

University Health & Safety Arrangements: Chapter 3

	Managing biological safety (including work on genetically modified organisms)
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Key word(s):	Biological Agent, Genetically Modified Organism (GMO), Biohazard, Local Genetic Modification and Biohazards Safety Committee (Local GM/Bio Safety Committee), Local Biological Safety Advisor (BSA), Faculty Biological Safety Manager (FBSM), University Biological Safety Advisor (UBSA), University Genetic Modification and Biohazards Safety Advisory Group (GMBioAG).
Target audience:	All those who approve, manage and monitor work with biological agents and genetically modified organisms, and all those who work with such agents or provide advice on this area.

Contents

Introduction	2
University Genetic Modification and Biohazards Safety Advisory Group:	2
Responsibilities of the University Biological Safety Advisor (UBSA):	4
Responsibilities of the Head of School (HOS) or equivalent:	4
Responsibilities of the Chair of the Local Genetic Modification and Biohazard Safety Committee:	5
Responsibilities of the Local Biological Safety Advisor (BSA):	6
Responsibilities of the Principal Investigator (PI):	7
Responsibilities of All who work with Biological Agents (including GMOs):	8
Overall procedure for determining risks and approving work activities involving Biological Agents and GMOs:	8
Diagram 1 – Completion and submission of Application / Risk Assessment forms:	11
Diagram 2 - Approval Process for Work with Biological Agents:	12
Table 1 – Route of approval based on nature of Biological Agents and level of risk:	13

Note.

"Senior Managers" are responsible for health and safety within their organisational unit, specified areas or as a consequence of their activities, and for any additional activities as agreed and delegated to them (eg where they accept responsibility for day-to-day safety arrangements for staff who have other line managers, for reasons of geographical or other convenience). They may be Deans, Heads of School, Directors of Institutes, Directors and Heads of Service in non-academic areas, the University Librarian, the Directors of the Manchester Museum and The Whitworth, and their equivalents.

Introduction

1. The University carries out work with biological agents (including genetically modified organisms) during the course of its teaching and research in a number of Faculties, Schools and Institutes.
2. This chapter describes the framework for managing such activities within the University, and outlines the responsibilities of different personnel who approve, manage and carry out work involving biological materials, as well as those who monitor and provide advice on these matters.
3. Faculties or Schools and Institutes that carry out work with biological agents are required to have arrangements in place to approve and monitor this work by means of Local Genetic Modification and Biohazards Safety committees. Local GM/Bio Safety Committees provide minutes to, and attend the University Genetic Modification and Biohazards Safety Advisory Group, which in turn reports to the University Health Safety and Wellbeing Committee as a means of providing assurance.
4. Advice on meeting statutory requirements is further provided by the University Biological Safety Advisor who also acts as a single point of contact with regulatory bodies relevant to work with Biological Agents and Genetic Modification.

University Genetic Modification and Biohazards Safety Advisory Group:

Reports to:

Health, Safety and Wellbeing Committee

Purpose:

To advise the Health, Safety and Wellbeing Committee on all matters relating to genetic modification and biohazards relevant to the University's research and teaching activities.

1. **Membership:**

Members:

- An academic colleague appointed by the Registrar, Secretary and Chief Operating Officer as Chair
- An academic colleague appointed by the Advisory Group as Deputy Chair
- Head of Safety Services
- Biological Safety Advisor as Secretary
- Chairs of Local Genetic Modification and Biohazards Safety Committees
- Trade Union Representatives for the University

In attendance (as required)

- Faculty/School/Institute Biological Safety Advisors
- University Safety Coordinators
- Manager of the Biomedical Services Facility
- Nominee of the Director of Estates and Facilities
- Occupational Health Physician or representative

By invitation

- Vice-President for Social Responsibility

Quorum

Majority of the members

2. Terms of Reference:

The University Genetic Modification and Biohazards Safety Advisory Group ([Advisory Group](#)) will:

- Consider all issues regarding genetic modification and biohazards relevant to the University's research and teaching activities.
- Advise the Health, Safety and Wellbeing Committee in relation to any of these issues.
- Submit to the Health, Safety and Wellbeing Committee for its approval, arrangements to ensure the University fulfils its obligations to staff, students and others with respect to all aspects of genetic modification and biohazards.
- Monitor compliance with legislative requirements and local biosafety arrangements, and recommend to the Health, Safety and Wellbeing Committee any action necessary to improve compliance and/or performance.
- Recommend to the Health, Safety and Wellbeing Committee any necessary actions to promote cooperation and communication between the University, its staff and students on any matters within the advisory group's scope.
- Set up working groups, when required, in order to achieve specific objectives
- Review these terms of reference every three years or on significant change and recommend appropriate revision as necessary.

The University Genetic Modification and Biohazards Safety Advisory Group must meet a minimum of three times a year.

Responsibilities of the University Biological Safety Advisor (UBSA):

- Ensure the University arrangements meet all of the latest statutory requirements.
- Report on the compliance with biological safety regulations.
- Review and analyse biological / GM safety training needs.
- Deal with issues raised by external agencies, including the Health and Safety Executive and the Counter-Terrorism Unit on biosafety and biosecurity.
- Act as a single point of contact with relevant regulatory bodies including notification relating to Biological Agents and GMO activities. Liaise between regulatory bodies and Principle Investigators (PIs) with respect to notifications.
- Contribute to the University Health, Safety & Wellbeing Committee, GM/Bio Safety Advisory Group and other committees where specialist understanding of work involving pathogens and GMOs is required.
- Act as Secretary to the University Genetic Modification and Biohazards Safety Advisory Group.
- Direct investigations into reported incidents concerning biological agents and GMOs and make recommendations, where necessary.

Responsibilities of the Head of School (HOS) or equivalent:

- Ensure that the local arrangements for biosafety management including GM activities are developed in line with the UoM [Organisation to implement the University's health and safety policy](#), and that they meet the requirements of this chapter and are described in the School or Institute policy. This should include details of the local Genetic Modification and Biohazards Safety Committee's membership and areas of responsibility.
- Ensure that there is a terms of reference document for each Local Genetic Modification and Biohazards Safety Committee that meets [University guidance](#).
- Ensure that each Local Genetic Modification and Biohazards Safety Committee is appropriately constituted and a Chair (with deputy) appointed.
- Sit on the Local Genetic Modification and Biohazards Safety Committee or use alternative methods to gain assurance from the Chair that the committee is functioning adequately.
- Provide the Local Biological Safety Advisor¹ with a letter of appointment

¹ The reference to Local Biological Safety Advisor (BSA) throughout this document may also be interpreted as Faculty Biological Safety Manager (FBSM), depending on local arrangements.

defining their role and areas of responsibility, in accordance with local arrangements

- Sign as necessary the CU2 statutory notification form for GM activities, the CBA1 notification of the use and consignment of biological agents. Ensure that SAPO licence application forms with respect to Specified Animal Pathogens are signed by appropriate personnel (*as for personal licences*).

Responsibilities of the Chair of the Local Genetic Modification and Biohazard Safety Committee:

- Ensure that the [Local Genetic Modification and Biohazard Safety Committee](#) meets regularly and that minutes and relevant papers are distributed to members.
- Ensure that the Heads of School or equivalent are provided with the minutes of the committee meetings and is informed of significant concerns, as well as points to note / consider.
- Ensure local arrangements are in place to advise on, review and approve application/ risk assessments for work with biological agents (inc GMOs), and to identify any requirements for further consultation with the Advisory Group or notification to the regulatory body.
- Ensure that the Principal Investigators (and the relevant local BSAs) are informed of the approval status of their application and risk assessment.
- Monitor the inspection programme and highlight significant findings and action taken in local minutes.
- Discuss findings and wider lessons learnt from investigations of adverse events (accidents/incidents/near misses) and non-conformances involving Biological agents and GMOs. Liaise and communicate on these matters with others as appropriate (including Faculty/School H&S committees).
- Provide finalised or Chair approved minutes for submission to the University GM/Bio Safety Advisory Group as necessary.
- Submit a summary/compliance report or use other means of providing assurance to the GM/Bio Safety Advisory Group to highlight pertinent matters from the local committee meeting minutes.
- Attend (or send a representative to) the GM and Biohazards Safety Advisory Group meeting, and provide feedback to the relevant Local Genetic Modification and Biohazards Safety Committee for further dissemination.

Responsibilities of the Local Biological Safety Advisor (BSA)²:

- Advise staff and students on matters including laboratory design and the use, containment requirements, transport, storage, and disposal of biological materials that pose a hazard to human health or the environment. Assist in the provision of training to further support these matters.
- Provide advice on application / risk assessments to work with biological agents (inc. GMOs), and direct completed applications toward the appropriate approval process according to the agents involved and level of risk. Review, approve or direct applications to other parties for consideration and approval as appropriate.
- Attend the Local Genetic Modification and Biohazards Committee.
- Keep a register of all human, animal and plant pathogens, toxins, GM activities and other activities including GM activities which form part of a "connected programme of work".
- Draw up an annual inspection plan with consideration to the hazardous nature of the work, and report progress along with any deficiencies identified during inspections to the Head of School (or equivalent), and Local GM/Bio Safety Committees.
- Monitor the effectiveness of the day-to-day supervision for work with biological agents in the School and compliance with relevant regulation and guidance.
- Liaise with the relevant Head of School or equivalent to investigate accidents involving hazardous biological materials and with the University Biological Safety Advisor with regards to reporting serious accidents/occurrences to the HSE.
- Ensure records of employees exposed to Hazard Group 3 biological agents are maintained (via Occupational Health).
- Inform the University Biological Safety Advisor where any biological hazards exist which may pose a threat to House Services staff, contractors, maintenance personnel or fire fighters in the course of their duties.
- Ensure there are adequate arrangements in place to cover emergencies associated with biological hazard.
- Ensure the archiving of relevant safety records relating to work with biological material such as servicing and testing certificates, risk assessments, standard operating procedures, any written safety arrangements and minutes of meetings where appropriate.

² The reference to Local Biological Safety Advisor (BSA) throughout this document may also be interpreted as Faculty Biological Safety Manager (FBSM), depending on local arrangements

- Review regularly the local health and safety policy with respect to biological safety.

Responsibilities of the Principal Investigator (PI):

- To ensure University governance processes are followed based on an assessment of the nature of the biological material and its hazardous properties as indicated in the approval process detailed [later](#).
- Complete and sign the appropriate University application/risk assessment [forms](#) , and submit to the Local BSA to begin the approval process. Carry out any changes recommended by the Local BSA, Local Genetic Modification and Biohazards Safety Committee, or University GM Bio Advisory Group.
- Attend the Local Genetic Modification and Biohazards Safety Committee meeting or send an appropriate representative when their application/risk assessment is being considered or when requested by the local Chair.
- Where directed (by Local GM/Bio committee or UBSA), complete application forms for notification of intended work with biological agents/GMOs (eg CU2, [SAPO](#), CBA1). Submit CU2 and CBA1 applications to the UBSA for forwarding to the relevant regulatory body. Liaise with the UBSA on progress of notifications and provide further information if/as required. Ensure that the UoM Regulatory Compliance Team is kept informed of SAPO licence applications and amendments.
- Ensure that appropriate application / risk assessment forms have been approved and any required notification has been acknowledged or consent received (as appropriate) prior to commencing work.
- Inform the University Biological Safety Advisor of any intention to work with any material covered by [Schedule 5](#) of the Anti-terrorism, Crime and Security Act 2005 (ATCSA), and comply with any recommendations regarding security of biological material made by the UBSA or Local Counter Terrorism Security Advisor (CTSA).
- Ensure that any relevant [licences or certificates](#) relating to importing material ([plant](#) or [animal](#)) for scientific research are in place, eg DEFRA, Animal and Plant Health Agency (APHA), [Phytosanitary Certificate](#).
- In line with the UoM [Organisation to implement the University's health and safety policy](#), ensure that risk assessments are reviewed and kept up to date, and that control measures are implemented and continue to be effective.
- Ensure all personnel involved in biological work are appropriately trained and/or competent for the activities undertaken, and receive adequate levels of supervision.
- Ensure all personnel carrying out biological work comply with all relevant risk assessments, local rules and other biosafety related documents.

- Ensure that laboratory personnel are referred to Occupational Health for health surveillance and vaccination in line with Risk Assessment details, and in accordance with university guidance.
- Upon termination of the project ensure that all biohazardous material has been appropriately disposed of and this process documented.
- Attend relevant training if advised by the Local Genetic Modification and Biohazards Safety Committee.

Responsibilities of All who work with Biological Agents (including GMOs):

- To comply with this Chapter and local policies, rules and arrangements relating to working safely with biological agents and GMOs.
- To work within the details set out in approved risk assessments relating to their experimental work.
- To follow information, instruction and training provided by Principal Investigator, line manager Faculty BSM and local BSA.
- To inform the Principal Investigator, line manager, Faculty BSM or local BSA of any accidents, incidents or near misses or other safety concerns involving work with biological agents or GMOs.
- To undergo health surveillance and follow advice provided by Occupational Health in line with local policy and university guidance.

Overall procedure for determining risks and approving work activities involving Biological Agents and GMOs:

- The process for applying to work with³ Biological Agents⁴ including Genetically Modified⁵ Organisms and approval to carry out such activities is outlined in [diagram 1](#) and [diagram 2](#). All applications/risk assessments are initially submitted to the Faculty Biological safety Manger or Local Biological Safety Advisor, who may recommend changes prior to directing to the relevant approval process.
- Depending on the level of risk determined by the assessment submitted and the type of work that is planned, some lower risk activities are reviewed and approved by the Faculty Biological Safety Manger or Local

³ For new work and significant change to previously approved work.

⁴ A biological agent is defined in [COSHH](#) as: ‘a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, toxicity or otherwise create a hazard to human health.

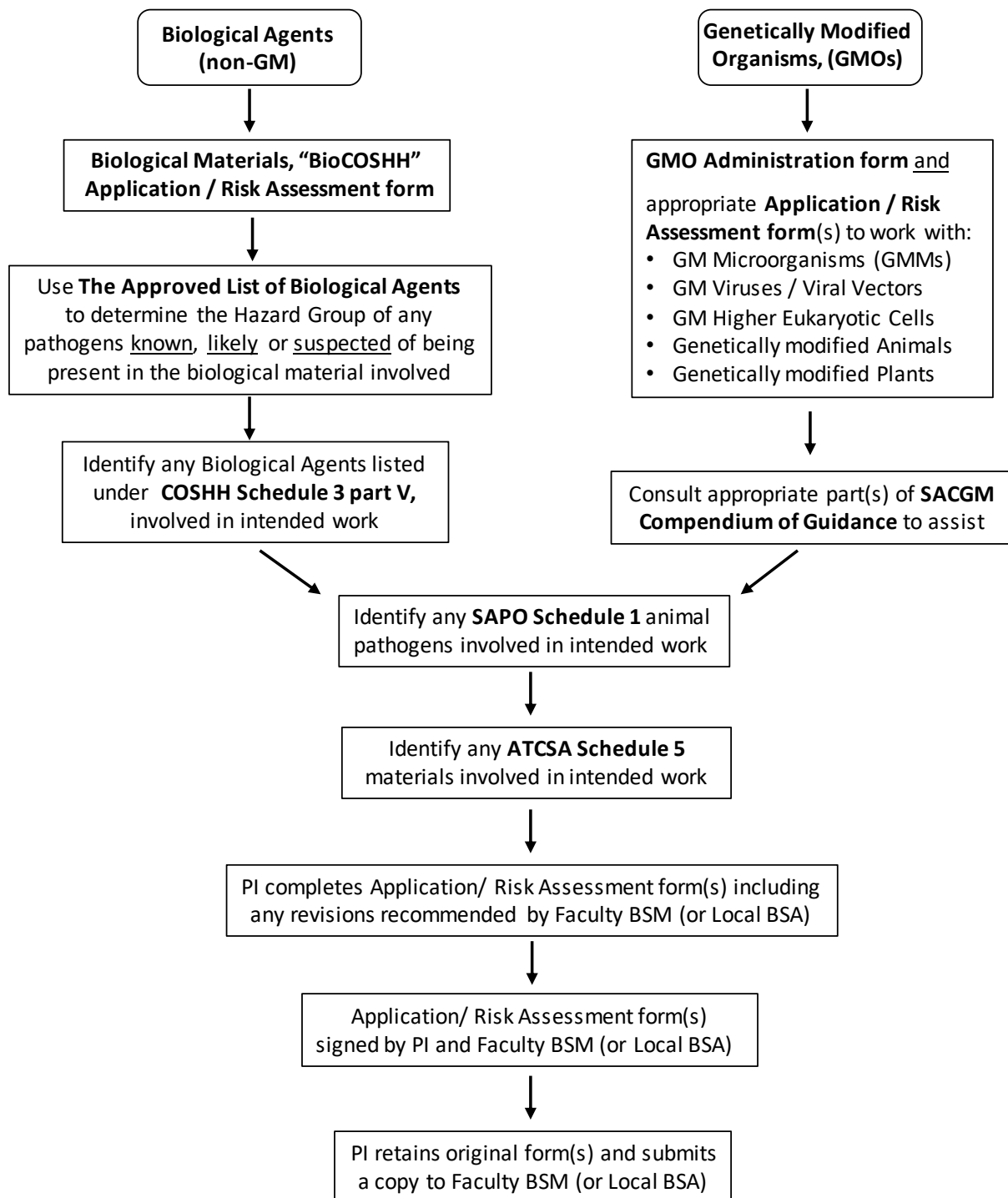
⁵ “genetic modification” according to [The Genetically Modified Organisms \(Contained Use\) regulations](#), in relation to an organism means the altering of the genetic material in that organism in a way that does not occur naturally by mating or natural recombination (or both). Genetic modification occurs at least through the use of the techniques listed in [Part 1 of Schedule 2](#):

Biological Safety Advisor, see [table 1](#). Whereas other applications must be reviewed and approved by the Local GM/Bio Safety Committee and may involve consultation with the Advisory Group if deemed necessary by the UBSA, Local BSA or Local Committee members.

- Some activities involving Biological Agents and GMOs will require notification to the relevant regulatory body, and receipt of acknowledgement or consent before the activity can go ahead. Work with some materials may require confirmation of particular arrangements in relation to Anti-Terrorism and Security requirements.
- Any laboratory activity involving a biological agent (non-GM) which appears either on the "[Approved List of Biological Agents](#)" or micro-organisms listed on the [Specified Animal Pathogens Order](#) must be risk assessed using the University ("BioCOSHH") [application form](#). The Biological Hazard Group must be identified from the Approved List, and it should be noted if the pathogen is listed in [SAPO Schedule 1](#) as well as [Schedule 3, Part V of COSHH](#).
- Biological material including clinical samples and cell cultures which are known to contain, may contain or are suspected of being contaminated with a biological agent which appears either on the "Approved List of Biological Agents" or micro-organisms listed on the Specified Animal Pathogens Order, must also be risk assessed using the [University application form](#) ("BioCOSHH" form).
- A [CBA1](#) form must also be completed for notification of use of Biological Agents under COSHH, when directed by the UBSA or Local GM/Bio Safety Committee.
- Any activity involving genetically modified biological agents (including SAPO micro-organisms) must be risk assessed using the [GM organism administration form](#) together with the [GM micro-organism form](#), the [GM higher eukaryotic form](#) and/or the [GM virus/viral vector form](#) as appropriate, in order to establish the GM Class involved.
- Where the activity involves the genetic modification of either plants or animals (larger GMOs), then the [GM animal form](#) or [GM plant form](#) along with the [GM organism administration form](#) must be completed.
- Planned activities involving GM Class 2 and Class 3 work, as well as larger GMOs which pose greater risk to human health than the wild-type (non-GM form of the organism), also require notification to the regulatory body using the [CU2 form](#). Any requirement for this will be directed by the UBSA or Local GM/Bio Safety Committee.
- If the planned activity is part of a "connected programme" of work which has previously been notified to the HSE, further notification will not be required. However this must be confirmed by the UBSA or Local GM/Bio Safety Committee.

- In cases of applications for GM Class 2 or Class 3 activities that involve certain aspects determined as Class 1 work, Class 1 activities may begin immediately on approval by the FBSM / Local BSA.
- For micro-organisms (non-GM and GM) listed on the [Specified Animal Pathogens Order](#), the [SAPO1 form](#) must be completed as/when directed by the UBSA or Local GM/Bio Safety Committee.
- Any planned work involving micro-organisms or other materials listed on [ATCSA Schedule 5](#), must be brought to the attention of the Faculty BSM/Local BSA as well as the UBSA, in order that any necessary coordination with the Local Counter Terrorism Officer can be arranged.
- Work (including storage of Biological agents and GMOs) must not commence until all the appropriate application / risk assessment forms have been approved and any required notification has been acknowledged / consent received (as appropriate). This also includes any Licences and Phytosanitary Certificates for importation of materials into the UK.

Diagram 1 – Completion and submission of Application / Risk Assessment forms:



Selection and completion of University Application/Risk Assessment for new* work with Biological Agents including GMOs, (*or significant change to previously approved activities)

Diagram 2 - Approval Process for Work with Biological Agents:

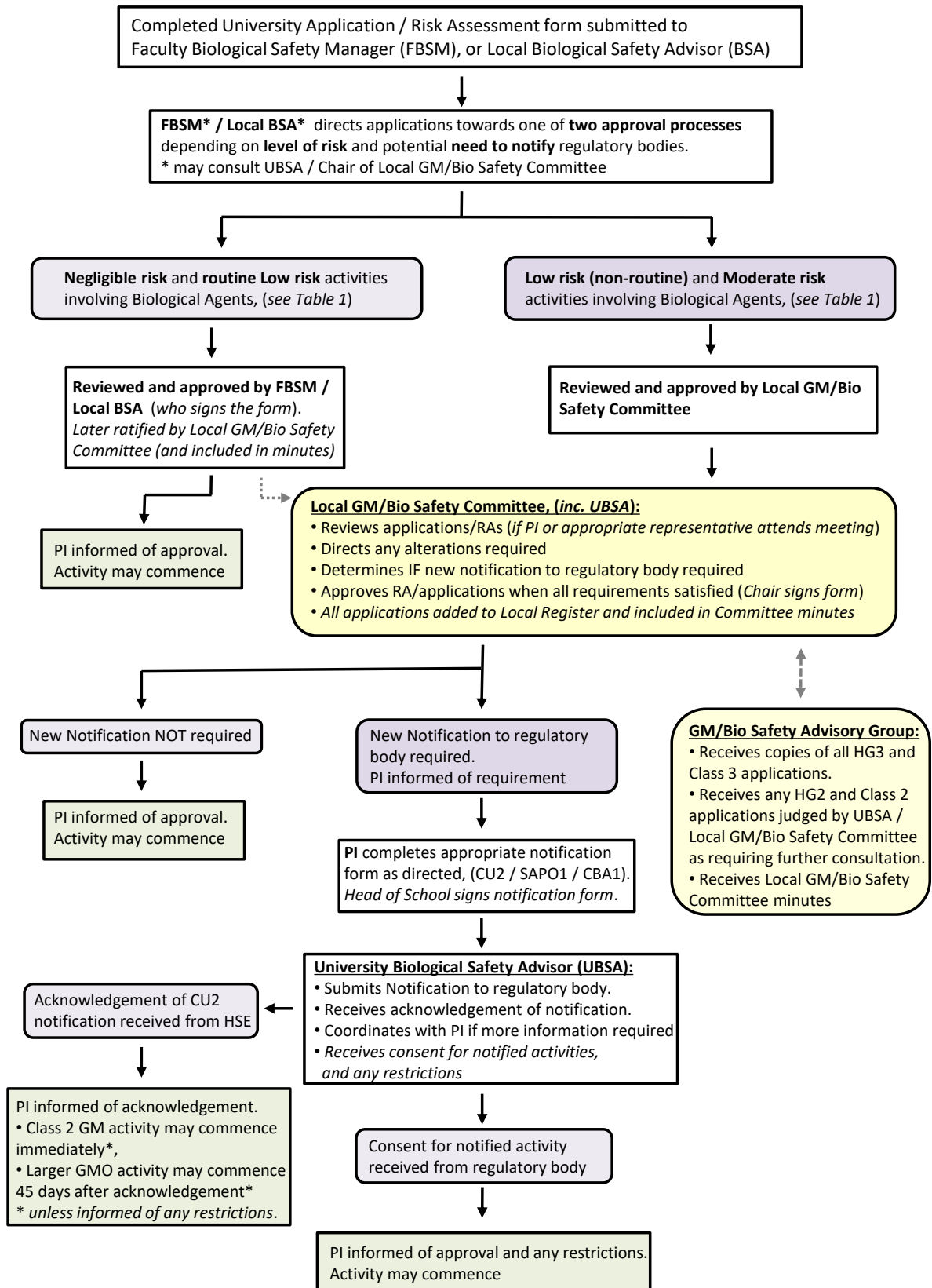


Table 1 – Route of approval based on nature of Biological Agents and level of risk (determined by assessment):

Negligible risk and routine Low risk activities approved by the FBSM / Local BSA	Low risk (non-routine) and Moderate risk activities approved by the Local GM/Bio Safety Committee
<ul style="list-style-type: none"> • Hazard Group 1 Biological Agents. • "Routine Hazard Group 2" work, eg using well characterised clinical samples / cell lines / other materials not suspected of being contaminated with Hazard Group 3, COSHH Sched 3 part V, SAPO Sched 1, ATCSA Sched 5 agents. • Class 1 GMOs (GMM, Viral, Higher Eukaryotic cells). • Larger GMO (animals/plants) with no greater risk to human health than wild-type (non-GM form of organism), and not posing risk to the environment. 	<ul style="list-style-type: none"> • Hazard Group 2 and Hazard Group 3 agents (Approved List), including agents listed on COSHH schedule 3, part V. • Samples or material which may contain Hazard Group 3, COSHH Sched 3 part V, SAPO Sched 1, ATCSA Sched 5 agents. • Class 2 and Class 3 GMOs (GMM, Viral, Higher Eukaryotic cells). • Larger GMO (animals/plants) posing greater risk to human health than wild-type, and/or posing risk to environment. • Pathogens listed on SAPO schedule 1 (non-GM and GM). • Material listed on ATCSA schedule 5 (non-GM and GM). • <i>Anything else advised by the Faculty BSM / Local BSA, or UBSA.</i>

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