University Health & Safety Arrangements: Chapter 3

Managing biological safety (including work on genetically modified organisms)

Key word(s):	GMOs, Contained Use Regulations, Local Biological Safety Advisor (BSA), University Biological Safety Advisor/Officer
Target audience:	All those managing work with biological agents and genetically modified organisms, and working with such agents.

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University Genetic Modification and Biohazards Safety Advisory Group

1. Membership

Members:
Professor S. Turner (Chair)
Dr C. Hillarby (Deputy Chair)
Dr Jonathan Gawn (ex officio, Secretary), University Biological Safety Officer
Chairs of Local Genetic Modification and Biohazards Safety Committees
Trade Union Representatives for the University

In attendance:
Head of Safety Services
Manager of the Biomedical Services Facility
University Safety Co-ordinators
School Biological Safety Advisors
Representative of the Director of Estates
Occupational Health Physician

By invitation
Associate Vice President for Compliance, Risk and Research integrity

2. Terms of reference

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

- advise the University Safety, Health & Environment Committee on all matters relating to genetic modification and biohazards associated with research and teaching.
- monitor compliance with legislative documents and local biosafety arrangements, and recommend to the University Safety, Health & Environment Committee any action necessary to improve compliance and/or performance.
- promote cooperation and communication between the University, its staff and students in all matters relating to GM and biohazards.

Overarching biosafety management

3. Responsibilities of the Principal Investigator:

3.1. To ensure proper administrative procedures, based on an assessment of the nature of the biological material and its hazardous properties as indicated in Diagram 1 and the approval process detailed in section 6 below.

3.2. Where appropriate, submit statutory notification forms to the Local Genetic Modification and Biohazards Safety Committee for approval, using the appropriate University application and risk assessment forms and carry out any recommended changes by the committee.

3.3. Ensure that appropriate application and risk assessment forms are in place and approved before commencing work.

3.4. Ensure all personnel involved in biological work are appropriately trained, including induction training, and supervised.

3.5. Ensure all personnel carrying out biological work comply with all relevant risk assessments and other biosafety related documents.

3.6. Attend the Local Genetic Modification and Biohazards Safety Committee meeting or send an appropriate representative when their notifiable activity is being considered or when requested by the local Chair.

3.7. Attend relevant training if advised by the Local Genetic Modification and Biohazards Safety Committee.

3.8. Provide the Local Genetic Modification and Biohazards Safety Committee with a copy of any personal licences issued by statutory bodies such as SAPO or DEFRA.

3.9. Inform the University Biological Safety Officer of any intention to work with Schedule 5 material and comply with any recommendations made by the Biosecurity Working Group.

3.10. Upon termination of the project ensure that all biohazardous material has been appropriately disposed of and this process documented.

3.11. Ensure that laboratory personnel are subject to medical screening by Occupational Health in accordance with University guidance.

4. Responsibilities of Head of School or equivalent:

4.1. Ensure that the local arrangements for biosafety management including GM activities are described in the School or Institute policy. This should include the local Genetic Modification and Biohazards Safety Committee's membership and its areas of responsibility.

4.2. Provide the local Biological Safety Advisor with a letter of appointment defining his/her roles and areas of responsibility.

4.3. Ensure that there is a terms of reference document for each Local Genetic Modification and Biohazards Safety Committee that meets University guidance.

4.4. Ensure that each Local Genetic Modification and Biohazards Safety Committee is appropriately constituted and a Chair appointed.

4.5. Sit on the Local Genetic Modification and Biohazards Safety Committee or use alternative methods to establish that the committee is functioning adequately.

4.6. To sign the CU2 statutory notification form for GM activities and the CBA1 notification of the use and consignment of biological agents as necessary.

5. Responsibilities of the University Biological Safety Officer (UBSO)[1]

5.1. Ensure the University arrangements meet all of the latest statutory requirements.

5.2. Report on the compliance with biological safety regulations.

5.3. Review and analyse biological / GM safety training needs.

5.4. Deal with issues raised by external agencies, including the Health and Safety Executive and the Counter-Terrorism Unit on biosafety and biosecurity.

5.5. Contribute to the University Safety, Health & Environment Committee, Advisory Group and other committees where specialist understanding of work involving pathogens and GMOs is required.

5.6. Act as Secretary to the University's Genetic Modification and Biohazards Safety Advisory Group.

5.7. Direct investigations into reported incidents concerning biological and GM agents and make recommendations where necessary.

Biological project assessment and monitoring

6. Overall procedure for determining risks associated with biohazard and GM.

6.1. Any laboratory activity involving a biological agent[2] which appears either on the "Approved List of Biological Agents" or micro-organisms listed on the

[1] The terms "officer" is used within the context of the Compendium of Guidance produced by the Scientific Advisory Committee on Genetic Modification, however, for simplicity this term has been used throughout the document in respect to all biological work.

[2] 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.*

Specified Animal Pathogens Order must be risk assessed using the University application form.

6.2. The approval process for applications involving hazard group 1 agents, hazard group 2 agents and hazard group 3 agents must follow the procedure shown for negligible (Diagram 2), low (Diagram 3) and medium risk (Diagram 4) activities respectively.

6.3. For biological agents which are classified as Hazard Group 3 agents and Hazard Group 2 agents listed under Schedule 3, Part V of COSHH , a CBA1 form must also be completed.

6.4. For micro-organisms listed on the Specified Animal Pathogens Order, the SAPO1 form must be completed and the approval process for medium risk activity (Diagram 4) followed.

6.5. Biological material including clinical samples and cell cultures which are likely, knowingly or suspected to be 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 be risk assessed using the University application form and follow the appropriate approval process.

6.6. For routine clinical samples or other biological material which are not knowingly contaminated, the approval process for negligible risk (Diagram 1) must be followed where advised by the local BSA.

6.7. Any biological agent or SAPO micro-organism which has been genetically modified must be risk assessed using the GM organism form together with the GM micro-organism form , the GM higher eukaryotic form or the GM virus/viral vector form as appropriate.

6.8. For GM class 1, 2 and 3 activities, the application approval process for negligible (Diagram 2), low (Diagram 3) and medium risk (Diagram 4) activities respectively must be followed.

6.9. Where the activity involves the genetic modification of either plants or animals then the either GM animal or GM plant form including the GM organism form must be completed.

6.10. Where the genetically modified organism poses a risk to either human health and/or the environment, the approval process for low risk activities (Diagram 3) is followed. If the genetically modified organism does not pose a risk to either human health or the environment, the approval process for negligible risk activities is followed.

Responsibilities of local committees and members

7. Responsibilities of the Chair of the Local Genetic Modification and Biohazard Safety Committee.

7.1. Ensure that the Local Genetic Modification and Biohazard Safety Committee meets regularly and that minutes and relevant papers are distributed to members.

7.2. Ensure that the Head of School(s) or equivalent(s) are provided with the minutes of the committee meetings and that significant concerns are highlighted.

7.3. Ensure that the Principal Investigators (and relevant local BSAs) are informed of the approval status of their application and risk assessment form.

7.4. Provide finalised or Chair approved minutes for submission to the University Advisory Group as necessary.

7.5. Monitor the inspection programme and highlight significant findings and action taken in local minutes.

7.6. To attend (or send a representative) the GM and Biohazards Safety Advisory Group meeting and provide feedback to the relevant Local Genetic Modification and Biohazards Safety Committee.

8. Responsibilities of the Local Biological Safety Advisor (BSA):

8.1. Advise staff and students on laboratory design and the use, containment requirements, transport, storage, and disposal of biological materials that pose a hazard to human health or the environment.

8.2. Attend the Local Genetic Modification and Biohazards Committee.

8.3. Draw up an annual inspection plan with consideration to the hazardous nature of the work and report any deficiencies identified during inspections to the Head of School or equivalent.

8.4. Monitor the effectiveness of the day-to-day supervision for work with biological agents in the School and compliance with relevant regulation and guidance.

8.5. 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".

8.6. Inform the University Biological Safety Officer 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.

8.7. Liaise with the relevant Head of School or equivalent to investigate accidents involving hazardous biological materials and with the University Biological Safety Officer with regards to reporting serious accidents/occurrences to the HSE.

8.8. Ensure there are adequate arrangements in place to cover emergencies associated with biological hazard.

8.9. 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.

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

Diagram 1 - Administrative Procedures Based on Biohazard

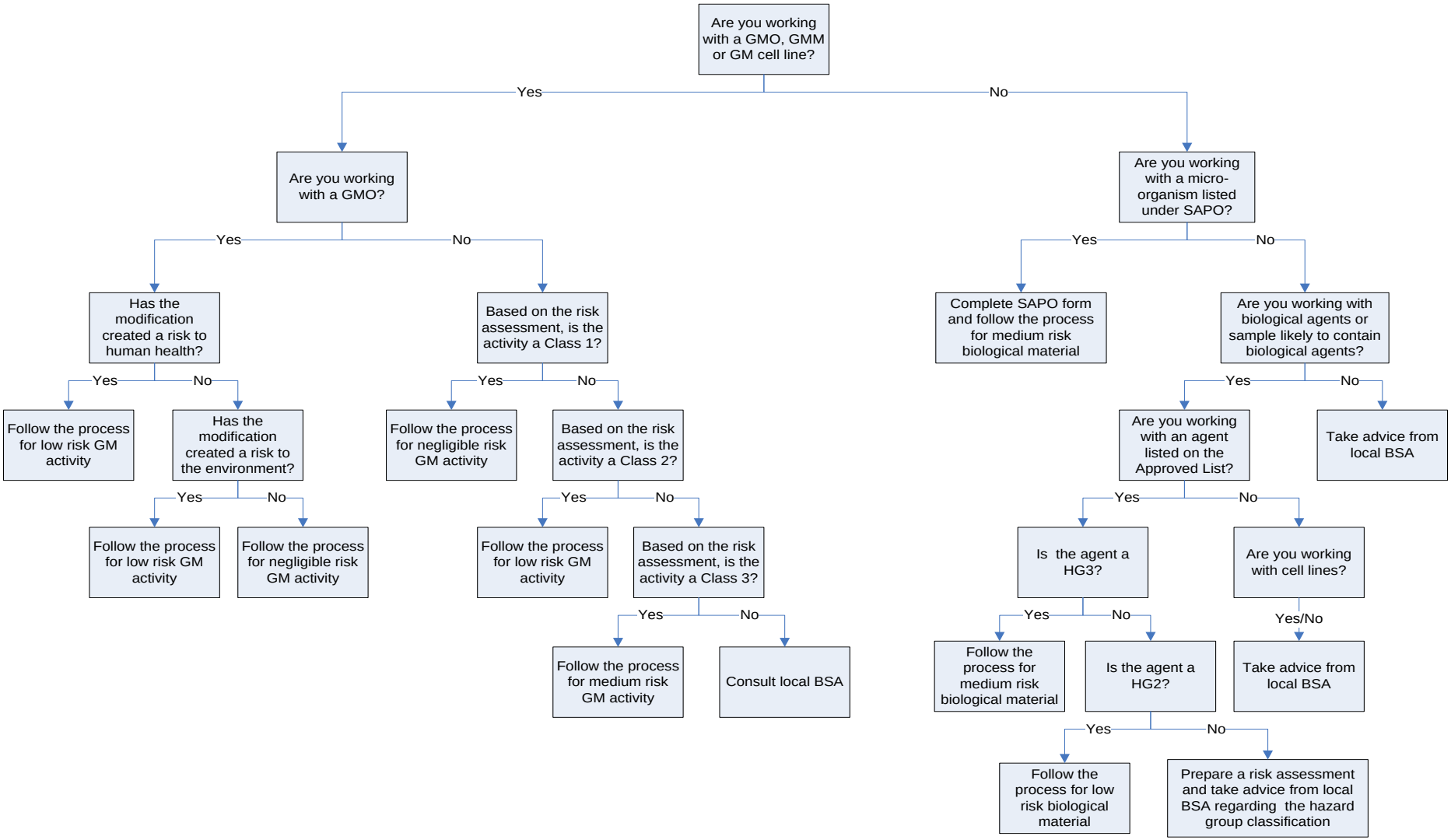
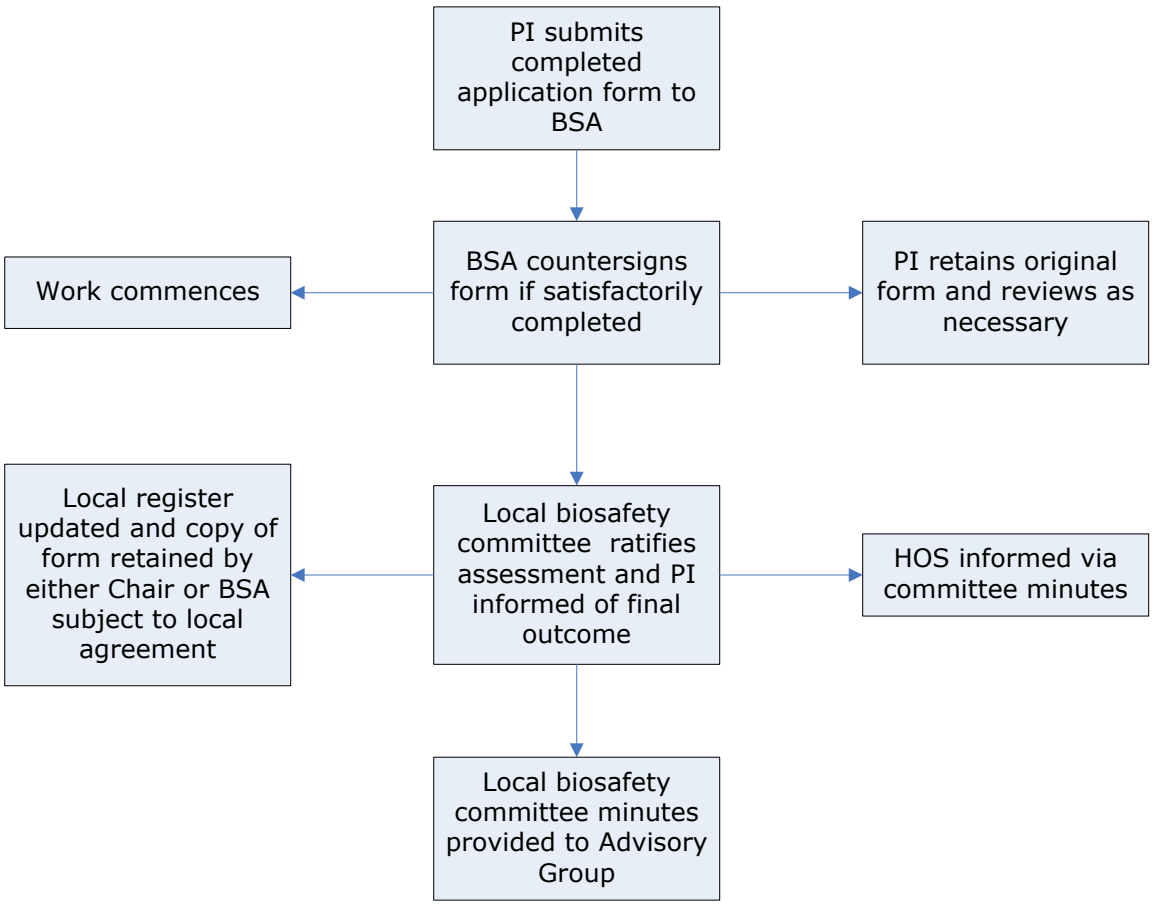
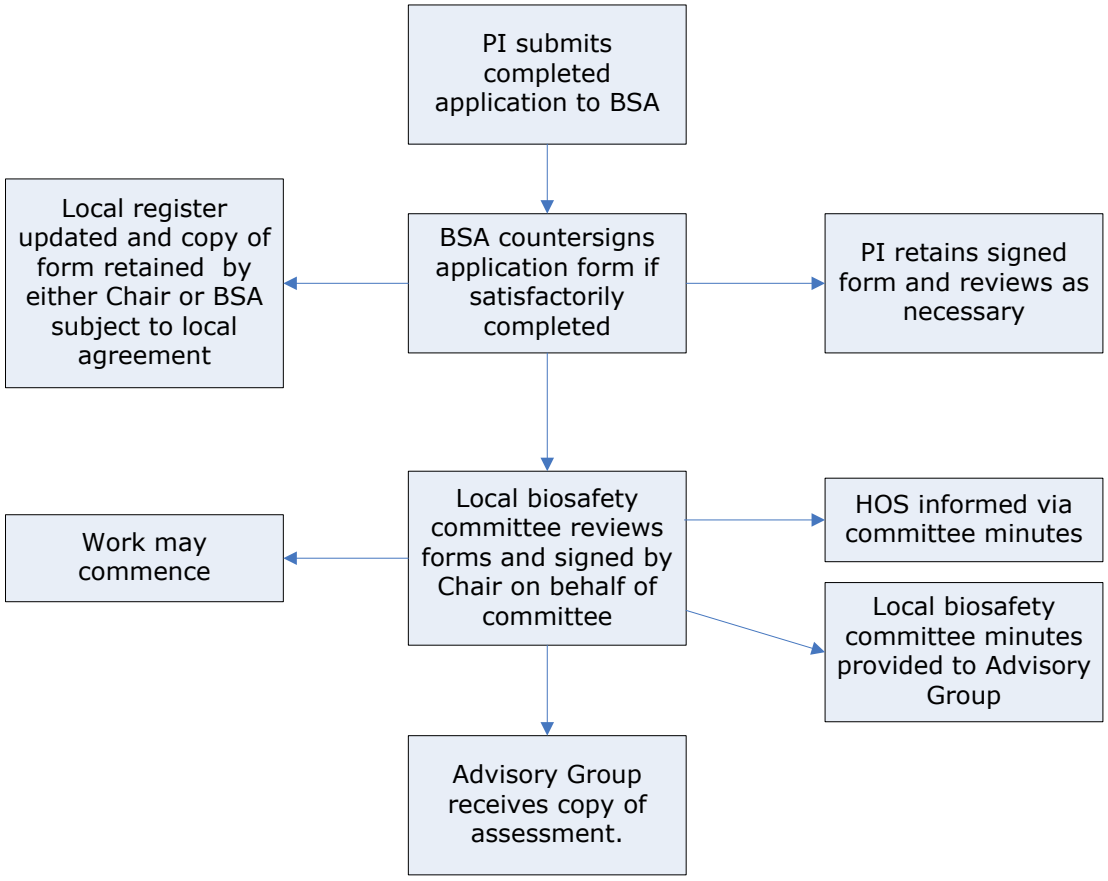


Diagram 2- Approval Process for Activities with Biological Material Posing a Negligible Risk*



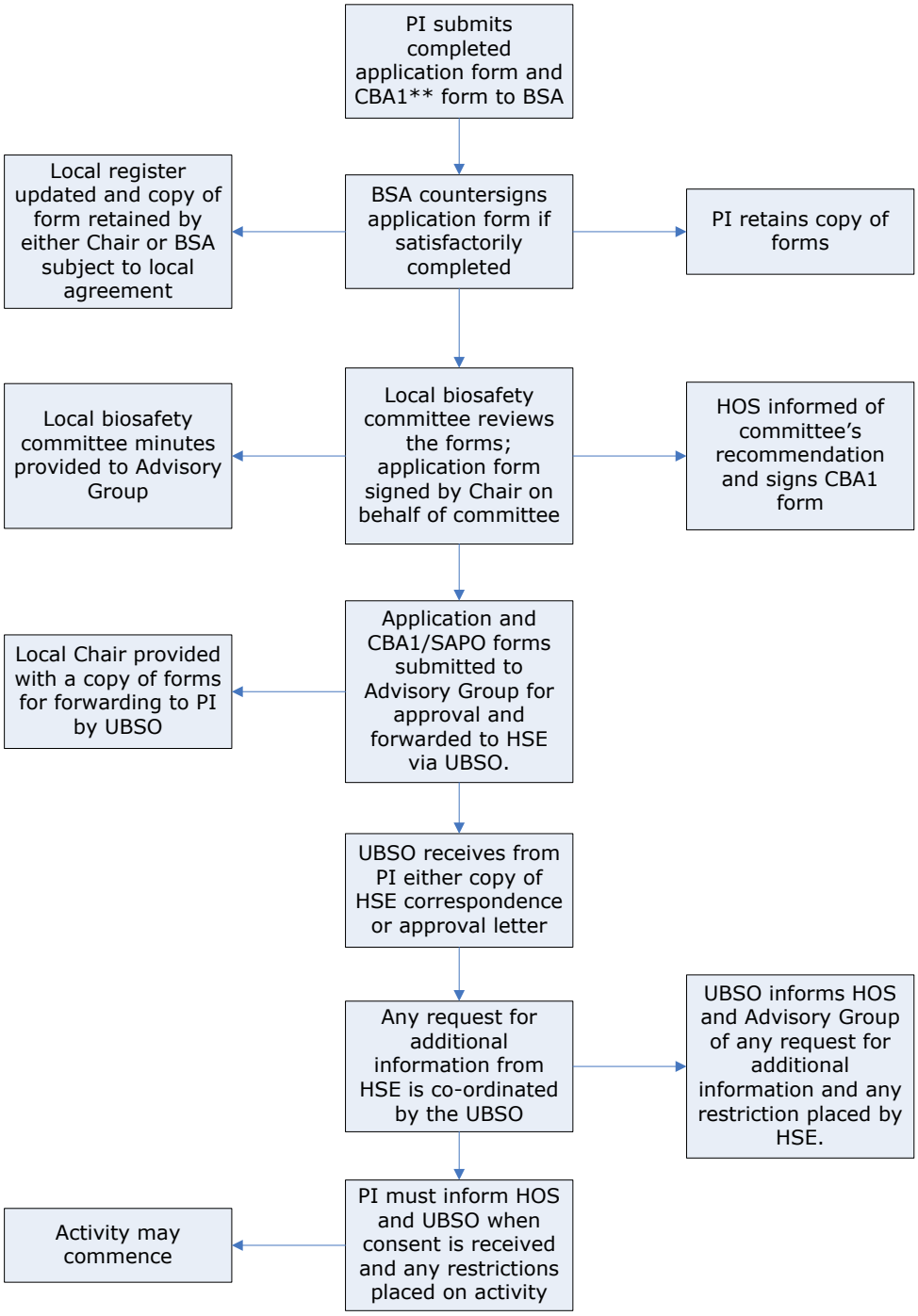
*Hazard Group (HG) 1 agents or where advised by BSA for routine clinical samples which are not knowingly contaminated with a biological agent

Diagram 3 - Approval Process for Activities with Biological Material Posing a Low Risk*



*Hazard Group (HG) 2 agents or uncharacterized clinical samples which are not suspected of being contaminated with HG3 agents.
NB. Excludes Hazard Group 2 agents listed under Schedule 3, Part V of COSHH

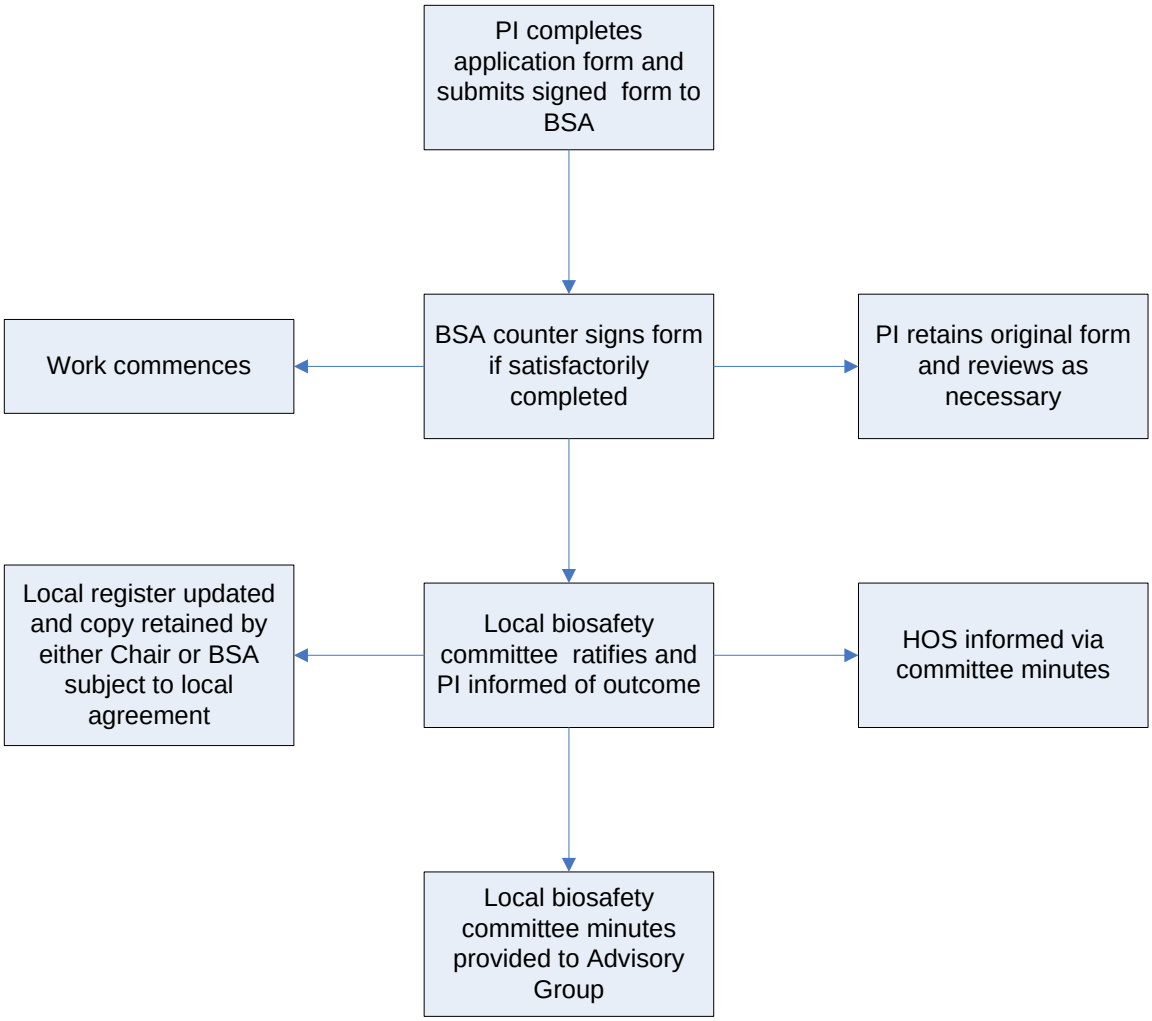
Diagram 4 -Approval Process for Activities with Biological Material Posing a Medium Risk*



*Hazard Group (HG) 3 agents or clinical samples which are suspected of being contaminated with HG3 agents (also including Hazard Group 2 agents listed under Schedule 3, Part V of COSHH)

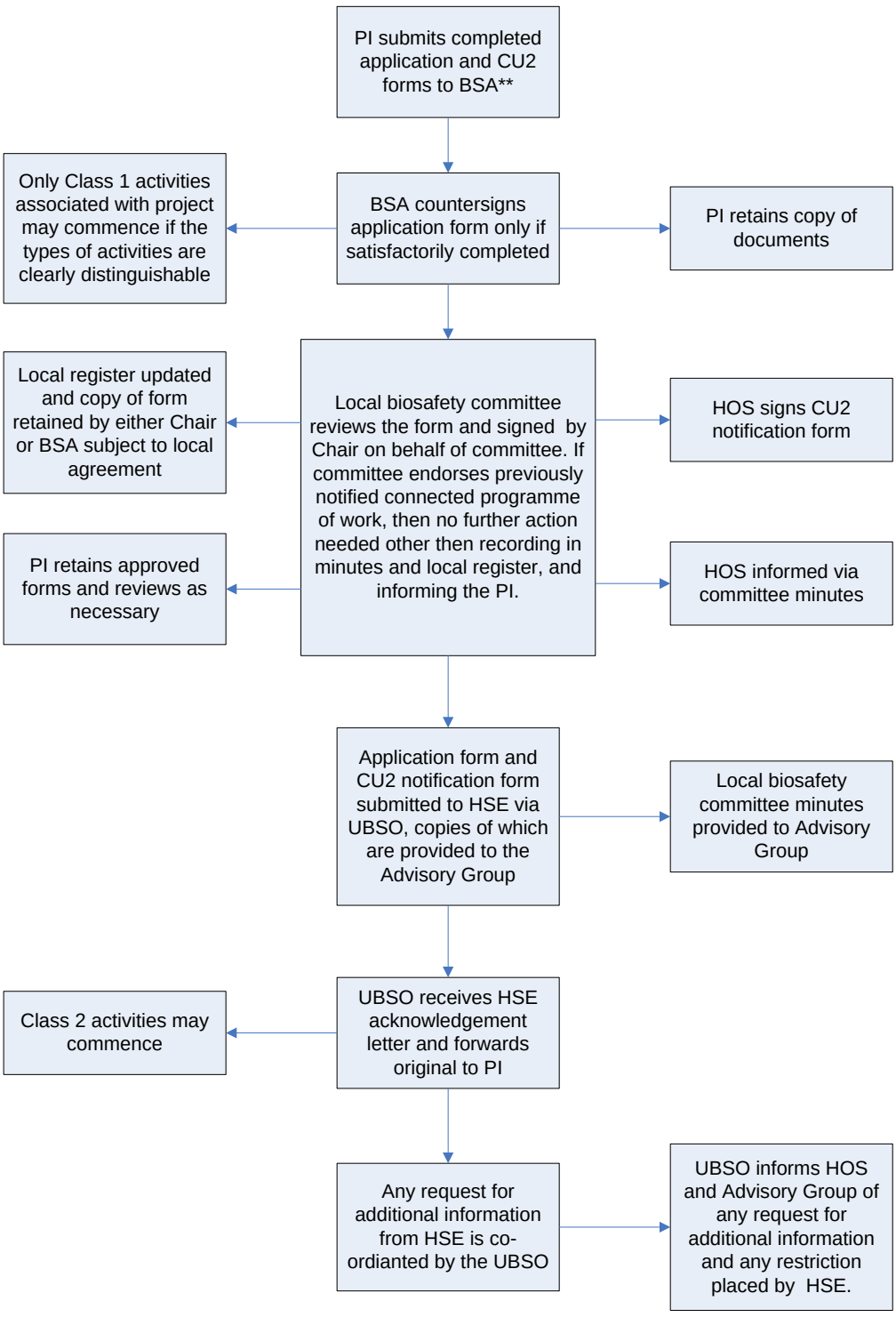
**use of CBA1 form at the discretion of UBSO

Diagram 5 - Approval Process for Negligible Risk GM Activities*



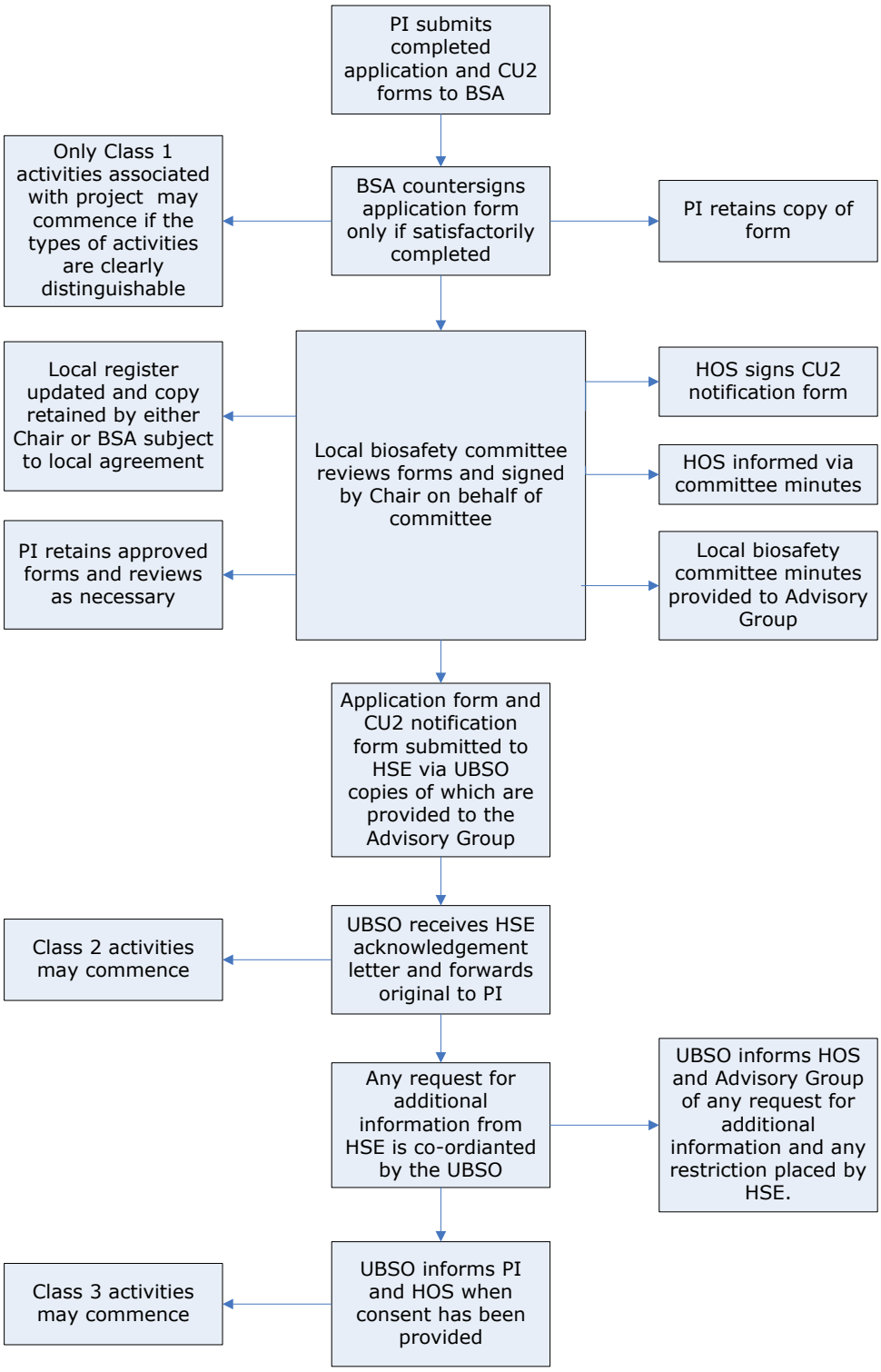
* Negligible risk activities including GM class 1 and transgenic species not posing a risk to human health and the environment

Diagram 6 - Approval Process for Low Risk GM Activities*



* low risk activities including GM class 2 activities and transgenic species posing a risk to human health and/or the environment;
** For activities to be considered as a connected programme of work previously notified to HSE, a copy of the approved CU2 form and HSE letter must be provided;

Diagram 7 - Approval Process for Medium Risk GM activities*



* medium risk activities refers to GM class 3 activities.

Document control box	
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