Intestinal Endoscopy	19	15



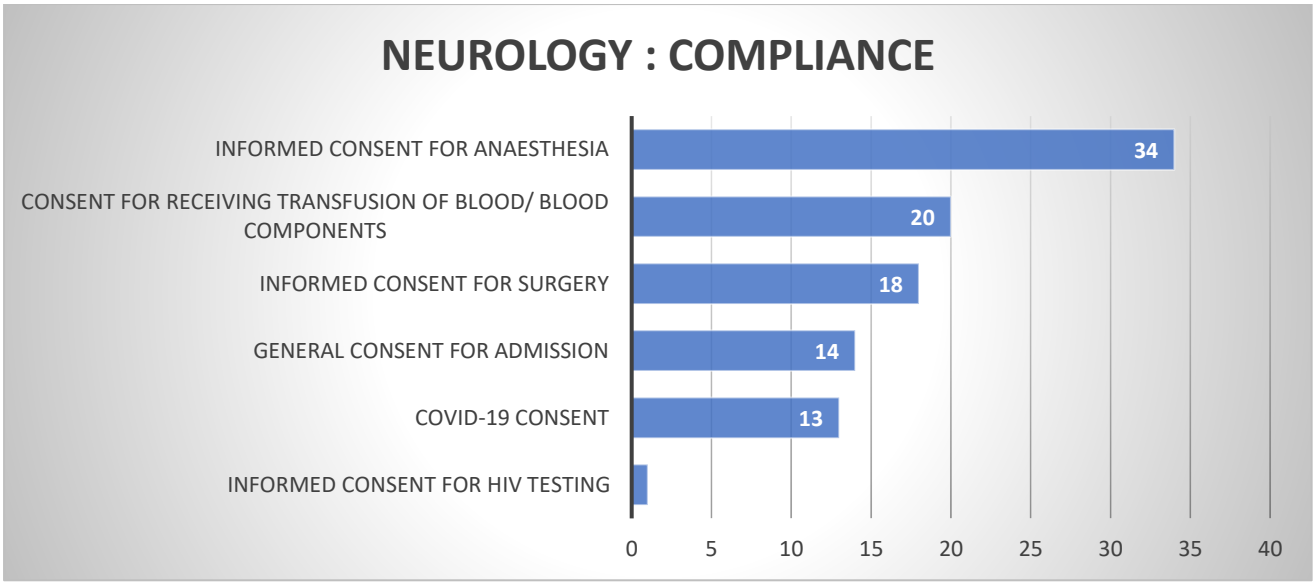
NEUROSURGERY

GRADE	COUNT OF GRADE
0	220
1	616

NEUROLOGY CONSENT FORMS	NON COMPLIANCE	NON COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	14	6
Covid-19 consent	72	33
General Consent for Admission	78	35
Informed Consent for Anaesthesia	29	13
Informed consent for HIV Testing	4	2
Informed consent for surgery	23	10



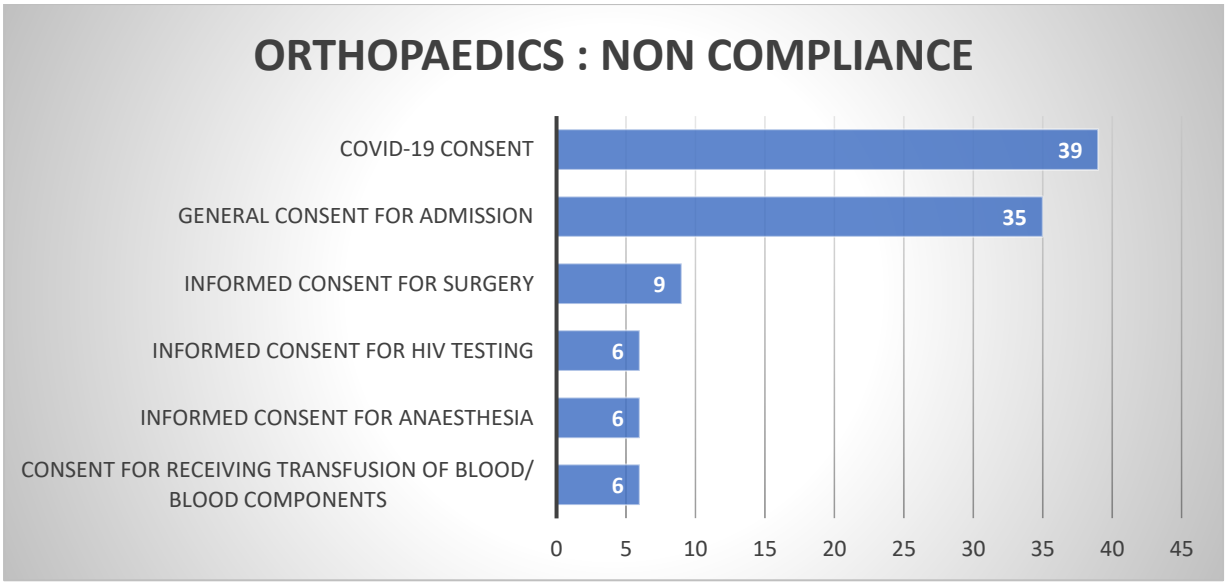
NEUROLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE%
Consent For Receiving Transfusion of Blood/ Blood Components	122	20
Covid-19 consent	79	13
General Consent for Admission	88	14
Informed Consent for Anaesthesia	209	34
Informed consent for HIV Testing	5	1
Informed consent for surgery	113	18



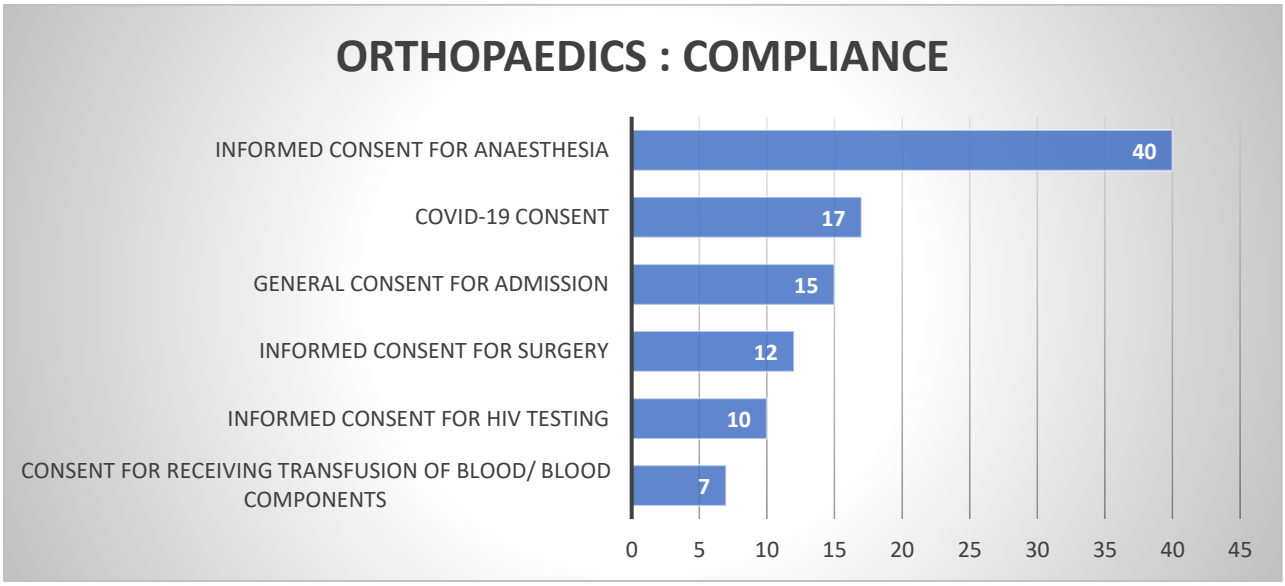
ORTHOPAEDICS

GRADE	COUNT OF GRADE
0	**139**
1	**420**

ORTHO CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE %
Consent For Receiving Transfusion of Blood/ Blood Components	8	6
Covid-19 consent	54	39
General Consent for Admission	48	35
Informed Consent for Anaesthesia	8	6
Informed consent for HIV Testing	9	6
Informed consent for surgery	12	9



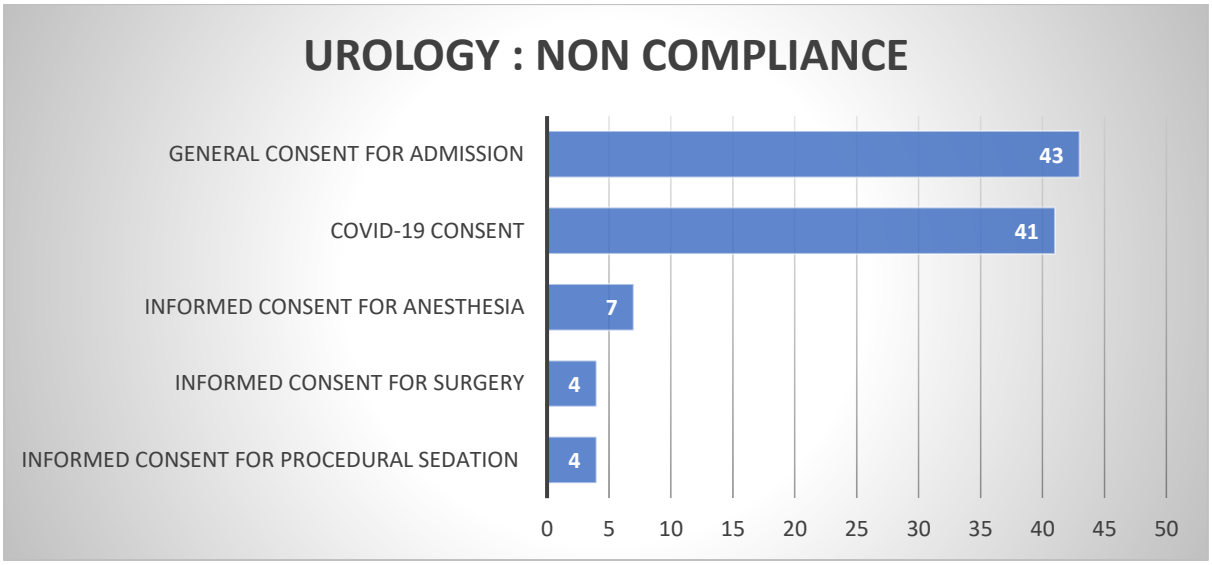
ORTHO CONSENT FORMS	COMPLIANCE	COMPLIANCE %
Consent For Receiving Transfusion of Blood/ Blood Components	29	7
Covid-19 consent	70	17
General Consent for Admission	61	15
Informed Consent for Anaesthesia	168	40
Informed consent for HIV Testing	42	10
Informed consent for surgery	50	12



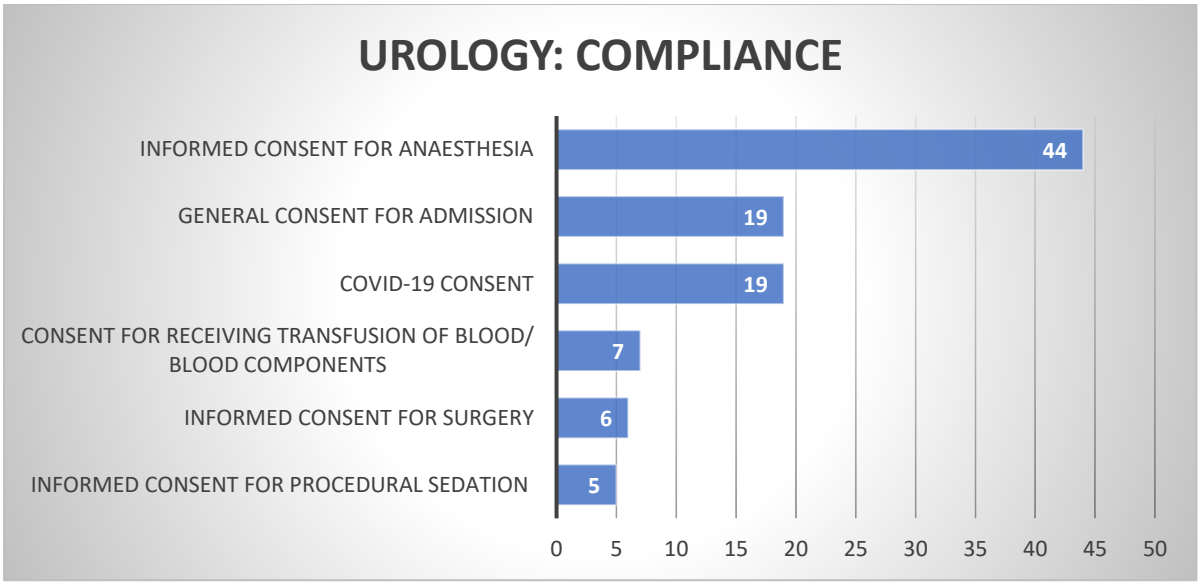
UROLOGY

GRADE	COUNT OF GRADE
0	**70**
1	**162**

UROLOGY CONSENT FORMS	NON-COMPLIANCE	NON-COMPLIANCE%
Covid-19 consent	29	41
General Consent for Admission	30	43
Informed Consent for Anaesthesia	5	7
Informed Consent for Procedural Sedation	3	4
Informed consent for surgery	3	4



UROLOGY CONSENT FORMS	COMPLIANCE	COMPLIANCE %
Consent For Receiving Transfusion of Blood/ Blood Components	12	7
Covid-19 consent	30	19
General Consent for Admission	31	19
Informed Consent for Anaesthesia	72	44
Informed Consent For Procedural Sedation	8	5
Informed consent for surgery	9	6



2.4 Data Interpretation: -

Out of 200 files studied, maximum parameters listed in the form i.e., Compliance was seen in Neurosurgery specialty followed by orthopedics and cardiology.

- Out of 14 samples in cardiology, non-compliance was seen in 247 parameters of consent form and compliance was seen in 396 parameters of consent forms. Noncompliance was highest seen in Informed Consent for Percutaneous Transluminal Coronary Angioplasty and compliance was seen highest in Informed consent for HIV Testing.
- Out of 7 samples in ENT, noncompliance was seen in 42 parameters of consent forms and compliance was seen in 103 parameters of consent forms. Noncompliance was seen highest in Covid 19 Consent and compliance was seen highest in Informed consent for Anesthesia
- Out of 12 samples of Gastro-enterology, non-compliance was seen in121 parameters of consent forms and compliance was seen in 234 parameters of consent forms. Noncompliance was seen highest in General consent for Admission whereas compliance was seen highest in Informed consent for Procedural Sedation.
- Out of 6 samples of General surgery, non-compliance was seen in 46 parameters of consent forms and compliance was seen in 188 parameters. Noncompliance was seen highest in Covid 19 consent and compliance was seen highest in Informed Consent for Anesthesia

- Out of 16 samples in Neurology, non-compliance was seen in 155 parameters of consent forms and compliance was seen in 130 parameters. Noncompliance was seen highest in General consent for Admission whereas compliance was seen highest in Informed consent for Surgery.
- Out of 23 samples of Neurosurgery, non-compliance was seen in 220 parameters of consent forms whereas compliance was seen in 616 parameters. Noncompliance was highest seen in General Consent for Admission and compliance was seen highest in Informed consent for Anesthesia
- Out of 18 samples of Orthopedics, non-compliance was seen in139 parameters of consent forms and compliance was seen in 420 parameters. Noncompliance was seen highest in Covid 19 Consent and compliance was seen highest in Informed consent for anesthesia
- Out of 9 samples of Urology, noncompliance was realized in 70 parameters of consent forms and compliance was seen in 162 parameters. Noncompliance was seen highest in General consent for admission and compliance was seen highest in Informed Consent for anesthesia.

2.5 <u>Recommendation: -</u>

- **PROCEDURE SPECIFIC STICKERS:** Using procedure-specific stickers in surgical and medical departments that employ consent forms that require handwritten inputs is straightforward and may be easily generalised. This implementation ought to be long-lasting given how simple and satisfying it is to use.
- Printed leaflets and fact sheets: Additionally educating patients about the clinical trial may also help them grasp it better.
- Audio-visual presentation: It has been shown that audio-visual methods are effective at communicating informed consent information. With the use of this instrument, textual knowledge can be immediately spoken reinforced, facilitating efficient comprehension and retention.

  Extended discussions about informed consent: Encouraging extended discussions between the patient, attendant, and medical team for greater understanding and information retention is another strategic method to improving the informed consent process.

2.6 Discussion & Conclusion: -

Although the historical evidence is somewhat ambiguous, informed consent in the sense in which it is understood and practiced today appears to be a relatively recent arrival in medical ethics. Consent has been an important area of clinical surgery since the early 20th century, with shift in attitude of clinical practice from an authoritative role of the physician or surgeon to a patient centred approach.

The "reference guide to consent" published by the department of health, stated that although not a legal requirement, the completion of consent forms is good practice where an intervention is to be undertaken.

The NABH guidance regarding consent states that the task of seeking consent is the responsibility of the doctor providing treatment. This responsibility may be delegated to someone else, as long as they are suitably trained and qualified. In particular, they must have sufficient knowledge of the proposed investigation or treatment, and understand the risks involved.

Audiotape analysis showed that consent information provided to patients through verbal discussion is often deficient. It has been reported that patient recall of the information at the consent interview is generally poor. The NABH guidance also states that information discussed with the patient and any written information given as well as details of any decisions must be recorded in the patient's medical records or a consent form.

However, there remain concerns regarding the quality of documentation of the consent process.

The aim of this study was to assess the documentation of the consent process FMRI, Gurugram undertaking a wide range of invasive procedures in different surgical specialities. In our study, we assumed that patients had a copy of the consent form if the "patient's copy" was not found in the medical records. Although the medical records were randomly selected, we believe that this study represents the current practice.

Initially only 20-25% of consent forms completely met NABH guidelines. This demonstrates an alarmingly poor adherence to such guidance that plays a vital role in patient safety, patient ethics autonomy, not to mention potential medico-legal and clinical governance implications for surgical practice.

Our intervention has improved the quality of consenting within our hospital according to these guidelines. With these interventions set to continue and further develop, we expect that the quality of the consenting process will continue to provide patients with all that it is designed to.

The results of this study led to several changes being made within the trust. We have developed a presentation to be given to all new doctors starting at the trust with the intention of giving appropriate training on the process of consenting of patients and how related

documentation should be completed. We have also increased the availability of patient information leaflets on common procedures, by placing them in clinics and wards. Staff awareness regarding importance of securely filing consent forms and the process of confirming consent in those patients consented in advance was increased.

To determine whether these interventions improved our adherence to consenting guidelines we completed a re-audit exercise. This involved the random selection of adult patient medical records who were undergoing procedures at our hospital. We examined the notes in the same way making note of whether the NABH guidelines for consenting were adhered to.

2.7 References: -

1. Panos A Dimitriadis, Stavros Constantinou: Audit of the quality of consent form completion and improvement of practice September 2012,
2. https://www.researchgate.net/publication/267423443_Audit_of_the_quality_of_consent_form_completion_and_improvement_of_practice
3. Messer NG. Professional-patient relationships and informed consent. *Postgrad Med J.* 2004;80:277–283. [PMC free article] [PubMed] [Google Scholar]
4. Giampieri M. Communication and informed consent in elderly people. *Minerva Anestesiol.* 2012;78:236–242. [PubMed] [Google Scholar]
5. Jones MA. Medical Negligence. 4th ed. Sweet & Maxwell, London: Indian Reprint 2010; 2008. p. 548.
6. Ratanlal R, Dhirajlal KT. The Indian Penal Code. 33rd ed. Nagpur: Lexis Nexis; 2011.
7. Raab EL. The parameters of informed consent. Trans Am Ophthalmol Soc 2004;102:225-30.

Fortis MEMORIAL RESEARCH INSTITUTE

Patie[redacted]
UID
Age [redacted] Bhargava Domestic Insurance
D.O.A. : _____ Unit : _____
ale / Female

INFORMED CONSENT FOR HIV TESTING

CONSENT FOR HIV ANTIBODY BLOOD TEST

Please read this consent form with care so that you can make an informed decision about getting the blood test done. You are welcome to ask your doctor or counselor any queries that you may have regarding this test.

1. INTRODUCTION: Acquired Immunodeficiency Syndrome (AIDS) is a serious disease caused by infection with Human Immunodeficiency Virus (HIV). Not all persons with HIV infection develop AIDS provided preventive treatment and other measures are started in time. However, anyone with HIV can spread it to others. HIV is spread through unsafe sex, sharing of needles, or receiving blood or blood products or other tissues infected with HIV. Infected others can spread HIV to their babies through their breast milk. The test for HIV detects the body's reaction to the antibody) and not the virus itself.

IAT THE TEST MEANS : If the test is NEGATIVE it means that antibodies (body's immune response to the ion) were not detected in the blood sample. This usually means that the person is not infected with HIV. However, in some cases the infection may have happened too recently for the antibodies to have been generated and the test to be positive. It may take up to six months for the antibody test to be positive after HIV infection.

If you test POSITIVE it means that antibodies (body's immune response to the infection) were found present in the blood sample this implies infection with HIV and you can pass it on to others. **It does not necessarily mean that you have AIDS,** which is the most advanced stage of HIV infection.

False results (negative test in someone who is infected with HIV or positive test in someone not infected with HIV) may occur. Indeterminate results (when it is unclear whether the test is positive or negative) may occur. When the test result is indeterminate, repeat test or special confirmatory test may help determine the person's true status.

3.BENEFITS OF BEING TESTED : There are substantial benefits of being tested for HIV. Knowing one's HIV status helps people make personal and lifestyle choices including those related to sex, contraception and pregnancy. Infected sons benefit as they can start appropriate treatment to delay or prevent AIDS and other serious infections.

SKS OF BEING TESTED : You may feel anxious till the test result is available. Repeat or further testing required in of an unclear result may cause further stress. A positive test result may cause severe stress, anxiety and depression. You would be asked to consider declaring the result to your partner. Persons with negative test results may be tempted to indulge in risky behavior which may further increase the chances of contracting HIV infection.

5. CONFIDENTIALITY :

The law requires that health care providers (hospitals) and laboratories report the details of persons infected with HIV to the local health department. This helps the government in knowing the disease burden in the society and take appropriate action. Hospitals or laboratories do not maintain a separate list of persons with positive HIV testing.

In case the hospital bill is being directly settled by my insurance company, the hospital is bound to provide all treatment papers & test reports to the TPA / Insurance Company and patient privacy shall be disclosed, as the same is under exception & exemption. For such disclosure(s) I hereby give my consent to the hospital.

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Patient's I
UID :
Age :
D.O.A. :
Female
Unit

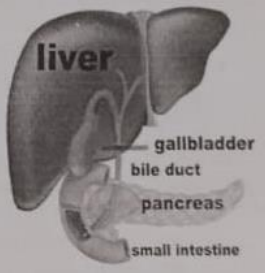
INFORMED CONSENT FOR LAPAROSCOPIC CHOLECYSTECTOMY

A. All fields must be completed by the person explaining the consent. Mark NA if a field is not relevant.
B. For information regarding Anesthesia type and its risks and complications, please see Anesthesia Consent Form.
*C. For further information, please see the **PATIENT INFORMATION LITERATURE** (if provided) or speak with your Doctor.*

PART A

1. Full Name of the Operation/procedure: **LAPAROSCOPIC CHOLECYSTECTOMY**

2. Details of operation/procedure: Laparoscopic Cholecystectomy means removal of the Gall Bladder with the help of a telescopic camera (laparoscope). In this operation, the abdomen is inflated with carbon dioxide gas and the laparoscope is inserted through a small cut near the umbilicus. Other smaller cuts may be made to insert other instruments required during the operation. The Cystic (bile) duct and blood supply to Gall Bladder is clipped and the Gall Bladder removed through one of the cuts. A suction tube may be left in the operated area to drain any secretions.



3. Intended benefits:

- ✓ Removal of the diseased Gall Bladder (e.g. Gall stones)
- ✓ Relief from the diagnosed illness (e.g. pain due to Gall stones)
- _____
- _____
- _____

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Patient's [redacted] /F

UID :

Age :

D.O.A. : / Female

Unit :

INFORMED CONSENT FOR CHEMOTHERAPY

I, _____, ☐ (the Patient) or ☐ representative of patient

(_____), have (please tick the correct option above and below)

- read
- been explained this consent form in _____ (name of language) which I fully understand,

and understood the information provided about CHEMOTHERAPY in this consent form.

I am aware that Chemotherapy is a treatment procedure wherein strong medicines are administered orally (by mouth) or by injection / infusion to treat difficult diseases (like cancer etc.). The intent of chemotherapy can be for curing (curative), for improving survival, for control of symptoms, for maintenance/palliation (keeping disease under control) for adjuvant/neo-adjuvant purpose (after or before definitive treatment to minimize risk of recurrence or shrink the disease) or a combination of one or more of these.

I am now aware of the intended benefits, possible risks & complications, and available alternatives to Chemotherapy given below. I am also aware that results of Chemotherapy can vary from patient to patient; and declare that no guarantees have been made to me regarding success of this procedure. I am aware that while majority of patients usually have an uneventful Chemotherapy session, some cases may sometimes develop complications. I also understand that sometimes a Chemotherapy session may need to be stopped, delayed and/or abandoned midway if the patient's clinical condition worsens, or if the patient cannot tolerate. I understand that if medical exigencies demand, further or alternative treatment measures may need to be carried out. I am aware that I may require administration of blood and/or blood products during or after the Chemotherapy session if found necessary by the doctor (for which a separate consent shall be obtained). I am also aware that sometimes admission to an Intensive Care Unit and/or extension of duration of hospitalization may be required.

Intended benefits: (TICK AS APPROPRIATE)

- Improved survival
- Control of symptoms
- Induction – therapy given in the acute state of the ailment aiming to shrink the disease/tumor
- Curative – to give the best possible chance of being cured
- Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms
- Disease control / palliative – the aim is not to cure but to control or shrink the disease. The aim is to improve both quality of life and survival