ELARA HEALTHCARE

Professional Compliance & Governance Policy Manual

Non-Clinical Support, Patient Freedom, Clinical Independence and Ethical Growth Framework

Prepared for internal governance, partner onboarding, website publication and downloadable policy use

Core Positioning Statement

Elara Healthcare operates as a non-clinical growth, coordination, communication and patient journey support organisation. It does not own, operate or represent itself as an ART Clinic, ART Bank, fertility clinic, laboratory or medical service provider. Elara does not provide medical consultation, diagnosis, counselling, prescriptions, clinical interpretation, treatment recommendations, success-rate discussions, ART/IVF/ICSI procedures, embryo or gamete handling, cryopreservation or any regulated clinical service. All clinical care and medical responsibility remain solely with the independent partner clinic and treating doctor.

Document Type	Professional Compliance & Governance Policy Manual
Version	1.0 - Professional Representation
Document Owner	Elara Healthcare - Management / Compliance Function
Applicability	Employees, consultants, patient coordinators, sales teams, marketing teams, vendors and all personnel acting for Elara
Primary Use	Internal governance, staff training, partner onboarding, website disclosure and downloadable policy publication
Review Frequency	At least annually and whenever laws, services, website content, partner model or operating processes change
Legal Review Status	Recommended before publication, partner contracting or regulatory submission

Contents

Structured professional policy manual

Important Disclaimer

Governance standard - not a substitute for legal advice

This manual is a professional governance document prepared for Elara Healthcare based on its described business model as a non-clinical support organisation serving independent fertility clinics and doctors. The manual is designed to describe internal rules, prohibited activities, operational controls, website disclosure standards and training requirements.

This document does not constitute legal advice, medical advice or regulatory approval. Elara should obtain review by a qualified healthcare, data privacy and commercial legal professional before publishing the manual, using it in partner agreements, relying on it for compliance submissions, or implementing it as a binding internal policy.

If any provision of this manual conflicts with applicable law, regulator direction, court order, partner contract or medical ethics requirement, the stricter and legally valid standard should apply.

1. Executive Summary

Elara Healthcare supports fertility clinics through non-clinical growth, coordination, communication, scheduling, reminders, documentation coordination, feedback collection and patient journey support. The purpose of this manual is to ensure that Elara's business activities remain clearly separated from clinical care and regulated ART services.

Elara's operating model must be transparent to patients, clinics, employees, vendors and the public. Elara must not be presented as a fertility clinic, ART Clinic, ART Bank, medical counsellor, clinical advisor, laboratory, referral agent with commission-based incentives or any entity with control over clinical decisions. The treating doctor and independent partner clinic must retain exclusive responsibility for medical care.

The manual converts Elara's core governance policies into a professional operating standard covering clinical non-interference, patient choice, no medical advice, data privacy, ethical marketing, partner due diligence, fixed-fee payment boundaries, patient communication, complaints and audit controls.

Executive compliance summary

Elara may support coordination and growth. Elara may not influence clinical selection, provide medical advice, interpret reports, discuss success rates, recommend treatment, own patient records, share in clinic revenue or receive outcome-linked payment.

Control Area	Required Standard	Owner	Evidence / Record
Clinical boundary	All medical care, diagnosis, counselling, procedures, prescriptions and clinical records remain with the partner clinic.	Compliance Officer	Website disclosures, contracts, scripts, training logs
Patient choice	Patients retain complete freedom to choose, continue, pause or discontinue consultation with any clinic.	Patient Coordination Lead	Call scripts, policy page, complaint log
No medical advice	All clinical questions are escalated to the treating doctor or partner clinic.	Operations Head	Escalation records, call audits
Payment model	Fixed-fee professional service only; no patient-linked or outcome-linked payment.	Finance / Legal	Contracts, invoices, pricing approvals

Control Area	Required Standard	Owner	Evidence / Record
Data and records	No ownership or control over patient records or clinical interactions.	Data Protection Lead	Access logs, consent records

2. Governance Scope and Accountability

2.1 Scope of the Manual

This manual applies to all Elara websites, landing pages, advertising, social media, sales calls, patient enquiry forms, clinic onboarding, partner communication, vendor activities, CRM usage, appointment coordination, feedback collection, staff training and downloadable policy publication.

2.2 Persons Covered

- Directors, officers, employees and management personnel.
- Patient coordinators, call agents, sales teams, relationship managers and clinic liaisons.
- Marketing teams, agencies, website editors, social media managers and designers.
- Technology vendors, CRM users, freelancers, consultants and outsourced service providers.
- Any person communicating with patients, clinics or the public on behalf of Elara.

2.3 Governance Ownership

Control Area	Required Standard	Owner	Evidence / Record
Management / Board	Approve policy, allocate compliance resources and review significant risks.	Leadership	Approval record, annual review note
Compliance Officer	Maintain manual, approve scripts, monitor incidents and conduct periodic audits.	Compliance	Policy versions, audit reports
Operations Head	Ensure team follows coordination and escalation rules.	Operations	Training attendance, QA logs
Marketing Head	Ensure all public content is truthful, non-misleading and compliant.	Marketing	Creative approval tracker
Data Protection Lead	Implement data minimisation, consent, access control and confidentiality standards.	Data/IT	Consent logs, access records, breach log
All Personnel	Follow policy, avoid prohibited conduct, escalate concerns and report incidents.	Every user	Attestations, incident reports

3. Regulatory Reference Framework

Elara is not an ART Clinic or ART Bank. However, because Elara supports patient communication and growth for fertility clinics, its public communications and internal controls should be designed around healthcare, ART, advertising, privacy and consumer protection risk.

The regulatory references below are included for governance orientation. They do not replace legal advice. Elara should obtain legal review for interpretation and implementation.

Control Area	Required Standard	Owner	Evidence / Record
Assisted Reproductive Technology (Regulation) Act, 2021	Regulates ART clinics and ART banks, including registration, duties, consent, records,	Compliance / Legal	Website disclaimer, partner agreement clauses

Control Area	Required Standard	Owner	Evidence / Record
	handling of gametes/embryos, prohibited sex selection and penalties. Elara should clearly disclose that it is not an ART clinic/bank and does not perform regulated ART services.		
ART Rules and Regulations	Operational rules and regulations under the ART framework may apply to partner clinics. Elara should not represent or borrow a partner clinic's registration.	Partner Clinic / Legal	Partner due diligence and licence verification
PC-PNDT / sex selection principles	Marketing and communication must not include sex selection, gender preference, sex determination or prohibited prenatal diagnostic messaging.	Marketing / Compliance	Creative approval records
Data privacy and confidentiality	Digital personal data and health-adjacent information must be handled using consent, purpose limitation, data minimisation, security safeguards and access controls.	Data Protection Lead	Privacy notice, consent logs, data register
Consumer protection and advertising standards	No misleading, unfair, unverifiable, guaranteed or exaggerated claims in patient-facing communication.	Marketing / Compliance	Claims substantiation file
Medical ethics and clinical independence	Clinical judgement, diagnosis, counselling, treatment, prescriptions and clinical explanations must stay only with qualified medical professionals.	Partner Clinic / Compliance	No-medical-advice training logs

Regulatory positioning note

Elara's strongest compliance safeguard is clear role separation: Elara supports non-clinical administration and growth; clinics and doctors deliver clinical care.

4. Key Definitions and Role Boundaries

Term	Meaning / Elara Policy Interpretation
Elara / Elara Healthcare	The non-clinical organisation providing growth, coordination, communication, scheduling, reminder, documentation coordination, feedback and patient journey support services.
Partner clinic	An independent fertility clinic or ART-registered clinic responsible for its own licences, staff, facilities, medical decisions, patient records and clinical liabilities.
Treating doctor	The qualified medical professional responsible for medical consultation, diagnosis, counselling, consent, prescription, treatment planning and clinical advice.
Patient / couple	A person or couple seeking fertility-related support from an independent clinic or doctor. The patient does not become a

Term	Meaning / Elara Policy Interpretation
	clinical patient of Elara.
Patient Journey Support	Administrative support limited to scheduling, reminders, documentation coordination, feedback collection and non-clinical communication.
Clinical service	Medical consultation, counselling, diagnosis, treatment recommendation, prescription, investigation, ART/IVF/ICSI procedure, embryo or gamete handling, cryopreservation, clinical interpretation or success-rate discussion.
Enquiry / lead	A non-clinical contact request or interest expression. It does not create a doctor-patient relationship with Elara.
Fixed-fee model	A professional service fee that is not linked to patient numbers, consultations, procedures, IVF cycles, treatment value, pregnancy outcomes or clinic revenue.
Clinical selection	A patient's decision to choose, continue, pause, switch or discontinue consultation with any clinic or doctor.
Clinical records	Medical records, consent forms, prescriptions, reports, treatment notes, clinical communication, lab data, imaging or procedure-related records held by the clinic.

Terminology standard

Where possible, use "support", "coordination", "scheduling", "communication" and "patient journey support". Avoid using "management" in a way that may suggest clinical management.

5. Clinical Non-Interference Policy

Policy intent

Elara must not interfere with, influence or appear to influence clinical care. All medical judgement and clinical governance must remain exclusively with the partner clinic and treating doctor.

Required standards

- Elara shall not participate in medical consultation, diagnosis, counselling, prescription, treatment planning or clinical decision-making.
- Elara shall not instruct a clinic on clinical protocols, patient eligibility, medication, tests, embryo transfer, gamete use, cryopreservation or procedure timing.
- Elara shall not communicate clinical conclusions to patients or translate clinical reports into advice.
- Elara shall not pressure partner clinics to accept, reject, prioritise or treat patients for business reasons.
- All clinical questions received by Elara shall be redirected to the partner clinic or treating doctor.

Prohibited conduct

- Discussing whether IVF, ICSI, IUI, donor gametes, surrogacy or any other treatment is suitable for a patient.
- Commenting on success probability, pregnancy chances, age-related outcome, risks or complications.
- Interpreting AMH, semen analysis, scan reports, hormone reports, embryo quality or prescriptions.
- Giving instructions about medicines, injections, tests, diet or procedure preparation beyond clinic-provided administrative instructions.
- Influencing a clinic to change clinical advice because of conversion, revenue or marketing targets.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Script approval	All patient-facing scripts must include escalation language	Compliance + Operations	Approved script library

Control Area	Required Standard	Owner	Evidence / Record
	for medical questions.		
Call review	Sample calls must be reviewed for medical-advice risk.	Operations QA	Monthly QA reports
Escalation process	Clinical questions must be escalated without substantive response.	Coordinator	CRM escalation notes
Training	All employees must complete no-medical-advice training before patient communication.	HR + Compliance	Training certificates

Records to be maintained

- Approved script library
- Call audit reports
- Escalation logs
- Training attendance and acknowledgement records
- Incident register

Suggested public disclosure language

Elara provides non-clinical coordination and growth support only. Medical consultation, diagnosis, counselling, prescriptions, treatment decisions and procedures remain solely with the partner clinic and treating doctor.

6. Patient Freedom of Choice and No Clinic Ranking Policy

Policy intent

Patients must remain free to choose, continue, pause, change or discontinue consultation with any clinic. Elara must not recommend, rank, endorse, prioritise or influence clinical selection of any ART clinic.

Required standards

- Elara may provide neutral administrative information such as city, appointment availability, clinic contact process and location details.
- Elara must not tell a patient that one clinic is clinically better, safer, more successful, more suitable or more recommended unless such statement is legally reviewed, factual and permitted.
- Elara must not design website or CRM flows that force a patient into one clinic without patient choice.
- If a patient asks which clinic to choose, Elara must respond neutrally and encourage the patient to discuss medical suitability directly with qualified doctors.
- Patients must be free to discontinue communication with Elara or a clinic subject to the clinic's lawful process.

Prohibited conduct

- Ranking clinics by success rate, outcomes or clinical capability.
- Using terms like "best clinic", "guaranteed results", "top IVF doctor" or "highest success" unless reviewed and fully substantiated.
- Pressuring a patient to continue with a clinic after the patient expresses a wish to stop or seek another opinion.
- Suppressing patient options due to commercial agreements with a clinic.
- Making clinical comparisons between doctors or clinics.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Neutral allocation	Where location or	Operations Head	Allocation logic note

Control Area	Required Standard	Owner	Evidence / Record
	appointment support is offered, criteria must be administrative, not clinical ranking.		
Patient disclosure	Website and scripts must state that clinic choice remains with the patient.	Compliance	Website screenshots, script archive
Complaint review	Any complaint alleging pressure or clinic steering must be reviewed.	Compliance Officer	Complaint file and outcome
Marketing review	No ranking, endorsement or superiority claim without legal approval.	Marketing + Legal	Claims substantiation

Records to be maintained

- Patient-choice disclosure
- Call scripts
- CRM notes
- Complaint records
- Marketing approval records

Suggested public disclosure language

Elara does not recommend, rank, endorse, prioritize or influence the clinical selection of any ART clinic. Patients retain complete freedom to choose, continue or discontinue consultation with any clinic.

7. No Medical Advice and Clinical Escalation Policy

Policy intent

Elara personnel must not provide medical advice, treatment recommendations, fertility counselling, success-rate discussions, clinical interpretation or any guidance that may influence treatment decisions.

Required standards

- All questions about symptoms, investigations, reports, treatment options, medicines, outcomes, risks or eligibility must be escalated to the partner clinic or treating doctor.
- Elara may help patients schedule a consultation so that a qualified doctor can respond to medical questions.
- Elara may share non-clinical administrative information provided by the clinic, such as appointment timing, address and document checklist.
- Any accidental receipt of clinical documents must be handled under the data privacy and records policy.
- Staff must use approved phrases when refusing to answer medical questions.

Prohibited conduct

- Interpreting reports or suggesting what results mean.
- Discussing success rates or pregnancy probability.
- Advising on medicines, injections, supplements, tests or cycle timing.
- Explaining clinical risks, complications or side effects.
- Offering fertility counselling or emotional counselling that could be understood as clinical counselling.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Approved refusal phrases	Staff must use approved response language for clinical	Compliance	Script library

Control Area	Required Standard	Owner	Evidence / Record
	questions.		
Clinical escalation tagging	CRM must allow tagging and tracking of clinical escalation requests.	Operations / IT	CRM logs
Staff QA	QA must identify and correct medical-advice risk.	Operations QA	QA sheet
Disciplinary action	Repeated or serious violation may trigger formal action.	HR + Compliance	Corrective action record

Records to be maintained

- Escalation logs
- Call recordings if used lawfully
- Training acknowledgements
- Corrective action records

Suggested public disclosure language

Elara's team can assist with scheduling and non-clinical coordination. Medical explanations, treatment recommendations and clinical interpretation must come only from the treating doctor or clinic.

8. Patient Communication and Coordination Policy

Policy intent

Elara may support administrative communication between patients and clinics only within non-clinical boundaries. Communications must be respectful, transparent, documented and escalation-ready.

Required standards

- Permitted communication includes enquiry acknowledgement, appointment scheduling, reminders, clinic address sharing, documentation coordination and feedback collection.
- Communication must not create the impression that Elara is the treating clinic or a medical advisor.
- Where communication relates to a clinic-specific instruction, Elara must identify it as information from the clinic, not Elara's clinical instruction.
- Sensitive or medical questions must be transferred to the partner clinic.
- Patient communication must be in clear language and must avoid fear-based, pressure-based or misleading claims.

Prohibited conduct

- Telling patients what treatment they should take.
- Stating or implying guaranteed pregnancy or guaranteed medical result.
- Discussing sex selection, gender preference or prohibited prenatal diagnostic content.
- Using urgency or fear to push immediate consultation without patient choice.
- Collecting excessive medical details unnecessary for appointment coordination.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Communication templates	All templates require compliance approval.	Marketing / Compliance	Template approval register
CRM notes	Notes must be administrative and factual, not clinical opinion.	Operations	CRM audits
Escalation handoff	Clinic handoff must be	Coordinator	Escalation record

Control Area	Required Standard	Owner	Evidence / Record
	documented when a clinical question is received.		
Feedback process	Feedback must focus on administrative experience and must not review clinical advice.	Operations QA	Feedback form records

Records to be maintained

- Approved templates
- CRM communication logs
- Feedback records
- Patient complaint records

9. Patient Journey Support Limitation Policy

Policy intent

Patient Journey Support is administrative and coordination-focused only. It is not clinical patient management, medical counselling, diagnosis, treatment guidance or clinical follow-up.

Required standards

- Scheduling support may include receiving patient availability and coordinating appointment timing with the clinic.
- Reminder support may include non-clinical reminders about appointment date, time, location and clinic-requested documents.
- Documentation coordination may include helping patients understand what documents the clinic has requested, without interpreting those documents.
- Feedback collection may include service experience, responsiveness, waiting time, communication quality and coordination issues.
- Non-clinical communication support may include process updates, appointment confirmation and administrative handoff.

Prohibited conduct

- Clinical follow-up after procedures or medication.
- Advising on what reports mean or what tests should be done.
- Counselling patients on fertility, treatment choices, risks or outcomes.
- Prioritising patients clinically or triaging symptoms.
- Providing emergency medical guidance.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Terminology review	Use “support” and “coordination” instead of clinical management terminology.	Content / Compliance	Website copy review
Journey SOP	SOP must define allowed and disallowed support steps.	Operations Head	SOP version record
Training	Coordinators must understand boundaries of patient journey support.	HR + Compliance	Training records
Feedback categorisation	Feedback forms must avoid clinical scoring or doctor outcome ratings unless legally	Operations QA	Feedback form archive

Control Area	Required Standard	Owner	Evidence / Record
	reviewed.		

Records to be maintained

- Patient journey SOP
- Website content approvals
- Training logs
- Feedback forms

Suggested public disclosure language

Patient Journey Support is limited to scheduling, reminders, documentation coordination, feedback collection and non-clinical communication support.

10. Patient Relationship, Lead Handling and Records Policy

Policy intent

All patient relationships remain exclusively between the patient and the independent ART clinic. Elara has no ownership, control or rights over patient records or clinical interactions.

Required standards

- An enquiry handled by Elara is an administrative contact request, not a clinical relationship with Elara.
- Doctor-patient relationship, if any, is formed only between the patient and the independent clinic/doctor according to that clinic's process.
- Elara may maintain limited enquiry data for scheduling, coordination, feedback, audit and lawful business records.
- Clinical records should remain with the clinic. Elara should not hold, interpret, modify or control clinical records.
- Patients seeking copies, corrections or explanations of clinical records must be directed to the clinic.

Prohibited conduct

- Claiming ownership over leads as patients in a clinical sense.
- Withholding patient information from the clinic where patient consent and lawful process permit sharing.
- Accessing, storing or sharing medical records without a defined purpose and consent.
- Editing, annotating, summarising or interpreting clinical records.
- Using patient health information for marketing beyond consented purposes.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Lead definitions	CRM fields must distinguish enquiry data from clinical records.	Operations / IT	CRM configuration
Access control	Only authorised staff may access patient enquiry data.	Data Lead	Access log
Record transfer	Any document transfer to clinic must follow consented and secure process.	Operations / Data Lead	Transfer log
Retention schedule	Administrative records should be retained only as needed under policy.	Data Lead	Retention register

Records to be maintained

- CRM records
- Consent logs
- Access logs
- Retention register
- Data transfer records

Suggested public disclosure language

All patient relationships remain exclusively between the patient and the independent ART clinic. Elara has no ownership, control or rights over patient records or clinical interactions.

11. Fixed-Fee Model and No Outcome-Linked Payment Policy

Policy intent

Elara's commercial model must be fixed-fee and independent of patient volume, consultations, procedures, IVF cycles, treatment value, pregnancy outcomes or clinic revenue.

Required standards

- Service fees must be documented in written agreements or approved commercial terms.
- Fees must relate to non-clinical services such as marketing support, coordination, communication, systems support, follow-ups, feedback and growth operations.
- No payment may be calculated as a percentage of treatment value, clinic revenue or procedure fees.
- No payment may depend on pregnancy outcome, live birth, treatment success, number of IVF cycles or consultation conversion.
- Finance must review invoices and contracts to ensure payment descriptions do not create referral, commission or outcome-link risk.

Prohibited conduct

- Per-patient commission.
- Per-consultation referral fee.
- Percentage of IVF/ICSI/IUI/ART procedure value.
- Revenue share linked to clinic revenue or treatment billing.
- Payment linked to pregnancy, live birth, embryo transfer, procedure success or outcome.
- Bonus for achieving clinical conversion, patient volume or treatment cycle targets.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Contract review	All partner contracts must include fixed-fee and no-outcome-linked payment clauses.	Legal / Finance	Contract review checklist
Invoice review	Invoice descriptions must reflect non-clinical services only.	Finance	Invoice approval log
Pricing approval	New fee structures require compliance review.	Management / Compliance	Pricing approval note
Audit	Periodic audit of contracts and invoices for commission-risk language.	Finance + Compliance	Audit report

Records to be maintained

- Partner agreements
- Invoices
- Pricing approvals
- Finance audit reports

Suggested public disclosure language

Elara receives no payment linked to patient numbers, consultations, procedures, IVF cycles, treatment value, pregnancy outcomes or clinic revenue. Elara operates only through a fixed-fee professional service model.

12. ART Compliance Charter for Elara Operations

Policy intent

Elara must maintain a clear public and operational distinction from ART Clinics and ART Banks. Elara must not claim, borrow, represent, use or rely upon any partner clinic's registration as its own.

Required standards

- Elara shall disclose that it is not an ART Clinic or ART Bank.
- Elara shall not perform ART procedures, handle embryos/gametes, undertake cryopreservation or operate a laboratory.
- Elara shall not use partner clinic licences in a manner that suggests Elara is itself clinically registered.
- Partner clinics remain responsible for their own registration, renewal, staffing, records, consent, reporting, facilities and clinical compliance.
- Elara may verify partner clinic documentation for onboarding but must not guarantee regulatory compliance to patients or the public.

Prohibited conduct

- Listing ART registration numbers as Elara's registration.
- Displaying partner licence details without permission and legal review.
- Representing Elara as a clinic branch, clinical provider, ART facility or bank.
- Handling gametes, embryos, clinical samples or lab reports as a clinical intermediary.
- Using terms such as "Elara IVF treatment", "Elara doctor treatment" or "Elara ART services" if they imply clinical delivery by Elara.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Website review	All pages must carry clear non-clinical disclaimer language.	Compliance / Website owner	Website screenshot archive
Partner documentation	Collect and verify basic partner licence/registration information where applicable.	Partner Onboarding Lead	Due diligence file
Brand usage	Clinic and Elara branding must not imply shared clinical licence.	Marketing + Legal	Brand approval records
Annual review	Review partner status and disclosures at least annually.	Compliance	Annual review report

Records to be maintained

- Partner onboarding records

- Website disclosures
- Brand approvals
- Annual partner review records

13. Partner Clinic Onboarding and Due Diligence Policy

Policy intent

Elara must onboard partner clinics through a documented process that verifies basic eligibility, clarifies role boundaries and confirms that clinical responsibility remains with the clinic.

Required standards

- Obtain clinic legal name, location, authorised contact, services offered and basic registration/licence information as applicable.
- Require partner clinic acknowledgment that it retains all clinical responsibility and patient records.
- Require partner clinic acknowledgment that Elara will not provide medical advice, rank clinics or influence patient clinical selection.
- Confirm public communication approval process for clinic-related materials.
- Document escalation contacts for medical questions, patient complaints, emergency referrals and record requests.

Prohibited conduct

- Onboarding a clinic without basic due diligence.
- Publishing clinic claims or success rates without substantiation and legal review.
- Using clinic registration as Elara's own credential.
- Accepting oral-only commercial arrangements without written role boundaries.
- Providing patient coordination for a clinic where role boundaries are not understood.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Due diligence checklist	Complete onboarding checklist before going live.	Partner Lead	Checklist file
Contract clauses	Agreements must include non-clinical role, payment model and patient choice clauses.	Legal / Management	Signed agreement
Escalation map	Maintain clinic contact for clinical and compliance escalations.	Operations	Escalation sheet
Periodic review	Review active partner details periodically.	Compliance	Partner review log

Records to be maintained

- Partner due diligence files
- Signed agreements
- Escalation contacts
- Content approvals

14. Data Privacy, Consent and Confidentiality Framework

Policy intent

Elara must process personal data only for lawful, defined and non-clinical coordination purposes. Health-adjacent information must be handled with confidentiality, minimisation and access controls.

Required standards

- Collect only information required for enquiry response, appointment scheduling, coordination, feedback, compliance, audit or lawful business record purposes.
- Provide clear notice explaining why data is collected and how it may be shared with the selected partner clinic.
- Obtain appropriate consent for collecting, using or sharing patient information with the clinic, where required.
- Limit access to patient enquiry data to authorised users with a genuine operational need.
- Maintain confidentiality of patient contact details, enquiry information and documents.
- Avoid collecting clinical records unless needed for administrative coordination and supported by consent and clinic-approved process.
- Implement deletion, correction, access, breach response and retention processes appropriate to applicable privacy law and contract obligations.

Prohibited conduct

- Using patient information for unrelated marketing without proper consent.
- Sharing patient information with unrelated third parties without lawful basis.
- Requesting sensitive clinical details unnecessary for coordination.
- Leaving patient data in unprotected spreadsheets, personal devices or open messaging groups.
- Using patient images, testimonials or stories without explicit written permission and compliance approval.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Privacy notice	Website and forms must include clear privacy and consent language.	Data Lead / Website owner	Privacy notice version
Access control	CRM and files must be role-based.	IT / Operations	Access list and logs
Consent records	Maintain consent record for data collection and sharing where required.	Operations / Data Lead	Consent log
Breach process	Potential data breaches must be escalated immediately.	Data Lead / Compliance	Breach register
Retention review	Review and delete data no longer required, subject to legal retention needs.	Data Lead	Retention log

Records to be maintained

- Privacy notice
- Consent records
- Access logs
- Data sharing records
- Breach register
- Retention schedule

15. Ethical Marketing and Public Communication Policy

Policy intent

All Elara marketing and public communication must be truthful, respectful, non-misleading, patient-sensitive and aligned with non-clinical positioning.

Required standards

- Marketing must clearly position Elara as a non-clinical support and coordination partner.
- Claims about clinics, doctors, facilities, services or outcomes must be factual, current and substantiated.
- Content must avoid guaranteed success, exaggerated outcomes, fear-based pressure and unfair comparisons.
- Content must avoid sex selection, gender preference, prohibited prenatal diagnostic claims or discriminatory messaging.
- Patient stories, images or testimonials require written consent and compliance review.
- Landing pages and advertisements must disclose that medical advice and treatment are provided only by independent partner clinics and doctors.

Prohibited conduct

- “Guaranteed pregnancy”, “100% success”, “assured result” or similar outcome claims.
- Sex-selection, gender-selection, baby gender, male child/female child preference or prohibited prenatal diagnostic messaging.
- Misleading before/after claims or unverifiable success-rate claims.
- Using doctor names or clinic credentials without approval.
- Using patient images or testimonials without consent.
- Ad copy that implies Elara itself performs IVF, ART or clinical services.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Creative approval	Every public-facing creative should be reviewed before publishing.	Marketing + Compliance	Approval tracker
Claims substantiation	Medical or performance claims require evidence and legal review.	Marketing + Legal	Claims file
Disclaimer inclusion	Ads and landing pages must include role clarification where space permits.	Marketing	Final screenshots
Periodic audit	Review active pages, ads and social profiles for compliance drift.	Compliance	Audit report

Records to be maintained

- Creative approvals
- Claims substantiation file
- Ad screenshots
- Social media archive
- Website copy approvals

16. Website Publication and Downloadable Policy Requirements

Policy intent

Elara must publish clear, accessible and downloadable policy disclosures explaining its non-clinical role, patient freedom, no medical advice, fixed-fee model and patient-record boundaries.

Required standards

- Website footer should include a legal disclaimer and link to a downloadable policy page.
- The downloadable policy should be available in PDF or browser-print format.

- Home, Services, Compliance, FAQ, Partner Network and Partner With Us pages should use consistent non-clinical positioning.
- Patient-facing forms should include privacy and role-boundary language.
- The website should avoid repeated copy-paste disclaimers by using natural, section-specific wording while retaining full meaning.
- The complete formal policy can remain in the downloadable policy document, while website sections may contain shorter summaries.

Prohibited conduct

- Removing role-boundary disclosures from pages that mention patient access, enquiry handling, appointment coordination or patient journey support.
- Using clinical terms that imply Elara provides treatment or manages patients clinically.
- Publishing clinic lists as rankings or endorsements.
- Publishing partner clinic registration numbers as if they belong to Elara.
- Making the policy hard to find or unavailable for download.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Policy page	Maintain a dedicated policy page with print/download option.	Website owner	Live URL / screenshots
Footer link	Include “Non-Clinical Policy” or similar footer link.	Website owner	Footer screenshots
Content review	Review website copy when pages are updated.	Compliance	Content approval log
Version control	Publish version date on downloadable policy.	Compliance	Policy version log

Records to be maintained

- Website screenshots
- Downloadable policy PDF
- Policy version history
- Content approval log

17. Staff Training, Scripts and Conduct Standards

Policy intent

No staff member should interact with patients, clinics or public enquiries unless trained on Elara’s non-clinical boundaries and approved communication scripts.

Required standards

- Training must cover non-clinical role, patient choice, no medical advice, clinical escalation, privacy, marketing restrictions and complaint handling.
- Scripts must include safe responses for clinical questions.
- Staff must know how to identify and escalate medical-advice requests.
- Staff must acknowledge the policy in writing or through digital training confirmation.
- Refresher training should occur at least annually and after major process or legal changes.

Prohibited conduct

- Allowing untrained staff to handle patient calls or messages.
- Using unapproved scripts for clinical, treatment or success-rate questions.

- Creating personal WhatsApp or informal channels for patient data exchange.
- Offering incentives that encourage staff to pressure patients toward clinic selection or procedures.
- Ignoring complaints about misleading communication or clinical advice.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Training completion	Mandatory induction and annual refreshers.	HR + Compliance	Training log
Script control	Scripts must be version-controlled and approved.	Compliance	Script version register
Performance metrics	Team targets must not promote clinical steering or patient pressure.	Management	KPI review
Supervisor review	Supervisors must review risky interactions.	Operations Head	QA records

Records to be maintained

- Training logs
- Policy acknowledgement records
- Approved scripts
- QA review sheets
- Corrective action notes

18. Incident Reporting, Complaints and Corrective Action

Policy intent

Elara must maintain a clear process to report, investigate and correct potential breaches of clinical boundary, patient choice, privacy, advertising, payment model or staff conduct standards.

Required standards

- Incidents may be reported by patients, clinics, employees, vendors or management.
- Examples include staff medical advice, clinic steering, misleading ad claim, privacy concern, commission-risk payment language, data breach or improper use of clinic registration.
- All incidents must be logged with date, issue, reporter, affected person if any, initial risk assessment, action owner and closure status.
- Serious issues must be escalated to management and legal counsel promptly.
- Corrective action may include content removal, patient clarification, clinic escalation, retraining, process change, disciplinary action or contract review.

Prohibited conduct

- Deleting or ignoring complaint records.
- Retaliating against staff or vendors who report a good-faith concern.
- Continuing a non-compliant ad or script after a credible concern is raised.
- Failing to notify relevant leadership about serious privacy or clinical-boundary incidents.
- Resolving incidents informally without documented closure.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Incident register	Maintain a central register for compliance incidents.	Compliance Officer	Incident register
Triage standard	Classify incidents as low/medium/high risk.	Compliance + Management	Risk rating

Control Area	Required Standard	Owner	Evidence / Record
Corrective action	Define owner, action and deadline.	Relevant function	CAPA log
Management reporting	Share periodic incident summary with management.	Compliance	Review minutes

Records to be maintained

- Incident register
- Complaint records
- CAPA log
- Training follow-ups
- Legal review notes

19. Monitoring, Audit, Review and Document Retention

Policy intent

Elara must periodically test whether the written policy is actually followed across website content, calls, CRM records, contracts, invoices, training and marketing.

Required standards

- Compliance review should include website pages, landing pages, ads, call scripts, CRM notes, partner agreements, invoices and privacy controls.
- Audits should focus on clinical-interference risk, no-medical-advice compliance, patient-choice language, payment model, data privacy, marketing claims and policy publication.
- Findings should be rated by severity and assigned to owners with closure deadlines.
- Policy documents should be reviewed at least annually and after any regulatory, business model or service change.
- Records should be retained for a reasonable period according to legal advice, contract obligations and data minimisation principles.

Controls and accountability

Control Area	Required Standard	Owner	Evidence / Record
Quarterly content audit	Review website, landing pages and active campaigns.	Compliance + Marketing	Audit report
Monthly call QA sample	Review calls/messages for medical-advice and pressure risk.	Operations QA	QA scorecards
Contract and invoice audit	Check fixed-fee/no commission compliance.	Finance + Legal	Audit sheet
Annual policy review	Management review of manual and public policy.	Compliance + Leadership	Version approval

Records to be maintained

- Audit reports
- Policy version log
- Training records
- Corrective action records
- Content archives

20. Implementation Roadmap and Management Sign-Off

The following roadmap is designed to convert this manual from a written policy into an operating governance system.

Implementation Step	Action Required	Owner	Output
Step 1 - Legal review	Obtain review by healthcare, data privacy and commercial counsel.	Management	Legal review note
Step 2 - Website update	Publish role disclosures, downloadable policy and footer link.	Website owner	Updated pages/screenshots
Step 3 - Contract alignment	Add fixed-fee, patient choice, no medical advice and clinical independence clauses to partner agreements.	Legal / Management	Updated contract template
Step 4 - Script rollout	Approve call scripts and escalation language.	Compliance / Operations	Script library
Step 5 - Staff training	Train all relevant staff and obtain acknowledgement.	HR / Compliance	Training logs
Step 6 - Data controls	Review forms, consent, CRM access, retention and privacy notice.	Data Lead / IT	Privacy implementation file
Step 7 - Audit cycle	Begin quarterly compliance audits and management review.	Compliance	Audit calendar

Management approval block

Approved by: _____ Designation: _____ Date: _____

21. Regulatory Source Notes

For legal verification and periodic review

This document was drafted using the uploaded Elara Governance Suite as source material for policy areas and the official India Code listing of the Assisted Reproductive Technology (Regulation) Act, 2021 as a key regulatory reference.

Regulatory references should be checked again before publication because healthcare, data privacy and advertising compliance requirements may change.

Reference Area	Purpose	Source / Owner	Use in Manual
Uploaded source policies	Clinical Non-Interference, Patient Freedom of Choice, No Medical Advice, Data Privacy and Consent, ART Compliance, Patient Communication and Ethical Marketing documents.	Internal source material	Uploaded governance suite
ART Act reference	The Assisted Reproductive Technology (Regulation) Act, 2021; Act No. 42 of 2021; enforcement date shown on India Code as 25 January 2022.	India Code / Ministry of Health and Family Welfare	Regulatory reference
ART operating topics	Registration, duties of	India Code sections list	Regulatory reference

Reference Area	Purpose	Source / Owner	Use in Manual
	clinics/banks, written informed consent, record-keeping, gamete/embryo handling, sex selection restrictions and offences/penalties.		
Data privacy reference	Digital personal data should be handled through notice, consent/purpose limitation, access control, security, retention and breach-response practices based on applicable law and legal review.	Data privacy legal review	Implementation guidance
Advertising/consumer protection reference	Public communication should be truthful, substantiated, non-misleading and free from guaranteed outcome or prohibited sex-selection language.	Legal/Compliance review	Marketing checklist

End of Policy Manual