# Institutional Biosafety Committee (IBC) Handbook

## Installing Effective Biosafety Committees in Pakistani Institutions

**Philippe Stroot, Zia Ashraf*, Khalida Asif*, Furqan Kabir*, Saeed Khan*, Muhammad Ali Malik*, Ali Raza Rajput*, Hajra Waheed, Zeba A. Rasmussen, Hashaam Akhtar* and Misbah Nazir***

*PBSA, equal contribution

**Pakistan Biological Safety Association**

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# Contents

# Preface

The purpose of this handbook is to encourage and facilitate the installation and operation of effective Institutional Biosafety Committees (IBCs) in all kinds of organizations that are confronted with biological risks in Pakistan. The document more specifically aims to explain the reasons why Pakistani institutions may need or want to create an IBC, the functions and types of committees that could be considered, their most desired features, as well as the approaches that can be used to design, install and run an IBC that effectively meets the needs of a given institution.

This handbook is published by the Pakistan Biological Safety Association (PBSA) as part of its continuous effort to develop and improve the management of biological risks in the country. It mostly results from the experience gained by the scientists and faculty members of selected institutions in two related projects on IBCs sponsored by the Fogarty International Center with the support of international consultants. The first one, in 2017-2018, consisted mainly in the organization of three workshops, which resulted in the creation of a few, some of the very first IBCs in some leading Pakistani organizations. The second project, conducted in 2022 and 2023, was based on a series of workshops held in different regions of Pakistan. Each of these workshops gathered key stakeholders from different institutions, some of which already had an IBC in place, the others planning or considering the possibility of having one. These workshops were followed by a 6-month support period through multiple videoconferences between the participants and the consultants, resulting in the progressive launch of more IBCs among the participating organizations. The whole process led to the development of wide practical experience in the various aspects related to the development of IBCs in Pakistani institutions, including issues and difficulties. The purpose of this handbook is to share this experience.

The approach used in this handbook is based on one of the basic observations made during these projects, namely that Pakistani institutions that may need or benefit from an IBC are extremely diverse with respect to:

- their sizes and complexity,
- their activities – ranging from health care in hospital diagnostics to biomedical and biotechnological research work, in the human, veterinarian or agronomic sectors, as well as large-scale development and production activities (e.g., vaccines),
- the level of biological risks involved in these activities,
- their culture, organization and actual functioning,
- and their needs, motivation or incentives to operate an IBC.

A major finding of these projects is that, even if IBCs would be beneficial to all institutions that face biological risks and need to manage and control them, there is no single model of an "ideal IBC" that could fit all institutions. Similarly, there is no unique way to manage to successfully install and operate an IBC. Several types of IBCs may be effective in responding to the needs of institutions, and different ways may be used to install and operate them. This is why this handbook is not designed as a specification or strict guideline on what an IBC needs to be and how it must be operated, but rather as a compilation of observations, ideas, suggestions and recommendations, as well as real examples from participating organizations. The hope is that these will help other organizations to make their way through the process of creating and operating an effective IBC.

Such a handbook cannot be exhaustive. More information, such as references and examples of documents used by the participating institutions can be found at 'link to the PBSA library'.

# Credits

## Project coordinator and international consultants

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Mr. Tim Trevan

Dr. Philippe Stroot

## Participating organizations, national stakeholders and consultants

The following organizations largely contributed to this handbook thanks to the active participation of their representatives (generally 5 per institution) in the workshops and other meetings.

**Balochistan**

- University of Balochistan, Quetta

**Islamabad (ICT)**

- Quaid-I-Azam University Islamabad

**Khyber Pakhtunkhwa (KP)**

- Abdul Wali Khan University, Mardan
- COMSATS University Islamabad (CUI), Abbottabad Campus, Abbottabad
- Khyber Medical University, Peshawar
- University of Agriculture, Dera Ismail Khan
- University of Haripur, Haripur

**Punjab**

- Government College University, Faisalabad
- Lahore University of Management Sciences (LUMS), Lahore
- Sheikh Zayed Medical College, Rahim Yar Khan
- University of Veterinary and Animal Sciences, Lahore

**Sindh**

- Aga Khan University (AKU), Karachi
- Dr. A. Q. Khan Institute of Biotechnology and Genetic Engineering (KIBGE), University of Karachi, Karachi
- Dow University of Health Sciences (DUHS), Karachi
- Liaquat University of Medical and Health Sciences (LUMHS), Jamshoro
- Shah Abdul Latif University, Khairpur
- University of Sindh, Jamshoro

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# Glossary of terms and abbreviations used

## Definitions

**Biosafety:** Principles, technologies and practices aimed at preventing unintentional exposure to biological agents or their inadvertent release.

**Biosafety Officer (BSO):** An individual designated to oversee facility or organizational biosafety (and possibly biosecurity) programs.

**Biosecurity:** Principles, technologies and practices aimed at preventing unauthorized access, loss, theft, misuse, diversion or release of biological agents.

**Genetically Modified Organism (GMO):** An organism (microorganism, animal, plant) whose genetic material has been modified using techniques of modern biotechnology.

**Institutional Biosafety Committee (IBC):** A committee created in an institution to act as an independent review group for biosafety issues, reporting to senior management.

**Pathogenic / Pathogenicity:** Able / ability to cause infection and disease.

**Standard Operating Procedures (SOPs):** A set of well-documented and validated stepwise instructions outlining how to perform laboratory practices and procedures in a safe, timely and reliable manner, in line with institutional policies, best practices and applicable national or international regulations.

**Terms of Reference (ToR):** A document that sets the purpose, responsibilities, principles, modes of functioning and other elements of a project, committee, meeting or any association of people who have agreed to work together to accomplish a shared goal.

## Abbreviations

**BSO:** Biosafety Officer

**GMO:** Genetically Modified Organism

**ERC:** Ethical Review Committee

**IBC:** Institutional Biosafety Committee

**IRB:** Institutional Review Board

**NBC:** National Biosafety Center

**PBSA:** Pakistan Biological Safety Association

**SOP:** Standard Operating Procedure

**ToR:** Terms of Reference

**VC:** Vice Chancellor

**WHO:** World Health Organization

# 1. Introduction – *What is an IBC and why are IBCs needed in Pakistani institutions?*

## 1.1. What is an IBC?

According to the World Health Organization (WHO)[1], an Institutional Biosafety Committee (IBC) is a committee created in an institution "*to act as an independent review group for biosafety issues, reporting to senior management*".

Other definitions found in various regulations, standards or guidelines present an IBC as an internal body established to support and oversee the development of a biosafety program or a biorisk management system.

The detailed functions of an IBC associated with these two types of definitions are similar: contribute to and develop the institution's biosafety policies and codes of practices, review new research projects, perform or review risk assessments and work practices, oversee biosafety and biosecurity training, request and oversee the results of inspections and audits, and review accidents and incidents, amongst others.

## 1.2. IBCs at the international level

The management of biological risks is a complex activity that requires multiple types of generally high level scientific and technical expertise, as well as strong management and communication skills. In addition, the control of biological risks through more or less demanding procedures is likely to have an impact on operations, and might even, in some instances, compromise the accomplishment of activities when risks cannot be controlled in a satisfactory manner. It is thus not a surprise that international guidelines and standards tend to recommend or require specific organizational features, such as a biosafety committee and a biosafety officer (BSO), to support the management of biological risks in institutions.

In the various versions of the 'Laboratory Biosafety Manual', including the latest one[1], WHO has considered a biosafety committee – together with the appointment of a BSO – an integral part of the management of the biosafety program of an institution. This is also the standpoint of the 'Biorisk Management Standard' ISO 35001[2], in which the biosafety committee is called a "biorisk management committee" and the BSO named "biorisk management advisor". The rationale for this is very clearly the need to set up an independent committee to support and oversee the biorisk management program or system, and designate a competent individual to provide advice, guidance and technical support.

Specifically in the biotechnology field, the 'Cartagena Protocol on Biosafety'[3] requires signatory countries to take necessary and appropriate measures to ensure the safe handling, transport and use of genetically modified organisms (GMOs), including the establishment of a

[1] 'Laboratory Biosafety Manual', 4th edition. World Health Organization (WHO), Geneva, 2020 (https://www.who.int/publications/i/item/9789240011311).
[2] 'Biorisk management for laboratories and other related organisations', ISO 35001, first edition, 2019 (https://www.iso.org/obp/ui/#iso:std:iso:35001:ed-1:v1:en).
[3] 'Cartagena Protocol on Biosafety to the Convention of Biological Diversity', Montreal, 2000 (https://www.cbd.int/doc/legal/cartagena-protocol-en.pdf).

national biosafety committee at government level, and an Institutional Biosafety Committee (IBC) in the concerned organizations.

Many countries throughout the world have therefore developed regulations that require IBCs to be created in order to ensure the management and control of biological risks, which could arise either from all biological activities that involve hazardous biological agents and materials (mostly but not exclusively pathogenic or infectious agents), or just from activities that involve GMOs.

## 1.3. Why an IBC in a Pakistani institution?

Pakistan, as a signatory party of the Cartagena Protocol, has established a regulation regarding GMOs[4]. In this regulation, operating and notifying an IBC to the authorities is an obligation for all institutions that import, use, develop, manufacture, store or sell genetically modified substances or even products thereof[5]. However, it is important to note that this regulation does not address biological agents that are not genetically modified, which are likely to pose substantial biological risks.

The first reason for wanting to create an IBC in Pakistan thus appears to be, for all institutions that conduct activities involving GMOs (and their products), the need to comply with this regulation. This is certainly the first motivation of a number of institutions, like those that have an IBC strictly formatted on the regulatory requirements and officially notified to the 'National Biosafety Center' (NBC)[6].

A second reason for wanting to establish an IBC in a Pakistani organization can be the desire to manage the biological risks generated by its activities in the most appropriate manner, whatever the nature of the activities and the level of risk. This justification was invoked by several institutions involved in this project. An underlying motivation for this, besides the commitment to better ensure the protection of their staff, the community and the environment, can be the will to have better access to international grants and collaborations, and to smooth the way for issues like obtaining import permits and facilitating transfers of biological materials between institutions. For all these institutions, obtaining an ISO 35001 certification when it will be possible in Pakistan[7] can be a logical longer-term objective. The IBCs (or planned IBCs) of institutions principally motivated by biorisk management efficacy are mostly based on the precepts of international guidelines or standards such as the WHO manual and ISO 35001.

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[4] 'Pakistan Biosafety Rules', The Gazette of Pakistan April 26, 2005, amended on January 18, 2024 (https://environment.gov.pk/SiteImage/Misc/files/Rules/BIOSafety%20Rules%202005%20(Amended2024).pdf) and completed by more detailed 'National biosafety guidelines' (2005) (https://environment.gov.pk/SiteImage/Misc/files/Guidelines/BiosftyGlines2005.pdf). The national Rules were translated in Punjab regulations (the 'Punjab Biosafety Rules' (2014)).

[5] From this standpoint, the 'Pakistan Biosafety Rules' go much further than the requirements of the 'Cartagena Protocol' in including the products of modern biotechnology, and not just living organisms. They also go much further than the Protocol in imposing obligations that are usually required for non-contained use of GMOs (such as field or clinical trials, or market release of GMOs), also extending to contained activities (such as laboratory activities, for instance).

[6] The list of notified institutions is available on the NBC website (https://environment.gov.pk/SiteImage/Misc/files/NBC/Notified%20IBC%20List.pdf).

[7] Efforts are currently being made at the level of the Pakistan National Accreditation Council (PNAC) to develop certification to comply with ISO 35001.

## 1.4. Different types of IBC in Pakistan

These two main justifications for an IBC – regulatory compliance and good biorisk management – should normally not exclude each other, since the final motivation of the regulatory authorities and the institutions is finally the same, that is to ensure the proper management of biological risks. Moreover, regulatory compliance is a clear requirement of ISO 35001, which means that any institution that would look for ISO certification should demonstrate full legal compliance.

Nevertheless, the limitation of scope and the very prescriptive requirements of the Pakistani regulations on one side (Box 1), and the philosophy and more flexible approach allowed by the international guidelines and standards (Box 2) may lead to IBCs working on different bases, with different objectives, structures and approaches, and therefore reaching different results.

**Box 1. Main characteristics of the Pakistan Biosafety Rules regarding IBCs**

The general principle of the Pakistani regulation is that the import, use, development, manufacturing, storage or trade of genetically modified substances or derived products are prohibited without a government license. This leads to the obligation not only to register an organization's IBC, but also to submit all projects or concerned activities for authorization. In addition, besides their more limited scope (only GMOs and derived products, but not natural infectious agents), the regulation is particular in being very prescriptive regarding IBCs: it provides, for instance, an exhaustive list of their roles and tasks, as well as strict requirements for their composition.

**Box 2. Main characteristics of the WHO Manual and ISO 35001 regarding IBCs**

According to both reference documents, the IBC is described as an independent committee in charge of reviewing biosafety issues and overviewing the biosafety program or biorisk management system. Principles are described, such as responsibilities and the need for independence, or the roles that the IBC should have in an organization. With respect to the composition of the IBC, the requirement is that it represents a cross-section of expertise "that reflects the size and complexity of the organization," or "appropriate to the nature and scale of the activities". In addition, ISO 35001 requires that the IBC be chaired by a person appointed by senior management and includes other requirements like the need for documented terms of references as well as a recording of decisions and follow-up of an action plan. When compared to the Pakistani regulation[8], these guidelines and standard are much less prescriptive, allowing the possibility of adaptation to respond to the needs and specifics of the institutions, provided that principles are respected.

From the panel of institutions involved in this project it appears that IBCs that are already in place are indeed of two basic types – the regulatory-based one and the biorisk management-based one –, but that in these two categories there were differences in the ways the IBC were actually functioning. Given the less prescriptive context of management-based IBCs, variations were more important in this last type of IBCs.

[8] A more detailed comparison of the Pakistan Biosafety Rules vs ISO 35001 is provided in the PBSA library (link to this document).

# *2.* Characteristics of an effective IBC

## 2.1. Main desired features

If an organization decides to set up an IBC, the most fundamental feature is that it should be effective in responding to its organizational needs. So, an IBC created for compliance with the Pakistan Biosafety Rules should not only adopt the formal requirements of the regulation itself, but also ensure that all projects are correctly assessed and authorized by the authority, and subsequently that all authorized activities stay within the limits of the license. Similarly, an IBC that has been created to improve biorisk management should demonstrate results in the improvement of the biosafety program and the safety practices, leading to improvement of the biosafety records. Therefore, the main desired feature is the effectiveness of the IBC in fulfilling its objectives.

Independence is another desired feature of an IBC, in order to ensure that its decisions and actions are mostly driven by biosafety and biorisk management considerations, rather than purely operational or financial considerations. This does not mean, however, that operational and financial aspects or issues should not be considered. The independence of the committee or its members is even considered a requisite in the WHO Manual and ISO 35001, respectively[9].

Another essential feature to justify an IBC in an organization is complementarity with other internal bodies – such as research review boards for those involved in research, or ethical review boards for those active in human or animal health. The IBC should have a distinct role, and bring added value to what is achieved by the other internal bodies.

To ensure effectiveness and complementarity with other internal bodies, an IBC also needs to be adapted to the needs and characteristics of the institution. This relates to the type of IBC, its mission and function in the organization, its structure and composition, and its operational approach.

## 2.2. Other desired features to ensure effectiveness

To reach effectiveness, an IBC should have a clear mandate, mission and scope, and thus a clear role in the organization. These should clearly be stated in Terms of Reference (ToRs).

The composition of the committee should be established on the basis of the mandate, mission, and scope. Members should be chosen according to their roles within the organization to accurately reflect its structure and complexity, and their competencies, to be able to contribute to the objectives of the IBC in dealing with the scientific, technical and management issues that will be addressed. Particular attention should be paid to specific competence in biosafety and biorisk management, including the possibility of having a dedicated BSO (Box 3). Qualities of leadership (especially for the chairperson of the committee) as well as personal awareness and motivation regarding aspects like health protection, staff safety and environmental issues should also be considered when selecting the IBC members.

[9] The 'Pakistan Biosafety Rules' do not mention anything about the independence of the IBC, but the accompanying 'Pakistan Biosafety Guidelines' mention that the IBC should be granted "principal authority on biosafety concerns, enabling it to exercise its power in undertaking all responsibilities and offer criticism and advice without contest".

### Box 3. The Role of a Biosafety Officer (BSO)

In the international reference documents (the WHO Manual, ISO 35001 and the Cartagena Protocol) and the Pakistan Biosafety Rules, the designation of a BSO is associated with the establishment of an IBC. The role of the BSO in the institution is to act as an advisor and to support the implementation of the biosafety or biorisk management program or system, e.g., through risk assessment, development of guidelines and specific SOPs, training, inspections and audits, or communication. His/her specific role within the IBC is to provide advice and guidance related to biosafety and biorisk management, and to assist the committee in reviewing projects and risk assessments, SOPs and biosafety records. The role of the BSO is pivotal as a liaison between the IBC and the rest of the organization and as a facilitator in the implementation of the programs developed and overseen by the IBC.

An IBC should also have clear functioning rules (or operational protocols) to facilitate collaboration and decision making, in order to ensure overall effectiveness. These rules should ideally cover aspects like project review processes, decision processes including possible voting rules, management of potential conflict of interest, specific roles in the IBC (e.g., chair and secretary), the possibility to invite experts on an ad hoc basis (i.e., for specific topics), and ways to document and communicate information, decisions and actions. The composition of the IBC and its rules for functioning should ideally also be stated in the ToR, while providing some possible flexibility to adapt to changes that may occur.

Options and practical ways to manage these important elements to ensure the effectiveness of the IBC, based on the experience gained in Pakistani organizations participating in this project, are developed in the following sections.

# *3.* How to create an effective IBC in a Pakistani institution?

## 3.1. Introduction

Establishing a new committee like an IBC in an organization is not necessarily an easy task. It depends on multiple factors, such as the complexity and culture of the organization, but also practical issues such as the availability of human and other resources. Making sure from the start that the IBC will be effective in its mission requires paying attention to a number of elements (as those mentioned in 2.2) in a rather pragmatic way.

Although the process is not necessarily fully linear, the main elements to manage for the creation of an effective IBC are presented here as steps.

## 3.2. Step 1: Define the institution's needs

This step of defining the needs of the institution correctly was considered essential by a number of participants in the project, including those from institutions that have an IBC in place. It is actually key, not only to convince senior management if needed, but also to design the IBC in the most appropriate manner.

The needs of an institution can be varied: legal compliance of GMO projects, more extended or efficient biorisk management, but also more specific needs like developing a safety culture or specific expertise in biosafety or biosecurity, creating or expanding a biorisk management program, ensuring better harmonization of safety practices between sites or departments, and enhancing national or international visibility. There can also be multiple requirements or needs within a single institution. It may therefore be useful not only to list the needs, but to identify those that are the most crucial, and should therefore be fixed as priorities.

Defining these needs should be based on the institution's size, structure and complexity, on current and projected activities, on its existing and desired management and safety culture, and on what is perceived as strengths and weaknesses with respect to the management of biological risks and/or legal compliance in this area. This requires a rather good knowledge of the institution and should ideally be assessed by a small group of people familiar with the nuts and bolts of the organization.

To be complete with respect to the institution's needs, biosafety compliance and some biorisk management may, in some organizations, already be ensured by another body, such as a review board or a general health and safety committee. If this is done in a satisfactory manner, there might be no need for an IBC as a distinct committee. However, this situation is not likely to occur frequently, since biorisk management requires specific expertise and, at least in institutions with some significant biological risk, a high level of commitment on biosafety and biosecurity issues.

A decision tree to help define the need for an IBC in an institution is provided in Figure 1.

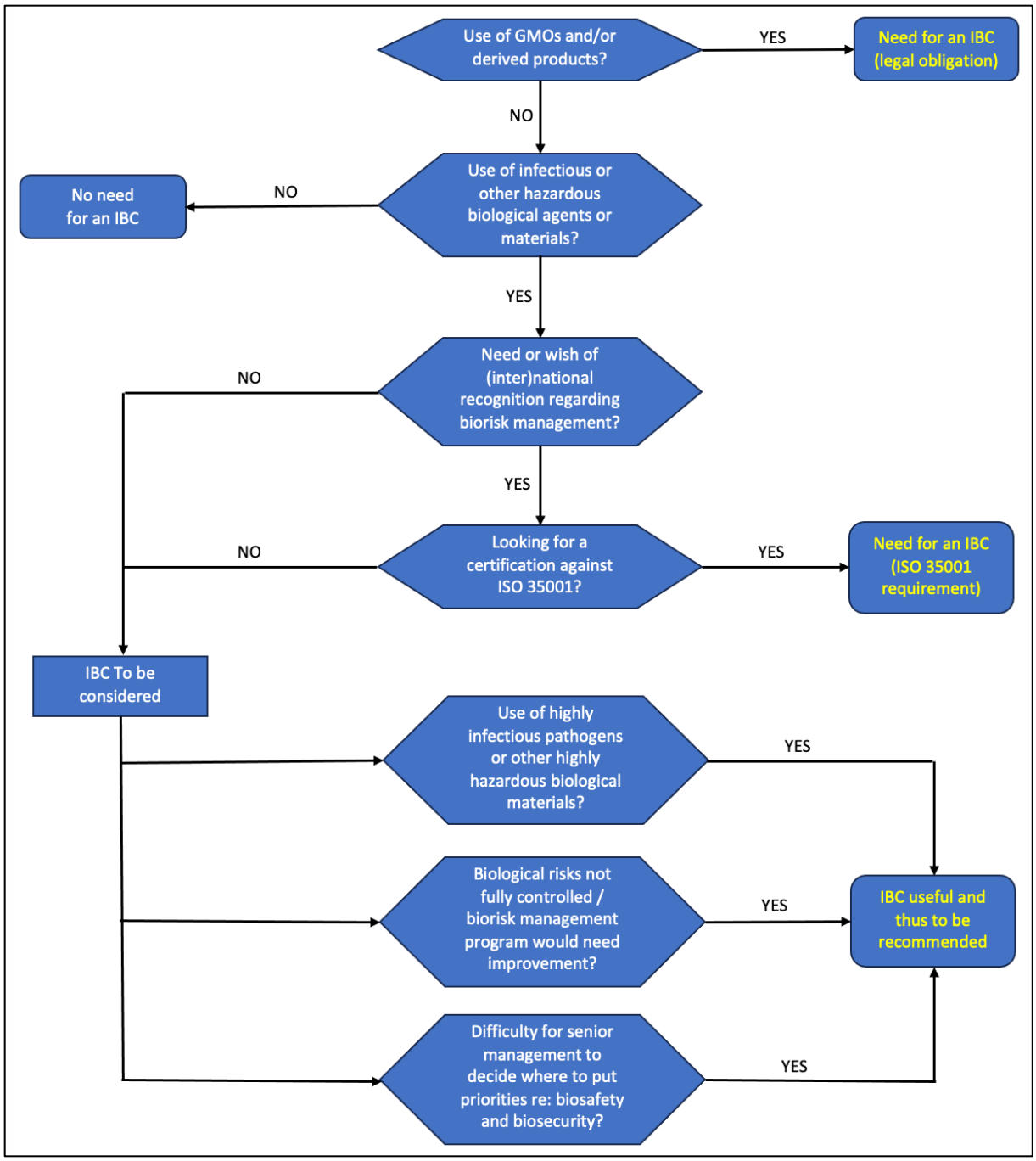


*Figure 1 - Example of a Decision Tree to define the need for an IBC in an institution*

## 3.3. Step 2: Define the IBC's desired mission and scope

Once the needs of the institution and possible priorities are defined, the desired mission and scope of the IBC can be developed. This should normally be done in the form of a proposal to be submitted to the Vice Chancellor (VC) or executive of the organization for further discussion and approval. This step is seen as a key one by all participants of this project, since it helps in defining the mandate that should be given to the IBC and allows further steps, such as developing the ToRs.

In defining the mission and scope of the IBC – and choosing its name (Box 4) –, one must make sure that they do not duplicate or overlap with the mission and scope of other institutional bodies, such as project or ethical review boards. If such bodies exist, the mission and scope of the IBC should be complementary to theirs – and attention should already be paid to how the various bodies would collaborate. This means that the mission and scope should be defined in terms that are precise enough to avoid conflicting with those of other bodies, and wide enough to cover the needs of the organization with respect to biosafety and biorisk management.

### Box 4. About the name of the IBC

While "Institutional Biosafety Committee" is the term used by WHO and the Pakistan Biosafety Rules, and therefore appears as the most natural term to adopt, ISO 35001 rather uses "biorisk management committee" (while mentioning that its role could be assumed by an IBC). Discussion about this arose during the workshops. Some participants argued that using either one of the names, depending on the mission and scope of the committee, would allow better distinction between both types of committees (i.e., the compliance-based and the biorisk management-based committees). On the other hand, most biosafety committees have an intermediate status. Also, other committees include the mission and scope usually ascribed to an IBC, as illustrated in the example given in Box 5. The conclusion was that "biorisk management committee" (or another name) could of course be used by some institutions (as it is for instance the case at the University of Karachi), but that a clear statement of the mission and scope is probably more important than the name.

The mission of the IBC should normally be focused on biosafety and biorisk management. For a compliance-type of IBC, it could, for example, be the review of new GMO projects, their risk assessment and the assurance that authorized activities stay within the lines of the authorization. Ensuring the latter implies some scrutiny and oversight of the activities, as well as possible corrective actions (e.g., changes of practices, or training) – and thus some level of biorisk management. For an IBC that aims at the management of all biological risks, it could be the launch, implementation and continuous improvement of a biosafety program or biorisk management system, which would encompass activities involving pathogens and infectious materials as well as GMOs. As it can be observed, the mission of both types of IBCs is not necessarily so different, but their scope is.

If the mission of the IBC should be focused on biosafety and biorisk management, it is not the only way to proceed, as illustrated by the example given in Box 5. A committee with a wider mission, such as the development and oversight of a general or laboratory safety program that would include biosafety could also be efficient, provided biosafety aspects are treated. This option may be more adapted to institutions with a large panel of lab activities, generating diverse types of risks, in which biological risk only constitutes a relatively limited part or mainly occurs together with other risks (such as chemical risks, for instance).

### Box 5. Example of LUMS

The Syed Babar Ali School of Science and Engineering (SBASSE) of the Lahore University of Management Sciences (LUMS) has established an Occupational Health and Safety (OHS) Committee that covers all aspects of health and safety, including biosafety and biosecurity. This safety committee aims to maintain a safe and healthy work environment within the school. It consists of faculty, staff, and students from various departments: representatives from chemistry and chemical engineering, life sciences, physics, electrical engineering, and facility management contribute to the diverse expertise required for the committee. Regular meetings are held to ensure the effectiveness

of the safety management system. In case of any issues, committee members work together to find solutions. The committee's primary objective includes ongoing improvements, regularly reviewing and upgrading safety measures to prevent people, property, and the environment from accidents.

Together with the mission, the scope should be well defined. It could focus on GMOs only (if only legal compliance is looked for), or on all biological risks. However, in an institution where activities involving natural (i.e., non-GM) pathogens are conducted as well as work on GMOs, it probably does not make much sense to focus only on GMOs and neglect other biological risks. From this standpoint, some participating organizations that had an IBC developed to respond to the legal obligations of the Pakistan Biosafety Rules have decided to or are considering enlarging the scope of their IBC to cover all biological risks.

The scope of the IBC should also define its power in the institution, as well as the limitations of its power, that is, what the IBC is responsible for, and what is not included in its responsibilities.

In relation to this, it may be judicious to mention independence in the mission or scope (e.g., in mentioning "independent" review or advising). Indeed, this is an essential feature which, according to experience, may pose a problem at least in some institutions or specific situations.

If not obvious, the scope of the IBC should also specify whether it concerns the whole institution, a specific campus or part of the organization.

In conclusion, both the mission and scope should be defined so that they are wide enough to respond to the needs of the institution, but also sufficiently clear to avoid misunderstanding and possible conflicting situations. When developing the desired mission and scope, one should also remember that they must be endorsed by the VC and senior management. Hence, the choice of the wording used may be of importance.

### 3.4. Step 3: Obtain approval and a clear mandate from the VC or Executive

Getting approval and a clear mandate from the VC or executive director of the organization is an absolute must: without such a mandate, it would be impossible for a committee to develop its activity and have an impact on the institution.

When the initiative to establish an IBC comes from the VC or senior management of the organization, this should not pose major problems provided the proposed mission and scope meet their expectations. However, there may be situations where the VC and senior management still need to be convinced about the appropriateness of an IBC (Box 6). They may also need to know the possible cost of running an IBC – and even more of having a BSO, if this option is envisaged (Box 7).

Box 6. Convincing Senior Management

In some cases, the need or interest to have an IBC may not be clearly identified or perceived by senior management, while being more obvious at a lower level in the organization – e.g., by the head of a department or laboratory involved in high level biotechnology work, or in activities that generate a significant level of biological risk. In others, the possibility is known, but senior management may have doubts about the appropriateness of an IBC for their organization.

In such situations, convincing the senior management about these is a necessary preliminary step. For this, solid arguments, as described in the introduction section (1), need to be presented, together with a clear view of the needs of the organization (see 3.2). However, this may not be sufficient since senior management may have specific concerns or objections. In some organizations, VCs and executives may have a background far from biology or medical sciences. Given their position, they may also be particularly sensitive to aspects like image and visibility, or finances and costs (see Box 7). It is thus important to know the profile and main concerns of the main decision-makers, as it may be judicious to focus on specific additional points, and to develop specific grounds to defend the idea of an IBC. This may also require involving influential personalities from the organization, with different backgrounds.

### Box 7. Financial and management aspects of an IBC and a BSO

Operating an IBC is not expected to generate any significant direct costs, since the IBC normally gathers a number of people who are already on the payroll of the institution. Usually, at least part of their work for the IBC, i.e., working at ensuring the safety of the activities conducted in their department or laboratories, is normally something they would also need to take care of. The number of IBC meetings should be rather limited.

Still, an IBC is likely to generate indirect costs, for instance when launching activities such as training or inspections, or putting in place preventive or protective measures that require the use of more or better protective equipment (e.g., personal protective equipment, biosafety cabinets). However, such expenses should actually not be just ascribed to the activity of the committee, but rather considered as normal costs to ensure (bio)safety at work and (bio)security in the institution, and that would thus be necessary anyway. Such costs should be balanced with the risks and costs of non-compliance and poor biosafety or biosecurity, including the impact on the institution's image, access to grants, etc. More interestingly from a management point of view, the recommendation or request of the IBC to incur such costs should come together with a rationale. The work of the IBC should help identify areas or activities in the organization where the risk is the least acceptable and most needs to be better controlled, therefore prioritizing investments. This would help manage biological risks on the basis of plans and a clear rationale, rather than having to respond to solicitations on a case-by-case basis. So, besides its role in ensuring compliance or better biorisk management, an effective IBC should also serve as a tool for senior management to establish investment or expense priorities.

When compared to the cost of an IBC, the appointment of a biosafety officer (BSO) is likely to generate additional costs. Depending on the size of the organization and the extent, diversity and nature of the activities that generate biological risks, the position of BSO may be a full-time or a part-time position; if part-time, it could be combined with other responsibilities in a lab or in management. The option of having an external biosafety expert acting as BSO does not seem to exist yet in Pakistan. In any case, all of these options have a cost, which should also be balanced with the benefits of having a designated person, with specific expertise (to be progressively developed), to ensure the liaison between the IBC and the laboratories, and to facilitate the implementation of biorisk management in the field.

Senior management may also want to know about some of the main operational aspects of the projected IBC before deciding. So, it may be preferable to already have some views on features such as the desired composition (3.5), meeting frequency and main functioning rules (3.6), and to be ready to share them. In some institutions that participated in this project, the stakeholders went to the VC with a rather complete proposal, including a draft of the Terms of Reference (ToR). In others, developing the ToR was the first task assigned to the IBC once the mandate was granted.

## 3.5. Step 4: Have the right people on board

In general, the VC or executive director designates the chair of the IBC when giving the mandate to the IBC, and often also nominates the other members of the committee. Otherwise, he/she may just nominate the chair and mandate the chair to come up with a proposal of composition. Anyway, whatever the process of establishing the complete membership of the IBC, composition appears essential for smooth and effective future operation. This was a topic that was much debated during the workshops, which explains why it is treated separately in this handbook.

Ideally, the composition of the IBC should not only reflect the structure of the organization but also include a panel of people with appropriate scientific, technical and/or management skills in order to be able to fulfill the mission of the IBC.

The Pakistan Biosafety Rules are highly prescriptive regarding the composition of the IBC, in imposing a minimum composition (Box 8). The National Biosafety Guidelines[10] offer a bit more flexibility, while stating that the Rules prevail in case of contradiction. Moreover, the Guidelines indicate that the composition of the IBC must be communicated to the NBC as part of the IBC notification.

### Box 8. Composition of the IBC according to the Pakistan Biosafety Rules

The national regulation requires as minimum composition of the IBC the head of the institution as chairperson, and as members, subject expert(s), a social scientist and/or economist (for social impact) and a representative of civil society.

The requirement to include a social scientist and/or an economist as well as a representative of the civil society in the IBC may appear a bit surprising and can be a source of difficulties. This requirement comes from the precepts of the Cartagena Protocol. It certainly makes a lot of sense when activities like field trials of genetically modified plants or the release of GMOs in the environment, for instance, are concerned. Such activities may indeed have a possibly major impact on the economy and society, and this impact needs to be assessed prior to the activities. However, it makes much less sense when contained activities, such as laboratory work, are concerned – and biosafety regulations that cover contained use activities do not include such a requirement.

Anyway, this requirement, and especially the need to have a representative of civil society as a member of the IBC, is a potential source of difficulties and was most debated during the workshops (see Box 9).

In contrast, the relevant international references are much less prescriptive with respect to IBC composition – except for the requirement of independence. According to the WHO, the IBC "should represent a cross-section of institutional expertise that reflects the size and complexity of the organization, the types of biological agents in use and the activities being carried out". According to ISO 35001, the IBC "shall include a representative cross-section of expertise appropriate to the nature and scale of the activities undertaken". As can be seen, these recommendations or requirements are much more flexible and allow tailoring the IBC composition to the needs of the institutions and the mission to be accomplished.

[10] 'National Biosafety Guidelines', Government of Pakistan, 2005 (https://environment.gov.pk/SiteImage/Misc/files/Guidelines/BiosftyGlines2005.pdf).

Despite their differences, the requirements from the Pakistani regulations and those from the international guidelines and standards are partly compatible. They could at least partly be combined in an IBC that would aim at the management of all types of biological risks (i.e., from natural biological agents and materials, as well as from GMOs). The main difficulty lies in the legal requirement of a representative member of civil society (Box 9).

### Box 9. A member of civil society?

The inclusion of a representative of civil society as a member of the IBC was much debated during the workshops.

The first issue is the idea of having an external person who is 'representative' of civil society. What does that mean? Civil society is complex. Moreover, the majority of citizens are not educated in biological or biomedical sciences, biotechnologies and related fields, and are thus not likely to understand the scientific and technical discussions that need to take place in an IBC, and certainly not in a position to appraise risks or the efficacy of preventive measures. So, taking any ordinary citizen as a member is certainly neither an option that would bring any added value, nor be in favor of effectiveness. There is also a risk of selecting someone who has some education in the concerned field of activities and who may have his/her own opinion and not be neutral; he/she may be either a supporter of or an opponent of GMOs, and may not really be representative of civil society.

In addition, having an external person on board may raise confidentiality issues (although these could partly be avoided through some kind of confidentiality agreement). However, perhaps more fundamentally, having an external person on board, whatever his/her profile (except an expert invited to help solve problems), is likely to limit the transparency of the discussions that need to take place in an IBC; openly identifying actual issues is necessary in order to be able to solve them, and generally possible internally but almost impossible in the presence of external people. Having a member of civil society on board is thus likely to negatively impact the functioning and outcome of the IBC.

Some institutions have circumvented this sort of problem by naming a relative as a representative of civil society, in which case his/her representativeness could be questioned. Also, it appears that usually civil representatives only rarely attend IBC meetings, which also raises the question about their actual role. Some other institutions consider the community representative as an invited member, who could or could not be invited depending on the meeting's agenda.

As a conclusion of the discussion, it seems to be preferable for most institutions – except if forced to do so – to avoid including a member of civil society in their IBC. Some transparency can be managed through other means, such as open communication with the neighborhood, using the media, or activities like open days. For the institutions that need to have an external member on board, some creativity may be needed to find the most appropriate person, including with respect to allowing the transparency needed in IBC discussions.

If a BSO is designated, as required by the Pakistani regulations and the international guidelines and standards, it is obvious that he/she should of course be part of the IBC given his/her major role in the development of the biosafety program or management system[11].

The established composition of the IBC should constitute the backbone of the IBC and ensure proper functioning and consistency. However, competence is key, but all the competences needed to deal with a range of highly complex scientific and technical subjects cannot always be gathered in an IBC. So, the possibility of inviting experts in specific matters on an ad hoc

[11] This is not stated clearly in the Pakistan Biosafety Rules (just that the BSO should "assist and liaise with" the IBC), but the BSO is of course to be considered a "subject expert," as mentioned in the regulation. Moreover, this is clarified without ambiguity in the National Biosafety Guidelines.

basis, according to the needs, should also be managed to complement the established membership.

Also, some critical competence may be lacking, such as specific competence in biorisk management, for instance in organizations that do not yet have a BSO. An option that could be considered in such cases where internal resources may not be sufficient is to have external experts hired as permanent members of the IBC (Box 10).

**Box 10. Example of LUMHS**

The new IBC of the Liaquat University of Medical and Life Sciences (LUMHS), in Jamshoro, was initially composed of 6 members from the university: a chairperson representing the VC, three subject matter experts and two BSOs. The mission granted by the VC was to initiate biosafety policy making, to review research proposals with respect to biosafety issues and to train research workers, paramedical staff, housekeeping staff and all those involved directly or indirectly in activities involving biological risks or biosecurity issues, in collaboration with the Research Ethics Committee. Later, four additional external experts were added in order to complete the expertise already present on board. These are experts in biosafety, biorisk management and infectious diseases from other institutions, as well as a specialist in biomedical equipment.

Given the importance of the composition of the IBC in its effectiveness, it is certainly worth thinking about it ahead of time in order to identify the right positions and profiles to ensure the needed representation and competence pool, and to share those thoughts with senior management before the establishment of the IBC.

## 3.6. Step 5: Develop the Terms of Reference (ToR)

Terms of Reference (ToR) (and/or other possible reference documents) appear particularly important, especially in Pakistan, where the concept of an IBC is quite new and where IBCs based on very different regulations and guidelines are being created (section 1.4).

The development of ToR is generally the first task assigned to a new IBC; these ToRs will generally need to also be approved by senior management since they will determine the integration and functioning of the IBC in the organization.

ToR should state the mission and scope of the IBC and the other elements considered important to guarantee smooth functioning to render the mission successful. Of course, these elements need to be aligned with the mission and scope.

Besides the composition of the IBC (3.5), aspects that should or could be defined in the ToR are:

- The responsibilities of the committee, including with respect to other internal bodies (such as the ERC or IRB);
- Functioning principles and rules (independence and conflict of interest issues, transparency, confidentiality, communication and sharing of information);
- Possibly some more operational aspects (such as the reviewing process, meeting frequency or agenda).

There are different ways to organize the ToR (Box 11): ToR could be standalone papers, or be complemented by other documents (a guideline, internal rules, part of a biosafety manual, an SOP, etc.). In this case, at least the principles, rules and other elements essential to fulfill the mission would be best stated in the ToR themselves. Other elements could then be the subject

of a distinct document or, especially those that could benefit from more flexibility, could even be set during the meetings and documented in the meeting minutes.

### Box 11. A few examples of organizing the ToRs and other reference documents

Some institutions, like LUMHS, developed ToR that were intentionally kept short (2 pages), simple and easily understandable. These include a few headings, like the composition of the IBC, its function, the meeting frequency, a protocol for the meeting agenda and the distribution of the minutes, the required quorum of participants and the voting rules.

Other institutions developed much more extensive ToR. The CUI Abbottabad Campus, for instance, included a comprehensive application form for biosafety clearance of research projects by the IBC.

Examples of ToR and similar or complementary documents developed by the various institutions are available in the PBSA Library (**Link**).

**Responsibilities**

The *responsibilities of the committee* are directly linked to its mission and scope. These could consist of a list of functions and tasks that should be performed by the IBC, or more general principles. Responsibilities should also indicate the limitation of responsibility of the IBC, for instance, that the decisions and recommendations of the IBC are subject to VC approval before their implementation. In institutions that have a BSO, the distinction between the role, function and tasks of the IBC and those of the BSO should be clearly made (Box 12).

### Box 12. About the roles of the IBC and the BSO in Pakistan

Based on the regulations, standards and guidelines, the role of the IBC is to support and oversee the development of a biosafety or biorisk management program or system, while the role of the BSO is to facilitate the implementation of the program or system through the provision of specialized advising (to the IBC and to the labs), training, inspections and audits, participation in risk assessments, drafting of SOPs and guidance documents, and other activities of support of the labs and their managers.

Currently, only a very limited number of institutions in Pakistan have an appointed BSO, even among those that have an IBC or are planning to establish one. When looking at the activities of the IBCs of institutions that do not have a BSO, it appears that the IBC itself, or some of its members, implement activities such as training or the development of SOPs. In such instances, the role of the IBC does not just appear as supervision and high-level support, but also direct implementation. This may not be an issue, especially in small organizations, but could pose several problems in larger or more complex ones. First, the IBC members involved in implementation activities, especially when devoted to parts of the organization that are not theirs, may spend too much time away from their main responsibilities, with a possible negative impact on these. Then, while fully competent in their field of activities, they may be less accurate when they deal with other issues in a different context. Last, overseeing a program and reviewing complex research proposals, for instance, require competences other than those required to facilitate field implementation.

From this standpoint, it appears preferable to differentiate the roles of the IBC and of the BSO, and therefore to nominate a BSO, either full- or part-time depending on the volume of work, with his/her own mission and job description. Several institutions that participated in this project are now either hiring a BSO or considering doing so. Having a person in place with BSO responsibilities should not only facilitate the implementation of the program but also allow the IBC to better focus on higher level supervision.

The distinction between the roles of the IBC and of the BSO is clearly made in international references such as the WHO Manual and ISO 35001, as well as in the Pakistan Biosafety Rules and Guidelines.

Among the responsibilities to be defined in the ToR are those related to other internal bodies, as for instance a research or an ethical review board, in order to clarify the links and relationships between the various committees. This is particularly important for an activity like the review of research proposals, which may require several approvals. In this respect, the responsibility of the IBC should ideally be to approve – and therefore also possibly rule out – a proposal on the basis of the risk assessment of the biosafety and biosecurity aspects of the project and planned activities. A more restrictive alternative option is to only give motivational advice on the biosafety and biosecurity aspects of a given project, and leave the decision to a higher-level authority. This kind of power and responsibility should be clearly stated in the ToR.

**Functioning principles and rules**

*Independence* of the IBC and its members is a leading principle and major feature of an IBC (2.1). So, it is certainly worth stating this principle in the ToR, at least if not mentioned in the mission. Together with this principle, a rule should be defined to *prevent conflict of interest*, that is to avoid the possibility that positions, decisions or actions of the committee could be impacted by the personal interest of one or several of its members (Box 13). The rule could be that committee members need to recuse themselves (i.e., excuse or withdraw themselves) from decision-making procedures (e.g., a vote) on issues where real or perceived conflict of interest exist", as stated in ISO 35001; in the standard, this statement is considered a requirement.

### Box 13. Understanding conflict of interest

Conflict of interest is a common issue in the workplace and any other type of organization or group of people. A conflict of interest occurs when an individual's personal interest – his/her own financial or social situation, or those of relatives or friends – could compromise his/her judgement, decisions or actions. The organization must protect itself from being impacted by such biased or unfair influences, and even from the possibility that its decisions or actions might be put into question or disputed because of a perceived conflict of interest.

Controlling the risk of conflict of interest requires first identifying real or potential conflicts of interest, and then preventing them from occurring by moving the concerned person away from exposure to the situation of conflict.

In an IBC, conflicts of interest may occur during activities like reviewing projects, establishing policies or priorities, or assessing facilities or work practices. In such situations, it may be prejudicial to the IBC to totally remove a person from a debate in which his/her expertise is needed, as it may also be unfair to that person to totally prevent him/her from voicing his/her opinion. In taking the example of the review of a research project, removing a head of service or an expert from the review because the project is proposed by a scientist from his/her laboratory (and could therefore benefit his lab) would constitute a loss of expertise and could also penalize the project. In such a situation, the best approach is probably to allow the person in a potential situation of conflict of interest to participate in the discussion but to have him/her withdraw from the decision making.

Some level of *transparency* should be developed in the discussions of the IBC, so that each member is able to describe issues and express concerns in an open way, without risk of blame or counterproductive reactions. This seems to be necessary to correctly identify issues that

would need priority actions. Transparency is of course part of the culture of the institution, but it may be worth mentioning this as a principle.

Moreover, transparency would also need to be managed in the *decision-making process*. This can be done by defining in a reference document (ToR or other) how decisions are taken. Possibilities include some kind of informal consensus or on the basis of a vote. Do all members have a voting right? In the case of a voting system, would a simple majority be sufficient, or would the proposal require a larger majority? What happens in the case of equal votes, i.e., a tie? Also, is a veto possible, and in this case by whom? In most cases a simple consensus-based system should be sufficient. However, even in this instance, provisions could be set to cope with more difficult situations.

Some level of *confidentiality* also needs to be managed, at least in the debates and individual opinions expressed, and with respect to the scientific and technical matters that are treated, at least when these relate to matters that are sensitive from an intellectual property or competitive standpoint. This mostly concerns communication by the IBC to the outside and is particularly crucial if external members, including possibly members of civil society (see Box 8), attend the meetings or receive documents. Rules need to be defined for this, including possibly the signature of a non-disclosure agreement by the external members, if they are not already bound by such an agreement, as is the case for external consultants, for instance.

In relation to confidentiality issues, the way to *communicate* the results and decisions of the IBC meetings also needs to be established. How and to whom should the meeting minutes be distributed? Should they be readily available in the organization, for instance on the intranet (Box 14), or only to part of the management?

**Box 14. Should the meeting minutes be made available to the whole organization?**

Total transparency could include making the IBC meeting minutes available to all in the institution. However, this is likely to have a number of drawbacks. First, it may generate confidentiality issues, since some sensitive information may be shared, and its further divulgence may become totally uncontrolled. On the other hand, controlling what is written in the minutes because these are going to be widely distributed may generate internal censure in how minutes are written, and thus impact the needed documentation of the discussions and decisions. So, it is most generally agreed that the meeting minutes, as such, should not be too widely distributed. In contrast, the operational decisions, as well as the announcement of information or training sessions, for instance, should be communicated throughout the organization. This should normally be done through the management line. Some organizations that want to promote openness and transparency may produce a short summary of the main topics discussed and of the decisions, to be distributed widely (e.g., through the intranet) in addition to the more restricted meeting minutes.

**Main operational aspects**

Some more operational aspects could be included in the ToR, although they could also be specified in other reference documents.

One of the operational aspects that need to be specified clearly is the process of reviewing research proposals, in relation to the committee's responsibilities in this regard (see above). Defining exactly what research proposals need to be reviewed by the IBC is likely to have a major impact on the workload and efficacy of the IBC. Clear criteria should be defined for this (e.g., based on the existence or possibility of generating biological risks). These could be part of a sort of checklist (example in Figure 2).

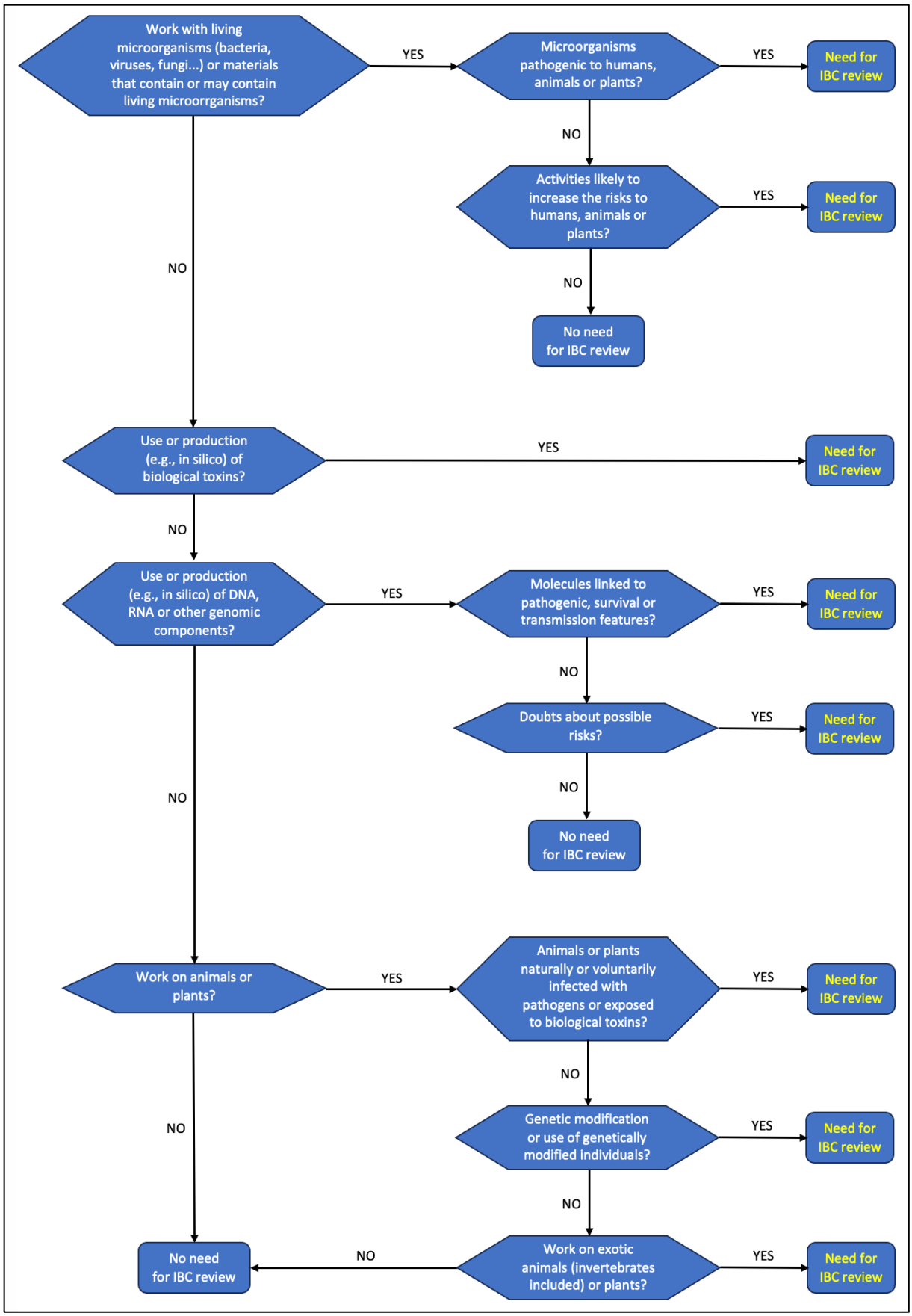


*Figure 2 - Example of a decision tree to define whether a research proposal needs to be reviewed by the IBC*

Also, defining the way to proceed with the review of research proposals, and more particularly the relationship between the IBC and other review committees such as an Ethical Review Committee (ERC) or an Institutional Review Board (IRB), should be specified. Different options are possible for that and are actually being applied in Pakistani institutions (Box 15).

### Box 15. Ways to organize the review of research proposals in participating Pakistani institutions

In a number of institutions, research proposals are sent to the IRB or ERC for review and approval. During its first review, the general review committee (i.e., the IRB or ERC) identifies possible biosafety or biosecurity issues. If such a potential issue is raised, the proposal is sent to the IBC for further review from a biosafety and biosecurity standpoint. It is then returned to the general review committee, together with an IBC recommendation or approval, for final approval at the institutional level.

In at least one participating organization, the IRB currently assigns one of its members to examine the proposals in preparation for the monthly IRB review. The intent here is that proposals that involve some biosafety and biosecurity aspects would in the future be sent to the IBC for this initial review. The model would then be quite similar to the previous one.

In other institutions, research proposals are automatically sent to the IBC based on some specific, well-defined criteria related to biorisk management (like those presented in Figure 2). This is generally done after a first screening at the department or faculty level. After the IBC review, the proposal is generally sent to the general review board for final approval.

A good way to facilitate interactions between the IBC and the ERC or another general review board is to have a member of the IBC, ideally the chairperson, also be a member of the general review board. This approach, which has been adopted by several institutions, favors communication both ways and limits the risk that a biorisk management issue would be neglected or omitted.

Other institutions seem to have adopted a different model, in which the IBC or the IRB conducts the review of the research proposals by looking at all aspects involved, including ethics, safety and biosafety aspects. This requires a wide range of competence on board, and the use of a very complete and detailed application form (such as the one mentioned in Box 11).

Other operational aspects, such as the meeting frequency and the ways to manage the agenda or follow up the action plan, should also be defined, but not necessarily in the ToR (see Box 11). They could either be part of another document or, for more flexibility, be discussed and agreed on during the meetings, and simply documented in the meeting minutes.

# *4.* How to operate an effective IBC in Pakistan?

## 4.1. Introduction

Once the mandate is granted, the composition of the committee established and the main principles defined, meetings of the committee can start. In a number of Pakistani institutions, the main task delegated to the newly established committee is to establish the ToRs and other reference documents. However, it appears that very rapidly, the institutions involved in this project started to work concretely on projects, such as conducting information sessions and training activities.

Given the diversity of institutions, their culture, their organization and their activities, it is not a surprise that there is not just one good way of functioning, but different ways that could all be suitable provided they respond to the needs of the institution and fulfil the mission for which the IBCs have been created. The purpose of this section is to describe a few methods to deal with some practical issues and to raise awareness about possible long-term issues that could be faced in running an IBC.

## 4.2. Some practical aspects

The first practical aspect is the *meeting frequency* (Box 16). Depending on the organization and specific needs, such as the development of a long term biorisk management program or mostly the review of research proposals, the frequency of the meetings could be set according to a fixed schedule or more on an ad hoc basis. Fixing the frequency and even dates ahead of time is generally important to ensure the supervision of a program and to make sure that all members can plan to attend the meetings. However, meetings gathered on request are more likely to ensure flexibility, for instance to review projects or in case of a more exceptional event (e.g., a construction project, or an accident). A mix of both can be a good option for a number of institutions, e.g., having a meeting planned every 6 months, plus the possibility of additional meetings according to the needs. In such a case, modalities should ideally be defined to arrange non-planned meetings.

Box 16. About the meeting frequency

The frequency of IBC meetings varies a lot from one organization to another. Those that participated in this project had their IBC meeting frequency ranging from once a month to once a year, but mostly between one meeting per quarter or semester (twice or 4 times a year). In several of them, the meeting frequency was very high during the first 6 months (up to once monthly meetings) but decreased afterward. The reason for this is that the first meetings were mainly devoted to the development of the ToR, while the subsequent meetings progressively became more “normal” IBC meetings.

Several other measures should help facilitate the preparation and running of the meetings. A first one is to provide a *meeting agenda* ahead of time (also as a reminder of the date!) and to circulate documents that need to be read or analyzed before the meeting (such as a draft SOP or research proposals, for instance). The agenda could also be a standard agenda, used for each meeting, but that could be populated by announcing more specific subjects that will need to be discussed. The advantage of using a quite standard agenda is to be sure that no relevant topics are missed (example in Box 17).

**Box 17. Example of a standard meeting agenda**

Example of standard agenda from a private development and manufacturing organization (information between brackets added as explanations on the topics covered).

1. Organizational aspects and committee's organization
2. Regulatory aspects - Permits and authorizations
3. Review of new research proposals and ongoing projects (based on risk assessments)
4. Facility management (construction or revamping projects, maintenance, technical issues…)
5. Documentation support (biosafety manual, SOPs, risk assessments, biological inventories…)
6. Information and training (planning, review…)
7. Inspections and audits (planning, review of results)
8. Review of incidents and accidents
9. Follow-up of action plan (for points not addressed earlier during the meeting)
10. Miscellaneous (any other biosafety- or biosecurity-related business)

If deemed useful, other modalities (e.g., the proposed review process, the way to follow the action plan) can also be defined ahead of time. However, these could as well be discussed and agreed on during the meetings. Once the principles are established, there is indeed a benefit to creating some flexibility in the IBC operation in order to be as reactive and effective as possible in dealing with the subjects addressed.

## 4.3. A few specific issues

IBCs that have been running for some years, in Pakistan and elsewhere, tend to face some specific issues. There is some advantage in being aware of them before they present and, if possible, integrating means to cope with them in the functioning of the IBC.

The first issue is *business continuity*. The business continuity of an IBC, or its way of functioning effectively, could be compromised by a number of events, such as organizational changes at the level of senior management or affecting some members of the committee, the departure of experts (including the BSO), etc. Such situations occurred during this project, slowing down the process of launching the IBC or impacting the IBC's effectiveness. All such situations cannot be anticipated, but some readiness can be useful, if only for simplifying administration. For instance, the composition of the IBC (see 3.5) could be defined in the ToRs in specifying titles and functions rather than names, if this is possible; it may not be the case for the NBC-registered IBCs. Otherwise, backup individuals could be identified to replace members who could not attend a meeting. If IBC members are expected to change over time (as in a very flexible or moving environment), it may also be useful to establish mandates with a pre-established duration (e.g., two or three-year mandates that could be renewed) to avoid the circumstance that too many members would leave the committee at the same time. Also, the meeting agenda could include a point on organizational matters to cover such issues, as in the example provided in Box 17.

Directly linked with business continuity is *capacity building* within the IBC, and therefore in the institution. One important aspect of operating an IBC in an organization is to *develop specific expertise* in biorisk management when treating the various subjects involved, for the obvious benefit of the institution. From this standpoint, it is certainly worth connecting with

other institutions and experts to benefit from some cross-fertilization. This was an objective of these IBC projects and is one of the main purposes of PBSA. It can also be fruitful for an institution to invite external experts to its IBC to complement its own experience in biosafety and biosecurity, as in the example provided in Box 10.

The appointment of a BSO is also an essential element of building specific biorisk management expertise. However, the position of BSO requires diverse scientific, technical and management competencies that are not easily available at the moment in Pakistan. This is a reality confronted by an institution that lost its BSO as well as the ones which tried to hire a BSO during this project. This means that the person designated as BSO needs himself/herself to be involved in a capacity building process. From this point of view, as discussed during the workshops, it may be easier and more interesting for an institution to select as BSO someone who has strong motivation, good behavioral skills (e.g., thinking, communication) and the willingness to learn, rather than trying to find an already fully-developed biosafety expert (provided such a profile exists). Similarly, it is good to offer that person opportunities to get trained, knowing that training in such a field also involves a lot of learning from doing.

Perhaps a last aspect related to business continuity is the *motivation* of the IBC members. Personal motivations can be very diverse, but what can be a major and positive motivation for many is to be part of a group that has a significant impact on the conditions of work of their peers, and on the functioning of their institution.


PAKISTAN BIOLOGICAL
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