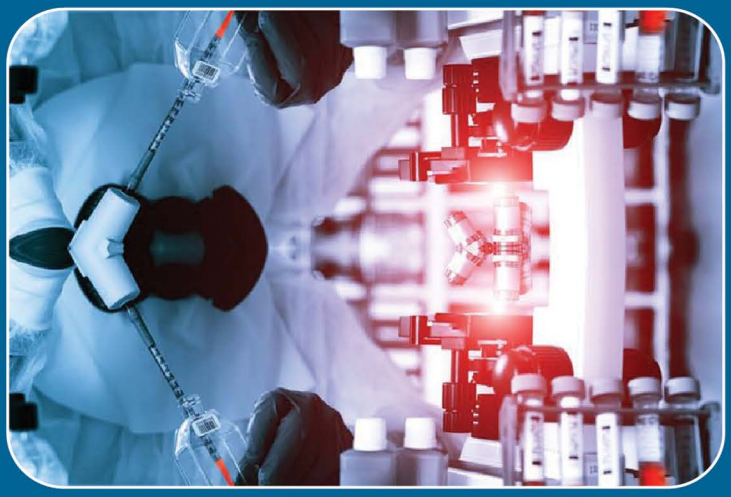

ISARCON 2017 Manual of Data Management and Quality Control, March to Perfection Complete Hands of IVF

Series Editors
Maninder Ahuja
Narendra Malhotra
Poonam Loomba

Indian Society for Assisted Reproduction

ISAR Haryana 2017

21st - 23rd April, 2017

Illuminating Fertility Treatments
Basics & Beyond

ISAR

Contents

1. **Introduction** 1
   Sapna Gandhi, Chand Mohammed, Keshav Malhotra
2. **Assisted Reproductive Technology Laboratory Designing and Work Station** 7
   Ajay Srivastava, Kruthi KB
3. **Staffing and Qualifications of the ART Team** 13
   Sweta Gupta
4. **SOPs and Policy Manual Writing: Why are they Important and How to Implement in Your Laboratory?** 19
   Shreyas Padgaonkar
5. **Data Management in the ART Laboratory: Requirements, Solutions and Benefits** 24
   Sanjeev Maheshwari
6. **Implementing a Quality Program in Your Laboratory** 29
   Alex Steinleitner
7. **Troubleshooting** 40
   Keshav Malhotra
8. **Semen Analysis** 45
   Charudutt Joshi
9. **Different Semen Washing Techniques** 55
   Pratixa Joshi
10. **Sperm DNA Fragmentation Analysis** 60
    Himanshu Patel
11. **Clinical Implications of DNA Fragmentation Test** 64
    Laxmi Shrikhande
12. **Reactive Oxygen Species (ROS) Determination** 67
    Vidisha Bhatt
13. **Semen Freezing** 69
    Komal Patel
14. **Incubators in ART** 72
    Anjali Awasthi Joshi
15. **Handling of Gametes and Embryos** 84
    Anjali Awasthi Joshi
16. **Embryo Transfer** 90
    Sarita Sukhija, Bhavana Mittal

SOPs and Policy Manual Writing: Why are they Important and How to Implement in Your Laboratory?

4

Shreyas Padgaonkar

WHAT IS QUALITY POLICY?

A quality policy is a predetermined course of action established as a guide toward accepted objectives and strategies of the organization. The policies should be a reflection of organization's mission and objectives.

1. We will provide patient satisfaction
2. Improve service quality
3. Ensure professional development of the employees.

Ones the policies are formulated then quality objectives are defined and these should be achievable within a defined time frame. After this procedures are developed and SOPs are created.

Good Quality Policy

- Reflects the mission statement
- Should be brief and precise
- Easy to translate into objectives that are measurable using quality indicators.

WHAT IS SOP?

An SOP or **standard operating procedure** is a set of step-by-step instructions compiled by an organization to help workers carry out routine operations.

The procedure of writing, revising, approving of SOPs and control of distribution of SOPs is an important Quality Assurance procedure.

For IVF laboratory SOPs are based on ISO 15189:2012 section 5.5. IVF Lab Director is responsible for the SOP preparation, implementation and review.

JAYPEE BROTHERS

What are the Aims of an SOP?

- Uniformity of performance
- Quality output
- Achieve efficiency
- Reduce miscommunication
- Improve compliance with the standards (regulatory/organizational)
- Useful training document
- Create a checklist, which coworkers can use to reinforce proper performance
- Check list for auditors
- Creates a historic record as systems change
- Useful template during investigation of a un-towards incidence.

Who Should Write an SOP?

- Individual with the knowledge of the activity and subject matter
- One performing the task regularly or directly responsible for the performance of the task should be ideally writing an SOP.

What are the Formats of SOP?

- *Simple steps format*: This is for routine procedures that are short, have few possible outcomes, and are fairly to the point. Apart from the necessary documentation and safety guidelines, it is really just a bullet list of simple sentences telling the reader what to do.
- *Hierarchical steps format*: This is usually for long procedures. List of main steps all with sub steps in a very particular order.
- *Flowchart format*: If the procedure is more like a map with many possible outcomes or when results are not always predictable.

Steps of SOP Writing

- Consider your knowledge of the procedure
- Take inputs from people involved in the process
- Take into account audience's knowledge of the process
- Take into account audience's language skills
- Writing should be concise and easy to read
- Avoid using "you" in SOP and start with command verb
- SOP review by intended users
- SOP review by quality assurance team and advisors
- Approval, distribution and implementation
- Review, update, reapprove and redistribute.

JAYPEE BROTHERS

Elements of SOP

- *Title page:*
  - The title of the procedure
  - An SOP identification number
  - Date of issue or revision
  - The name of the agency/division/branch the SOP applies to
  - The signatures of those who prepared and approved of the SOP.
- *Table of contents*: This is only necessary, if your SOP is quite long, allowing for ease of reference.
- *Scope and applicability*: Purpose of the process, its limits, and how it is used. Include standards, regulatory requirements, roles and responsibilities, and inputs and outputs
- **Equipment and supplies**
- *Methodology and procedures*: Steps with necessary details, sequential procedures and decision factors
- **Clarification of terminology**
- **Health and safety warnings**.

Following is an example of an SOP:

S. 14	*Vitrification thawing of embryos*	
Sr. No.	*Process flow*	*Responsibility*
	Materials	
1.1	Center well	
1.2	60 mm Dish -1	
1.3	Mineral oil, Media to pour on outer moat of center well	
1.4	Media: Gynemed Vitristore thaw media (Vitristore thaw 1, Vitristore thaw 2, Vitristore thaw 3, Vitristore thaw 4)	
1.5	Marker pen	
1.6	Thermocol box	
1.6	1 mL insulin syringe-4 nos	
1.7	Aluminum foil	
1.8	Liquid nitrogen	
1.9	Insulated gloves, protective shoes, goggles and plastic mug	
1.10	Timer	
1.11	EZ grip	
1.12	Denupet 175 tips	
1.13	Droplet culture dish (Ref: SOP 4, 1b)	

Contd...

JAYPEE BROTHERS

Contd...

	Method-Preparation for thawing	
2.1	Start the laminar hood and stage heaters on at least 1 hour before the procedure (Ref SOP: S1, 2.1–3.1)	**Embryologist**
2.2	Write the name vit thaw 1 on the lid and bottom of the center well dish	
2.3	Take the 60 mm Petridish and turn upside down. With the marker draw two lines on the bottom to divide into three sections. Write VT2, VT3, VT4 in the three sections respectively.	
2.4	Bring the media out from the refrigerator. Shake the vials vitristore Thaw 1, 2, 3, 4 well.	
2.5	Take the center well and pour buffer media on the outer moat.	
2.6	With the insulin syringe draw out 0.8–1.0 mL of vitristore thaw 1 and dispense in the centre well. Cover the lid with aluminum foil to protect from light. Keep at 37°C	
2.7	Keep 60 mm Petridish on the unheated surface	
2.8	With the insulin syringe draw and dispense two 50 microliter droplets of vitrification thaw 2 solution in the designated slot.	
2.9	Similarly dispense vitrification thaw 3 and vitrification thaw 4 solution in the designated areas	
2.10	Quickly cover with mineral oil. Cover with lid. Place aluminium foil to protect from light. Shift the dish to 37°C. Cover with aluminum foil	
2.11	Wait for an hour.	
	Method – Thawing of embryos	
3.1	Attach the 175 stripper tips to the EZ Grip.	
3.2	Set the timer for 3 min, 2 min, 2 min and 1 min	
3.3	Wear protective gloves and goggles. Pour liquid nitrogen into the plastic mug. Fill the Thermocol box with liquid nitrogen (Ref SOP; S4)	
3.4	Open the Jumbo tank	
3.5	Identify and lift the correct canister. Remove the correct cane after reading identification and place in the Thermocol box. Confirm the name on the cane. Take the Thermocol box and place it near the hood.	**Embryologist Witness**
3.6	Bring the center well under the microscope	
3.7	Quickly remove the Cryoleaf from the cane and immerse in liquid nitrogen	

Contd...

JAYPEE BROTHERS

Contd...

3.8	Between the thumb and forefinger of one hand hold the leaf, and twist the top of the leaf with the other hand	
3.9	Holding the leaf between thumb and forefinger warms the top of the leaf allowing it to regain flexibility and break the seal with the outer sheath	
3.10	When the leaf loosens, immediately extract the leaf from the outer sheath and immerse in the liquid nitrogen	
3.11	Hold the leaf under liquid nitrogen, unlock the green sheath and pull backwards	
3.12	Shift the leaf from the liquid nitrogen and immerse the bead in the thawing solution after holding in air for a fraction of a second	
3.13	Start the 3 min timer (37°C) Remove the thermocol box from the hood	
3.14	At the 3rd min start collecting the embryos with little Vt 1 and place them in Vitrification thaw solution 2 (VT2) first drop at 37°C. Start 2 min timer after a few sec shift to the second drop. Keep for 2 min	
3.15	After 2nd min collect and place embryos in Vitrificationthaw 3 (VT3) at 37°C. Start timer	
3.16	As soon as 2 min in VT3 gets over shift embryo to VT4 at 37°C for 1 min.	
3.17	Take out the culture dish and transfer the embryo to the culture droplets as soon as 1 min gets over.	**Embryologist Witness**
3.18	Shift the dish to the Incubator	

JAYPEE BROTHERS

Available at all medical bookstores
or buy online at www.jaypeebrothers.com

JAYPEE BROTHERS
Medical Publishers (P) Ltd.
www.jaypeebrothers.com

Join us on facebook.com/JaypeeMedicalPublishers

ISBN 978-93-5270-079-0