Accreditation Standard for IVF Center

(ASIC: 2020)

1st April, 2021

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Indian Society for Assisted Reproduction

&

Forum for Enhancement of Quality in Healthcare



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**Preamble**

With the 21st Century well set in, we can now see many changes in Indian Industries. Healthcare has attained the status of Industry and is no exception to such changes. Today’s patients are well informed and come with high expectations. The nature of diseases have changed, which has made communication, response time & visible quality as important ingredients. Third party endorsement is common and well sought after.

Health awareness in India is on the rise and many doctors want their IVF Centers to meet recognized standards. The expectations of patients have gone up and they are looking for third party accredited services.

**IVF Centres Standards**

Due to change in life style, unhealthy food habits, delayed age of marriage, stress etc. the need of conceiving through IVF has increased manifold. This has encouraged Doctors and Corporate to start IVF centres. Vision of ISAR is that there should be self-discipline amongst the members in managing IVF Centres. In collaboration with FEQH, as a third party partner, ISAR developed standards for IVF Centres which are inclusive and progressive.

ISAR has put in immense efforts to ensure that more and more members adhere to the standards and manage their Clinics in an ethical way. Self-regulation is always a better and effective option to improve the Quality and Confidence of Society.

The task before ISAR & FEQH was to create standards both from infrastructure point of view and Standard Operating Procedures (SOP). These were required in order to make the facility more reliable, user friendly and safe for patients as well as for health care workers. Due care was taken to make these Standards simple, easy to understand and implement & cost effective for overall improvement in the quality of healthcare services.

**Objectives of Accreditation:**

* Create measurable and practical Standards for IVF Centers in terms of infrastructure and equipment.
* To follow standard operating procedures for IVF Centers.
* To assist Doctors in creation of a safe and Infection-free environment.
* Assist Society, Insurance Companies, Corporate to select quality IVF Centers.
* To Enhance Patients Safety.

*Professional competence of medical professionals and their decision of referral practice and clinical judgment in managing patients are out of purview of this standard.*

**Validity of certificate:**

ISAR & FEQH jointly will issue Accreditation Certificate which will be valid for a period of 3 years from the date of the certificate, subject to IVF Center maintaining surveillance audit schedule. The ownership of the certificate will be with ISAR and the IVF Center will have to return the said certificate after expiry / withdrawal by FEQH / ISAR due to failure on the part of IVF Center in not complying to audit findings.

Reference Material:

1. For reference and adequacy of documents, forms, formats, records, consent forms, legal requirements for special procedures, suggestions regarding record keeping etc. IVF Center can refer to the ICMR Guidelines & www.clinic21st.com

**1.0** Procedure for Certification to Accreditation Standard for IVF Centers (hereafter called as ASIC).

**Intent**

*To define well-laid procedure for Accreditation so that IVF Center can upgrade and is well aware of steps required.*

* 1. Interested IVF Center will procure Start-up kit from ISAR’s office by making payment of Rs.6,000 + 18% GST Rs.1,080 = Rs.7,080 favoring “Indian Society of Assisted Reproduction”
	2. The IVF Center shall upgrade its facilities in order to meet the requirements of ASIC.
	3. IVF Center will approach FEQH along with audit fee, IVF Center Profile and duly filled in formats & annexures (Refer Page No. 12 to 23)
	4. **A** FEQH and ISAR will scrutinize Application and if found acceptable, nominate Audit Team which will visit/ Virtual Visit the IVF Center on a mutually convenient date & time and conduct the audit.

**B** If the Application Form is incomplete or has deficiencies, IVF Center will be informed accordingly to enable them to re-submit the same after necessary corrections. After receipt of acceptable form, steps mentioned in 1.4 A will be followed.

* 1. The IVF Center will be informed about the outcome of the audit within 30 days. The audit team will either-
		1. Approve the IVF Center for certification.

or

* + 1. Ask to make modifications to meet ASIC and email the NC closure with documentary evidence.

* 1. Certified IVF Centers will be informed about acceptance and will be conferred with the Certificate. Their names will be put under Certified Members on the website www.clinic21st.com & will be allowed to use FEQH registered logo.
1. Facility Standard for IVF Centers.

Definition: Any commercial / charitable establishment registered as Daycare Centre/Hospital/Nursing Home with local Government Body and registered under PCPNDT ACT.

**Intent**

*To specify minimum infrastructure requirements and their objective elements.*

**2.1** **Scope of the services:**

**a)** Name of the IVF Center and its permanent location with relevant details, year of establishment & the services provided shall be documented & made public. (Refer IVF Center Profile as in Format-3)

**2.2** **Medical & Technical Professionals:**

1. IVF Center shall list all the Medical Professionals, Technical, Administrative & Support staff (e.g. Medical Director, Gynecologist, Andrologist, Clinical Embryologist, Counselor, etc.), whose services are available in IVF Center. The list shall include their names, degrees, Medical Council registration number for doctors, experience and contact details & conforming to ICMR Guidelines. (Refer *Anx.-2*)

**2.3****Waiting room:**

1. Shall be well-lit, comfortable with recreation material to make waiting experience educative, informative and relaxing. Emergency light, clean toilet and safe drinking water should be available free of charge.
2. Quality Policy shall be displayed. (For guideline refer Format – 2)
3. Patients’ Rights and Responsibilities shall be displayed. For guidelines refer *Format – 3*)

**2.4 Examination rooms:**

Shall be well-lit, comfortable and have basic necessities like examination table, provision for height and weight measurement, x-ray viewer, BP apparatus, examination trolley, wash basin, etc. There should be facility to provide necessary privacy during examination.

* 1. **Observation / Recovery Area**
1. Shall be provided with all essential items like cot with call bell, side table, wall clock, toilet, bathroom, stand for IV fluids, chair for attendant etc.
2. Portable suction machine, ambu bag should be available if required.
3. Patients’ linen shall be changed daily or earlier, if soiled.
	1. **Operation Theatre:**
4. The size & recommended list of items and medicines which shall be available are detailed in *Anx. 3*. IVF Center shall prepare explanatory note if they are deviating from the standard.
5. IVF Center shall maintain records of vital processes like Autoclave Register, Cleaning Register pertaining to O.T. sterilization and the same should be available in the vicinity
6. There shall not be any expired medicine in IVF Center. Expiry check should be documented.
	1. **Embryology laboratory**
7. The size should be minimum 100 sq feet.
8. Infection control practices shall be observed.
9. The Centre should validate HEPA filters as per manufacturer’s recommendations.
10. Air Sample and swabs shall be checked at least once in 3 months for microbial count for laminar flow hoods, laboratory tables, Incubators and other areas where sterility is required.
	1. **Procedure Rooms e.g. Semen Processing Room, IUI Room**
11. The size should be adequate for the purpose.
12. Should have adequate furniture, equipment and infrastructure.
	1. **Records:**
13. IVF Center shall maintain list of important files / registers. (Refer Anx.-4).
14. For every admitted patient, IVF Center shall maintain detailed record and information of name, address, contact number, medical history, allergies, treatment rendered, medicines prescribed, etc.
15. Consent Form shall be an integral part of patient record.
16. All notes should be legible, signed, named, timed & dated and shall be an integral part of patient record.
17. All old records shall be maintained at least for 10 years, filed date-wise and be retrievable in reasonable time
18. Pre-operative check list shall be an integral part of patient’s record.
19. All records should be maintained on real time basis.
	1. **Purchase procedure:**

1. IVF Center should maintain list of approved suppliers. (Refer *Anx.- 5)*
2. IVF Center should verify purchased products.
	1. **Control on outsourced activities:**
3. Periodic monitoring / inspection of outsourced activity should be ensured.
4. All the pathology reports should be signed by M.D. Pathologist / M.Sc / PhD Microbiology.
	1. **Mandatory permissions:**

|  |  |
| --- | --- |
| mandatory-general-2 | IVF Center shall have up-to-date list of mandatory permissions*. (*Refer *Anx. – 6)* |

**3.0** Staff:

**Intent**

*To groom staffs as good healthcare workers in a safe environment. To encourage human resources to orient with good practices in Infection Control, Sterilization & Patient’s Care.*

**3.1****Staff – Nursing, Technical & Others:**

1. Biodata of all employees shall be maintained at IVF Center.
2. Photostat copies of qualification certificates shall be maintained at IVF Center
3. Staff shall be provided with lab coat/uniform and identity card.
4. Staff shall be aware of the ASIC Accreditation program.
5. Staff coming in contact with patients shall undergo health check-up for communicable diseases once in three years.
6. Staff shall undergo training for bio-medical waste disposal.
7. All new Staff shall undergo induction training before assuming duties (refer *Format No.7*).
8. Staffs should be trained in maintaining Patients confidentiality and protecting their rights.
9. All the staff should be trained to identify & report early detection of problem.
	1. **Infection control:**
10. Waste segregation, hand wash procedures and other preventive practices are well practiced.
11. All nursing & technical staff members shall be immunized against communicable diseases.
12. Adequate hand wash facility and / or hand scrubs should be available.

**4.0** **Facility management and safety:**

**Intent**

*Provision of safe and secure environment for patients, their families, staff and other visitors.*

**4.1 Risk Mitigation:**

1. The IVF centre should possess Fire NOC & shall have adequate number of fire extinguishers (1.5 Kgs per 1000 Sq.Ft.), Cryo PPE for handling liquid Nitrogen & first aid box. Safety issue should be looked into on a case to case basis.
2. Evacuation route and documented exit plan should be displayed. Emergency exit door should be marked
3. IVF centre should conduct Fire Mock Drill every 6 months and record maintained.

**4.2** **Emergency services:**

1. In the event any emergency arises, there should be tie-up with Emergency Response System (ERS) provider or cardiac ambulance service & details of this arrangement should be displayed in waiting room prominently.
2. There should be documented procedure to shift frozen embryos to safer place in case of any emergency
3. Evacuation plan should be ready for disaster management.
4. Staff should be trained in fire and non-fire emergencies.

**5.0 Suggestion / Complaint box:**

**Intent**

*Suggestions and complaints are learning tools for any organization and need to be looked into seriously.*

*Suggestions and complaints from other stake holders also need to be obtained.*

**5.1 Patients grievances:**

1. A Suggestion/Complaint Box shall be available at convenient locations for patients/visitors/stakeholders to lodge their complaints or submit suggestions. The patients should be informed about the procedure to voice their complaint.
2. There should be a mechanism to redress all complaints/ suggestions

**6.0 Equipment:**

**Intent**

*The intent of the standard is to ensure that all the equipment are in well maintained condition and are dependable.*

**6.1** Equipment – List, maintenance & calibration status

1. IVF Center shall have a list of important equipment along with their calibration status. Refer *Anx. -7*
2. All equipment should be clean, stain-free and in well maintained condition.
3. Equipment, which are not working, should be suitably identified.
4. All the equipment should have history card/ logbook / register with service / repair record.
5. Manuals & software CDs, if any, pertaining to equipment should be readily available for reference.

**7.0 Continual improvement:**

**Intent**

*To incorporate and document the history and pathway to take the IVF Center to newer heights.*

**7.1 IVF Center should have objectives to improve its services.**

1. The intent of the standard is to encourage IVF Center to innovate and improve continually. Documented evidence of improvements made from previous audit should be available.

**8 Additional requirements**

**The IVF Center should fulfill below mentioned additional requirements:**

1. IVF Center shall maintain Temperature log of refrigerator & Temperature & Humidity log of OT, Semen Collection Room & temperature of Incubator.
2. Emergency medicines shall be available at a place other than OT.
3. IVF Center shall maintain master file containing all stationery, formats, forms, brochures etc. used in IVF Center.
4. IVF Center shall have adequate power back up.
5. Wherever video cameras are installed, suitable warning shall be prominently displayed.
6. Staff should be aware about patient’s rights and responsibilities.
7. IVF Center should maintain list of consent forms used in the set up and staff shall be aware about the same (Refer *Anx.No.8*).
8. All notes should be legible, signed, named, timed and dated.
9. IVF Center should be aware about procedure to register MLC and foreign nationals.
10. IVF Center should define procedure to dispose unused portion of the samples.
11. IVF Center should have written Standard Operating Procedures for various procedures as detailed in *Anx. No.9*
12. The organisation should have a file with all the format & forms used in the IVF centre.

***Note:***

1. **During the audit, activities not documented will not be considered as done.**
2. **“Shall” mean compulsory and “should” means recommended.**

**Quality Endorsed**

The mark of excellence for IVF Centre is the logo which they are entitled to use after the accreditation audit.

**LOGO**

****

We will share the logo to the centre/ hospital after they have completed the process of accreditation which they can use in their stationery. Logo can be used only during the validity of the certificate. If you wish to continue using the Logo in your stationery then you should get your centre/ hospital recertified before its expiry.

**Annexure - 1**

**Audit fee with effect from 1st April, 2021**

**Start-Up Kit**

Amount of Rs. 6,000 + 18% GST Rs.1,080 = Rs.7,080 will be payable to ISAR at their Mumbai office for provision of start-up kit which consists of following:-

1. Soft and printed copy of standard
2. Annexures and Formats
3. Counselling session for explaining details of audit process on any online video format.
4. For the time being all the audits will be Virtual Audit till further notice.

**Audit Fees**

Certification audit & Intermediate Surveillance Audit (after 18 months) fees is Rs.23,010 for 3 years

Payment can be made through Cheques or Online transfer

Cheque favoring “**FEQH**” and send to 201 ONYX, 36, Union Park, Chembur, Mumbai 400 071

**NEFT/RTGS**:

Account name: FEQH

Bank Name: Bank of India

Account Number: 000 9201 1000 0287

IFSC: BKID0000009

Branch: Chembur, Mumbai 400071

The audit fee is **exclusive** of following:-

1. Applicable service and other taxes
2. Travelling and conveyance expenses
3. Boarding and lodging expenses
4. Out of pocket expenses

**FEQH Contact Details**

Mr. P.P. Gadgil

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Mr. Jitesh Rao

**Mobile No**. 98332 44779

**Annexure – 2**

List of Medical Professional, Technical, Administrative and Support Staff

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Sr.No.**  | **Employees' Name** | **Type of services provided** | **Qualification. Starting Basic Degree** | **Council Name & Registration** | **Joining date (dd.mm.yy)** | **No.of Years of ART Experience** | **Area/ working department** |
|   |   |   |   |   |   |   |   |
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**Annexure - 3**

List of items and drugs required in Operation Theater

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr.No.** | **Element** | **Requirement** | **Remarks** |
| 1 | **Infrastructure** |  |  |
|  | Space in Sq.Ft. (aseptic zone) | 100 |  |
|  | Changing area - Defined | Protective zone – Defined |  |
| 2 | **Equipment** |  |  |
|  | Boyle’s apparatus  | Pulse Oximeter |  |
|  | Cardiac Monitor with defib. | Ceiling Light – 1 no. |  |
|  | Light | Suction machine – 1 no. |  |
|  | Emergency electric back-up. | Scrub basins with elbow opening taps – 1 no. |  |
|  | Electric autoclave | O.T. table – Hydraulic |  |
|  | Instrument Trolleys |  |  |
|  | **Anesthesia equipment** |  |  |
|  | 1. Laryngoscope with 4 blades.
2. E.T.tubes (full set)
3. Ambu bag
4. Masks
5. Airways
6. Oxygen supply
7. Suction catheter
8. Oxygen masks/Prongs
9. Ryle’s Tracheostomy set
10. Sterilizing drums
11. Bucket with cover
12. Dressing trays
13. X-ray view box
14. Tube
15. Mcgills forceps
16. Patient transfer trolley
 | 1. Sticking plaster
2. B.P. apparatus
3. Stethoscope
4. Thermometer
5. Syringe/needle destroyer
6. Torch
7. Scissors
8. Ampoule cutters
9. I.V. stands
10. Cleaning solutions
11. Sterilizing solutions
12. Syringes &needles
13. Scalp vein sets.
14. I.V. cannulae
15. Sand bags
16. Cotton bandages / POP bandages
 |  |
|  | **Furniture & fixtures**1. Revolving stool
2. Fixed stools & stepping platform
 | 1. Wall clock with second hand
2. A.C. unit (1tonne/100sq.ft.area)
3. Fan (wall mounted)
 |  |
|  | **Essential Drugs**1. Atropine / Glycopyrrolate
2. Adrenaline
3. Mephentine
4. Dopamine
5. Xylocard
6. Calcium gluconate
7. Sodium bicarbonate
8. 25% Dextrose
9. Mannitol
10. Dexamethasone
11. Hydrocortisone
12. Antihistaminic (e.g.Avil)
 | 1. Ranitidine
2. Perinorm
3. Diazepam
4. Phenergan
5. Deiphylline/Aminophylline
6. Nitroglycerine(inj./patch)
7. Pentazocine
8. Lasix
9. Voveran
10. Paracetamol
11. Xylocaine jelly
12. Haemostatic material like gelfoam,botropase etc.
13. I.V.fluids; 5%Dextrose, DNS, RL, NS.
 |  |

**Annexure – 04**

List of important files / registers:

|  |  |  |
| --- | --- | --- |
| **Sr.No.** | **Title of Register** | **Location of storing** |
| 1 | IPD register |  |
| 2 | Autoclave register |  |
| 3 | Fumigation register |  |
| 4 | OT register |  |
| 5 | OPD register |  |
| 6 | Drug / material order register |  |
| 7 | PNDT register |  |
| 8 | Drug store register |  |
| 9 | Daily log book for incubator |  |
| 10 | Records book for calibration of equipment |  |
| 11 |  |  |
| 12 |  |  |
| 13 |  |  |
| 14 |  |  |
| 15 |  |  |

**Annexure - 5**

List of approved suppliers:

|  |  |  |
| --- | --- | --- |
| **Sr.No.** | **Name & Address** | **Items supplied** |
|  |  |  |
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**Annexure - 6**

List of mandatory permissions:

**Note:** If you are situated in hospital and permissions are in the name of the parent organisation, the same is acceptable.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr.No.** | **Permission title** | **Permission No.** | **Validity date** | **Remark** |
| 1 | Nursing home registration |  |  |  |
| 2 | PNDT Registration |  |  |  |
| 3 | BMW Authorisation for generation & disposal |  |  |  |
| 4 | Agreement with authorised waste handler |  |  |  |
| 5 | PAN No. |  |  |  |
| 6 | TAN No. |  |  |  |
| 7 | GST No. |  |  |  |
| 8 |  |  |  |  |
| 9 |  |  |  |  |
| 10 |  |  |  |  |
| 11 |  |  |  |  |
| 12 |  |  |  |  |

**Annexure - 7**

List of equipment:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr.****No.** | **Equipment title** | **Location of Installation** | **Servicing arrangement** | **Calibration****Frequency** |
| 1 | Laminar flow bench with thermostatically controlled heating plate |  |  |  |
| 2 | Stereo Microscope |  |  |  |
| 3 | High powered binocular light microscope |  |  |  |
| 4 | High resolution inverted microscope |  |  |  |
| 5 | Micromanipulator |  |  |  |
| 6 | CO2 incubator |  |  |  |
| 7 | Hot air oven |  |  |  |
| 8 | Laboratory centrifuge |  |  |  |
| 9 | Liquid nitrogen storage tanks |  |  |  |
| 10 | Refrigerator |  |  |  |
| 11 |  |  |  |  |
| 12 |  |  |  |  |
| 13 |  |  |  |  |
| 14 |  |  |  |  |
| 15 |  |  |  |  |
| 16 |  |  |  |  |

**Annexure - 8**

List of Consents forms recommended by ICMR, please delete which ever are not applicable to you:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sr. No.** | **Consent form title** | **When to fill this form** | **Name / Post of responsible person for filling** | **Name / Post of responsible person for verifying** |
| 1 | Consent Occyte Retrieval/ Embryo Transfer |   |   |  |
| 2 | Consent Form to be signed by the Intended Parents of IVF/ICSI |   |   |  |
| 3 | Consent for Frozen Embryo Transfer |   |   |  |
| 4 | Consent for Freezing of Oocytes |   |   |  |
| 5 | Consent to extend the storage of Sperm Sample |   |   |  |
| 6 | Consent to Transfer the Frozen Oocytes |   |   |  |
| 7 | Consent for extending the storage of Embryos |   |   |  |
| 8 | Consent form to Dispose Cryopreserved Embryos |  |  |  |
| 9 | Consent form for Cryopreserved Sperm |  |  |  |
| 10 | Consent to the use of fresh Donor Eggs/Embryos without HIV Quarantine |  |  |  |
| 11 | Consent of Husband |  |  |  |
| 12 | Consent for the Procedure of PESA & TESA |  |  |  |
| 13 | Consent Form for the Donor of Eggs |  |  |  |
| 14 | Consent for Artificial Insemination or Intrauterine Insemination with Donor Semen |  |  |  |
| 15 | Consent for Freezing and Complementary Storage of Embryos for 3 months |  |  |  |
| 16 | Declaration form and instructions for semen sample collection |  |  |  |

**Annexure - 9**

List of SOPs available.

|  |  |  |  |
| --- | --- | --- | --- |
| Sr.No. | SOP No. | SOP Title | Applicability |
| 1 | S.01 | Embryology lab quality control guidelines  |  |
| 2 | S.02 | Incubator temp and CO2/ O2 quality control  |  |
| 3 | S.03 | Dry bath quality control |  |
| 4 | S.04 | Cryobiology laboratory rules of operation  |  |
| 5 | S.05 | Cryobiology bio safety norms  |  |
| 6 | S.06 | SOP for specimen storage  |  |
| 7 | S.07 | SOP for destruction of unused portion of specimen |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Format - 1**

IVF Centre profile

|  |  |
| --- | --- |
| Organization name  |  |
| Legal status: |  |
| Name of directors / proprietor with mobile number |  |
| Address of operation: |  |
| Year of establishment: |  |
| Number of employees: |  |
| Co-ordinator / Position & mobile number: |  |
| Waiting room details: Nos./ area each in sq.ft: |  |
| Examination area:Nos./ area each in sq.ft: |  |
| Operation theaters:Nos./ area each in sq.ft: |  |
| Embryology LaboratoryNos./ area each in sq.ft: |  |
| Procedure rooms Nos./ area each in sq.ft: |  |
| No. of beds / Area of IVF Centre in sq.ft. (Carpet) |  |
| Services offered: |  |

**Format - 2**

Quality Policy

We shall strive to achieve leadership position in infertility management by providing the most effective equipment, trained manpower & hygienic environment while meeting the needs and expectations of patients & society at large.

*We commit to be an organization which:*

* *Meets all the regulatory & obligatory requirements.*
* *Promotes respects & protects patient’s rights, responsibilities and education.*
* *Adheres to the best medical, nursing & infection control practices.*
* *Encourages feedback to enhance patients’ satisfaction.*
* *Implement ASIC in true spirit.*

Name of the Doctor:

Date of implementation

**Format – 3**

Healthcare is a partnership in which patients and doctors have reciprocal obligations.

Trust and transparency between patients and doctors are essential elements of this healing relationship.

*We, the members of Clinic21st respect you, our patient, as a person, acknowledge your moral right to bodily integrity and self-determination and hereby pronounce our commitment to the following rights:*

* *Your right* to ethical and fair treatment.
* *Your right* to information regarding your health, diagnosis and treatment and the costs involved in the same.
* *Your right* to participation in decisions taken about the treatment undertaken and medication used, from the range of options available.
* *Your right* to confidentiality regarding your health issues and all other information shared and to nondiscrimination even in case of HIV infection.
* *Your right* to giving a suitable, informed consent before any surgical procedure.
* *Your right* to receiving a documented summary of the treatment received and access to records pertaining to your treatment.
* *Your right* to competent treatment and hence promise to keep ourselves knowledgeable and updated with developments in our specialty.
* *Your right to obtain second opinion on your own responsibility when you so desire.*
* *Your right to access lifesaving first aid in emergency situations from any doctor.*

We respect your social rights.

While offering you these rights we, the members of Cliniq21st also expect from you the following commitments:

* *That you share with us truthful and complete information regarding your health.*
* *That you comply with our advice for investigation, treatment and inform us of any intention to act otherwise.*
* *That you keep in mind the dignity and self-respect of your doctors and be sensitive with your demands on their time.*
* *That you settle the predetermined fees of your treatment on time.*

A "Patient 1st" initiative

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