

CHAPTER 2.3

TRAINING PERSONNEL AND IRB MEMBERS

SOP NUMBER: SOP/005/01



INSTITUTIONAL REVIEW BOARD (IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

www.kgumsb.edu.bt

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1. PURPOSE

The purpose of this section shall be to inform the IRB personnel and members why training is necessary and how the members shall seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics. Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB) recognizes the importance of training and continuing professional development, therefore the University shall allocate an annual budget for specific training and study visits for IRB personnel and members. New IRB members shall possess adequate knowledge or undergo a training program prior to joining the Board.

2. SCOPE

The SOP shall apply to all personnel of the IRB.

3. RESPONSIBILITY

- 3.1. The University shall be responsible to provide training and education to the IRB members, whenever necessary.
- 3.2. The IRB members shall pursue for further training and education in the relevant fields as mandated.

4. FLOW CHART

No.	Activity	Responsibility
1	Topics for training ↓	KGUMSB/IRB members / Secretariat
2	How to get trained ↓	KGUMSB/IRB members / Secretariat
3	Keeping the training record.	KGUMSB/IRB members / Secretariat

5. DETAILED INSTRUCTIONS

5.1. Topics for training

IRB members shall maintain competence by ensuring currency of their knowledge of:

- Good Clinical Practice (GCP)
- CIOMS Guideline
- Declaration of Helsinki
- Ethical Issues
- Relevant laws
- Developments in relevant science, technical and environmental, health and safety aspects
- Relevant requirements of health, safety and environmental laws and regulations and related documents
- IRB Standard Operational Procedures
- Audit procedures
- Other relevant fields.

5.2. Training Procedures

- 5.2.1. The procedure for selection of candidates, identification of institute and training completion mandates shall be governed by the COS, KGUMSB and/or RGOB rules.
- 5.2.2. The secretariat shall initiate, propose and process for training of the IRB members.
- 5.2.3. The training shall be in the form of workshops, conferences, seminars, study visits, tailor-made courses, structured courses, etc.

5.3. Keeping the training records

- 5.3.1. Fill in the form *AF/01-005/01* to record the training/workshop/conference activities in chronological order.
- 5.3.2. Make a copy of the form.
- 5.3.3. Keep the original form as your record.
- 5.3.4. Give the copy to the secretariat to keep in the IRB file.
- 5.3.5. Submit a copy of evidence of training/workshop/conference activities (e.g., copy of attendance sheet or certificate) to the Secretariat for record.

5.4. Training Frequency

- 5.4.1. Minimum of 2 in-house training per year
- 5.4.2. Minimum of 1-3 full days training per year

6. GLOSSARY

Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Workshop	A group of people engaged in study or work on a creative project or subject
Study visit	A visit by an individual or a group of people to another site or country to update or gain knowledge in relevant fields.
COS	Condition of Services
RGOB	Royal Government of Bhutan

7. REFERENCES

- 7.1. WHO. Standards and operational guidance for ethics review of health-related research with human participants (2011).
(http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf - accessed 28 October 2017)
- 7.2. ICH HARMONISED GUIDELINE. INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) Current Step 4 version dated 9 November 2016
(https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2_Step_4.pdf - accessed 28 October 2017)

8. ANNEX

ANNEX 1 AF/01-005/01: Training Record Form

Training Record Form

Name:	
Staff / Membership since:	Gender:
Education Background:	
Work Experience:	

Training Experience:

No	Courses / Workshops / Conferences / Meetings Attended	Organized by:	Place	Duration	Source of Funding
1					
2					
3					
4					
5					
6					
7					
8					
9					