

## **Work with Genetically Modified Organisms (GMOs)**

### **Memorandum of Agreement and Statement of Responsibilities between:-**

- (1) Queen Mary University of London (QMUL) and
- (2) Barts Health NHS Trust (BHT)

In relation to *peer review advice* on Genetic Modification Organism (GMO) Activities provided by the Biological & Genetic Modification Safety Committee (BGMSC) of QMUL entered into, pursuant to a Memorandum of Agreement (MOA) between QMUL and BHT.

### **1. Introduction and applicable legislation**

- 1.1. The legislation and regulations involved in Genetic Modification Organism (GMO) Activities are noted below in 2.1. The purpose of the legislation is to protect humans and the environment from known, potential and unknown hazards of exposure to GMOs. Particular emphasis is placed on a detailed and thorough risk assessment. This includes the management of clinical and laboratory waste and the measures that will be taken to prevent any actual or potential exposure of people or the environment to the agents involved.
- 1.2. In addition, these regulations cover work involving wild-type micro-organisms and synthetic oligo-nucleotides or genes, *when* they are used for the genetic modification of other micro-organisms, cells or whole organisms and subsequently used in patient / veterinary clinical trials.
- 1.3. BHT and QMUL singularly and collectively undertake research involving the use of genetically modified organisms (GMOs) including plants and animals, genetically modified micro-organisms (GMMs) including cells and other related biological products such as recombinant antibodies, synthetic gene 'bio-bricks'. The term GMO used hereafter will include all these.
- 1.4. The Genetically Modified Organisms (Contained Use) Regulations 2014 requires that duty holders comply with their legal duties in relation to working with GMOs in contained facilities. The Regulations describes the law that applies, sets out the containment measures and other risk controls that need to be considered and explains the role of the competent authority.
- 1.5. Regulation 8 of the Contained Use Regulations state that a person responsible for contained use must obtain advice on a risk assessment from either (a) a person, or (b) a genetic modification safety committee, with expertise in risk assessment relating to Contained Use.
- 1.6. The risk assessment assesses a 'GMO Activity' which involves the creation, use / handling, storage and disposal of a GMO.
- 1.7. Where the risk assessment indicates that the Contained Use is classified as Class 2 or above, the advice must be obtained from a genetic modification safety committee.
- 1.8. Where other related genetic modification and environmental legislation specifies, advice should also be obtained from a competent adviser or committee.

### **2. QMUL Biological & Genetic Modification Safety Committee - Remit and functions at QMUL**

- 2.1 The QMUL Biological & Genetic Modification Safety Committee (BGMSC) fulfils the statutory duties under the Genetically Modified Organisms (Contained Use) Regulations 2014 and other related genetic modification and environmental legislation\*

to ensure safe working with the organisms by QMUL staff, students and others, and to prevent accidental or unintentional human exposure or environmental release.

\* the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (as amended); the Specified Animal Pathogen Order 2008, Section 108 (1) of the Environment Protection Act 1990, The Genetically Modified Organisms (Risk assessment) (Records and Exemptions) Regulations 1996, The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997, The Anti-Terrorism Crime and Security Act 2001, 'Schedule 5'.

2.2 The QMUL BGMSC is comprised of representatives from all QMUL Schools / Institutes / Directorates undertaking GMO work, representatives from partner organisations (such as Barts Health NHS Trust) and is chaired by a senior academic with extensive GMO experience.

2.3 The QMUL BGMSC Chair informs QMUL senior management of the status of GMO activity management by presenting meeting minutes and attending the QMUL Health and Safety Advisory Group.

2.4 The QMUL Biological Safety Adviser functions as the statutory GM Biological Safety Officer (GM BSO) and competent adviser for QMUL and as the Secretary of the QMUL BGMSC.

2.5 The full Terms of Reference can be found at the QMUL BGMSC webpage - <http://www.hsd.qmul.ac.uk/a-z/health-and-safety-advisory-group/health-and-safety-advisory-group/bgmisc/>

### 3. QMUL and Barts Health NHS Trust – General H&S Responsibilities

3.1 Section 2 of the Health and Safety at Work etc. Act 1974 requires employers to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all their employees. The Act also states that employers have a duty of care for the health and safety of their employees who are working in another person's premises.

3.2 Section 3 of the Health and Safety at Work etc. Act 1974 requires employers to conduct their business in such a way as to ensure, so far as is reasonably practicable, that they do not expose people who are not their employees, but who could be affected by the work or the workplace, to unacceptable risks to their health and safety. In the case of QMUL and BHT this applies to visitors, students and contractors. Contractors are persons working on the premises who are employed by a separate employer, or who are self-employed.

3.3 Regulation 11 of the Management of Health and Safety at Work Regulations 1999 requires employers sharing a workplace to *cooperate* and *coordinate* their activities to ensure that workplace health and safety provision is compliant with relevant legislation and that information relating to the risks to the health, safety and welfare of persons working in the undertaking is shared.

3.4 In order to ensure acceptable means of cooperation and coordination are in place, it is important to establish which employing entity is responsible for which aspect of occupational health and safety.

3.5 Therefore, this document sets out the Memorandum of Agreement and Statement of Responsibilities for the *provision of peer review advice* on GMO Activities provided by the BGMSC of QMUL to BHT with respect to the aspects referred to above.

### 4 Management of GMO Activities and Responsibilities of Barts Health Trust

- 4.1 In the absence of a constituted GMSC in BHT and in light of the historical and current collaborative and shared nature of clinical research activities involving GMOs / GMMs between BHT and QMUL, and statutory guidance issued by the Competent Authority (the Health & Safety Executive) to facilitate such provision, the QMUL BGMSC is able to provide BHT with *peer review advice and recommendations* to fulfil the requirements of the Genetically Modified Organisms (Contained Use) Regulations 2014 as a minimum, and where necessary, on other relevant GM and related Environmental legislation noted in 2.1 above.
- 4.2 BHT have (as they are required to by law and/or in accordance with best practice) their own health and safety policy and their own health and safety procedures. Where necessary, such policies and procedures seek to take into account advice and recommendations on Genetic Modification Contained Use Activities and where relevant, other GM and Environmental legislation noted in 2.1 above, given by the QMUL BGMSC.
- 4.3 Where appropriate and necessary, the BHT policy and procedures may be required to stipulate additional requirements on staff working for BHT, in the context of their duties to fulfil the requirements of the Genetically Modified Organisms (Contained Use) Regulations 2014 and where necessary, other related GM and Environmental legislation noted in 2.1 above.
- 4.4 It is BHT's responsibility to ensure the *systems* for adequate training, information, instruction, supervision and when required by risk assessment, health surveillance is provided for BHT staff and others that they are responsible for, in connection with GMO Contained Use Activities.
- 4.5 It is noted that some staff working for QMUL are also employed under contracts with BHT, or have joint or honorary contracts of employment with BHT. This may also occur *vice versa*. Therefore, it is important the roles and responsibilities for the safe management of GMO activities are clearly defined.
- 4.6 The safe management of the GMO activity either at QMUL or BHT is the responsibility of the named GM Project Supervisor (and in their absence, the Deputy GM Project Supervisor). The GM Project Supervisor and the Deputy GM Project Supervisor will be named on the GMO risk assessment form.
- 4.7 The GM Project Supervisor at BHT is accountable to their Head of Department, and through the line management chain to the Chief Executive of Barts Health NHS Trust to ensure that the GMO activity is compliant with the relevant Regulations and through the applied risk controls, ensure that the activity poses negligible risk to humans and the environment.
- 4.8 Where a GMO activity crosses from QMUL into BHT premises and control (and *vice versa*), the primary responsible person *remains* the named GM Project Supervisor. Where for location, task, line management or other justifiable purpose/s the GM Project Supervisor is unable to fulfil the function, either a joint GM Project Supervisor or the Deputy GM Project Supervisor is named in the GMO risk assessment as specifically responsible for those delineated part/s of the GMO activity.
- 4.9 Further responsibilities due to BHT by exclusions from the QMUL BGMSC responsibilities and scope of services are identified in sections 5 and 6 below.

## 5. The Responsibilities of the QMUL BGMSC

- 5.1 *Peer review* of GMO risk assessments submitted under the Genetically Modified Organisms (Contained Use) Regulations 2014, in line with the process and timelines set out in section 17 of the [QMUL GM policy](#) and summarised on the [BGMSC web page](#).
- 5.2 *Provision of accurate, timely advice and information* to the GM Project Supervisor that assists in assuring compliance with the Genetically Modified Organisms (Contained Use) Regulations 2014, and where relevant, other GM and Environmental legislation noted in 2.1 above.
- 5.3 Where necessary, issue a *report with recommendations* for improvements and compliance measures to the GM Project Supervisor.
- 5.4 *Facilitation or provision of training* to GM workers in BHT that enables competence and awareness for the safety of GMO Activities (QMUL courses on GM risk assessment and notification are open to applicable BHT staff, a course fee / charge is payable by those with no QMUL contracts or connection with the proposed GMO work).
- 5.5 *Provision of monitoring by an inspection and report* to the GM Project Supervisor that the facilities, procedures and arrangements for Genetic Modification Contained Use Activities and where relevant, other GM and Environmental legislation noted in 2.1 above are compliant (or non-compliant) with the Regulations.
- 5.6 *Facilitation of the notification of Barts Health Trust premises* under the Genetically Modified Organisms (Contained Use) Regulations 2014 to the Competent Authority (the Health & Safety Executive). These will be notified under the QMUL GM Centre 774 notification.
- 5.7 *Facilitating the notification* of GM Class 2 and above GM Contained Use Activities to the Competent Authority (the Health & Safety Executive).
- 5.8 The QMUL BGMSC will only provide local peer review advice on \*other GM and Environmental legislation and will *not* provide or facilitate any statutory notification/s or compliance reports under these to the relevant Competent Authority.

\* the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (as amended); the Specified Animal Pathogen Order 2008, Section 108 (1) of the Environment Protection Act 1990, The Genetically Modified Organisms (Risk assessment) (Records and Exemptions) Regulations 1996, The Genetically Modified Organisms (Deliberate Release and Risk Assessment-Amendment) Regulations 1997, The Anti-Terrorism Crime and Security Act 2001, 'Schedule 5'.

- 5.9 Peer review advice, compliance reports or any statutory notification for intentional work with 'wild type' biological agents [as defined under the Control of Substances Hazardous to Health (COSHH) 2002 (as amended)] where there is no intention of genetic modification will *not* be provided to BHT by the QMUL BGMSC.
- 5.10 The QMUL BGMSC will not provide any other peer review advice, compliance reports or any statutory notifications for any other health & safety legislation to BHT.

## **6. Scope of Services Provided by QMUL BGMSC to BHT under the Agreement**

- 6.1 *Peer review advice and GMO risk classification* of all GMO Activity projects submitted to the QMUL BGMSC by Barts Health Trust under the Genetically Modified Organisms (Contained Use) Regulations 2014 by means of a completed risk assessment on the QMUL GMO Activity risk assessment template (available from the BGMSC webpage). This involves the *recommendation* of the *suitable level of containment and risk control measures* for the proposed work. The advice can be also disseminated to other parties involved in the submitted GMO Activity project (e.g. the clinical gene therapy trial sponsoring company). Advice and peer review classification will be provided by written means to the GM Project Supervisor (e.g. by email and/or tracked change amendments of the risk assessment).
- 6.2 QMUL BGMSC will only provide *local peer review advice* to BHT *on other GM and Environmental legislation* noted in 2.1 / 5.8 above to the GM Project Supervisor and will *not* provide any risk classification for those activities. In addition, peer review advice for 'wild type' biological agents' work is not provided by the QMUL BGMSC where the work is solely under the Control of Substances Hazardous to Health (COSHH) 2002 (as amended).
- 6.3 *Taught course training* for GMO Activities for BHT GMO workers as available from the portfolio of courses available to QMUL staff via the QMUL CPD Booking system. Additionally, bespoke courses for GMO Activity work can be developed and provided upon request. (QMUL courses on GM risk assessment and notification are open to applicable BHT staff; a course fee / charge is payable by those with no QMUL contracts or no connection with the proposed GMO work as per the QMUL Health & Safety Directorate training policy).
- 6.4 *Assistance* to BHT (GM Project Supervisor) *with GMO Activity accident or incident investigation and statutory reporting* to the Competent Authority (the Health & Safety Executive) in order to assist in compliance with prevailing GMO legislation. The QMUL BGMSC will *not* be the reporting body to the Competent Authority unless the GMO Activity accident or incident occurs on QMUL premises.
- 6.5 *Assistance* to BHT (GM Project Supervisor) to *identify any lessons learnt* from unplanned GMO adverse events (accident or incident involving a GMO Activity) and recommend measures to reduce the risk of a recurrence. The responsibility for carrying out any recommendations is entirely the remit of BHT.
- 6.6 To *carry out inspections of laboratories / facilities* where GMO work is being proposed for *the first time* at BHT and to *recommend the containment level standards* required for the GMO Activity to BHT (GM Project Supervisor). The responsibility for carrying out any recommendations is entirely the remit of BHT and the named GM Project Supervisor.
- 6.7 To periodically *inspect* laboratories or other facilities carrying out GMO work, to prepare inspection reports, and provide *recommendations for improvement* by means of a written report to BHT (GM Project Supervisor). The responsibility for carrying out any recommendations is entirely the remit of BHT and the named GM Project Supervisor.
- 6.8 *Facilitation of the notification of Barts Health Trust premises and higher risk GMO Activities* under the Genetically Modified Organisms (Contained Use) Regulations 2014 to the Competent Authority (the Health & Safety Executive). These will be notified under the QMUL GM Centre 774 notification. The QMUL BGMSC will *not* provide or facilitate any statutory notification/s under any other legislation to the relevant Competent Authority.

- 6.9 Any *payment of a fee or charge required for a notification* is the responsibility of Barts Health Trust. Written evidence of the fee payment must be provided to the QMUL GM BSO for records validation.
- 6.10 Any other statutory or civil claim payment applicable to Genetic Modification Organism (GMO) Activities in BHT is the responsibility of Barts Health NHS Trust.
- 6.11 To *provide legislation and sector best practice updates* for GMO Activities to review and revise existing policies and practice. The QMUL BGMSC will not provide policy and procedure documents for BHT but is able to review and provide assistance in terms of documents relating to GMO Activities.
- 6.12 The outcome of each meeting (meeting minutes) of the BGMSC will be provided by email to the BHT BGMSC representative.
- 6.13 Key Performance Indicators (i.e. timescales for response, method of response) for GMO peer review and advice are noted in the document for [QMUL Peer Review, Approval & Notification Process](#) and expanded in the [QMUL GMO Policy / QMUL Service Level Document](#).

## 7. Service Contact and Location

- 7.1 The QMUL BGMSC is *serviced* by the QMUL GM BSO who is a QMUL staff member in the Health and Safety Directorate which is located at 404 Bancroft Road, London E1 4DH on the Mile End Campus of QMUL.
- 7.2 The QMUL GM BSO will be the first point of contact for BHT GMO Activity projects.

## 8. Duration of Agreement and termination process

- 8.1 This agreement will commence on 01/12/2018 for a period of *one year* in the first instance. The agreement can be rolled on for a subsequent year if there are no objections from either party to the agreement.
- 8.2 The agreement will be *reviewed* annually by the key representatives for both organisations – the Chair (and Deputy) of the QMUL BGMSC and the nominated Barts Health Trust Representative/s in conjunction with the QMUL GM BSO and the QMUL Director of Health & Safety.
- 8.3 The agreement may be *updated* at any time through written agreement of each organisation's key representatives. Either party can terminate the agreement with 30 days written notice.

## 9. Key Representative Contacts

BGMSC Position	Name	Contact Details
QMUL BGMSC Chair	Prof Tyson Sharp (Professor in Molecular Oncology, Barts Cancer Institute, QMUL)	<a href="mailto:t.sharp@qmul.ac.uk">t.sharp@qmul.ac.uk</a> 020 7882 3848

QMUL BGMSC Deputy Chair	<p>Dr James Whiteford</p> <p>(Research Fellow, William Harvey Research Institute, QMUL)</p>	<p><a href="mailto:j.whiteford@qmul.ac.uk">j.whiteford@qmul.ac.uk</a></p> <p>020 7882 3909</p>
QMUL GM BSO	<p>Dr Mark Ariyanayagam</p> <p>[H&amp;S Manager (SMD) and Biological Safety Adviser (QMUL), QMUL H&amp;S Directorate]</p>	<p><a href="mailto:m.r.ariyanayagam@qmul.ac.uk">m.r.ariyanayagam@qmul.ac.uk</a></p> <p>020 7882 8378</p>
QMUL Director of Health & Safety	<p>Mrs Zarah Laing</p> <p>Mrs Rebecca Jones (from 01/10/2018 – interim Head of Health &amp; Safety)</p> <p>(QMUL H&amp;S Directorate)</p>	<p>020 7882 8967</p> <p><a href="mailto:Rebecca.jones@qmul.ac.uk">Rebecca.jones@qmul.ac.uk</a></p>
BHT representative to QMUL BGMSC	<p>Mr Nathan North</p> <p>(Chief Biomedical Scientist, Microbiology Barts Health NHS Trust, Royal London Hospital)</p>	<p><a href="mailto:nathan.north@bartshealth.nhs.uk">nathan.north@bartshealth.nhs.uk</a></p> <p>020 324 60306</p>



10 Signatures of Key Stakeholders noting full agreement

Key Representative 1 (for QMUL): Full Name Prof Tyson V. Sharp  
Position: QMUL BGMSC

Chair

Date of Signature: 16-07-18  
Signature



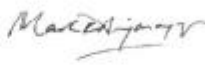
Key Representative 2 (for QMUL): Full Name Dr James Whiteford  
Position QMUL BGMSC Deputy Chair

Date of Signature 09/10/2018  
Signature



Key Representative 3 (for QMUL): Full Name Dr Mark Ariyanayagam  
Position H&S Manager (SMD) and Biological safety Adviser (QMUL)

Date of Signature 16 July 2018

Signature 

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Key Representative 4 (for QMUL): Full Name: Zarah Laing  
Position: Director of Health and Safety  
Date of Signature: 16/07/2018

Signature: 

Key Representative 1 (for BHT): Full Name: Nathan North  
Position Chief Biomedical Scientist, Microbiology  
Barts Health NHS Trust

Date of Signature 9-10-18

Signature 

Key Representative 2 (for BHT): Full Name  
Position  
Date of Signature  
Signature

Advanced by email to  
Dr Simon Hamrod  
Medical Director, Barts Health NHS Trust  
20 Dec 2018.

END.