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RISK ASSESSMENT FORM

GENETICALLY MODIFIED ORGANISMS (GMOs) -

CONTAINED USE ACTIVITIES INVOLVING

MICRO-ORGANISMS AND CELLS

*As required under Regulation 5 of the GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2014*

# *INFORMATION ON THIS PAGE IS CONFIDENTIAL*

**1. PROJECT SUPERVISOR**

*Person who has overall responsibility for the work. Include name, full address, e-mail and telephone number(s)*

# 2. DEPUTY PROJECT SUPERVISOR(S)

 *Responsible person(s) in the absence of the project supervisor. Include name, full address, e‑mail and telephone number(s)*

**3. LABORATORY / ROOM / FACILITY WHERE THE WORK WILL BE CARRIED OUT**

*Please identify* ***all*** *rooms / facilities where GMOs will be handled and stored, including the name of the Trust Building(s) and Campus / Site location. Provide floor plans clearly annotated with the areas where the GMO is stored/ prepared/administered to patients as applicable.*

# 4. DESCRIPTIVE TITLE OF PROJECT

*Provide a descriptive title of the project in no more than one or two sentences.*

**5. PROJECT SUMMARY FOR LAY REVIEWERS**

*Provide a short (one or two paragraphs) summary which describes in terms understandable to a* ***LAY PERSON,*** *the nature and aims of the project, and why the use of GMO / GMMs is important for this work. In lay terms, identify and explain the level of risk posed to human health and the environment. Note which step(s) and / or feature(s) of the work produces significant risk(s) to human health and the environment, and what containment (or infection control) measures are appropriate to mitigate the risk(s).*

# 6. SCIENTIFIC OVERVIEW OF PROJECT

*Please complete a brief* ***scientific resume*** *of the project in no more than three paragraphs. Additional information can be attached, if necessary, to explain further.*

# 7. ORGANISMS, VECTORS AND GENE INSERTS

*Please list the host organism/s (micro-organism, cell line), vector(s) including any plasmid(s) and foreign gene insert(s) that will be used in the project, this should include the source, supplier or origin (e.g. catalogue number(s) and commercial supplier, providing researcher name / organisational affiliation). This can be done in generic terms for commonly used vector / plasmid e.g. K12 strain. Identify the ACDP Hazard Group listing (*[*http://www.hse.gov.uk/pubns/misc208.pdf*](http://www.hse.gov.uk/pubns/misc208.pdf)*) for parental or wild type organism/s if relevant. For cell line/s, give strain/line information as well as species. If GMOs / GMMs have been imported into the site, information on the construction of the GMO / GMM must be obtained from the supplier.*

# 8. IDENTIFICATION OF POTENTIAL HARMFUL EFFECTS AND HAZARDS IN RESPECT OF HUMAN HEALTH

*This section looks at the possible harmful effects / hazards to human health from the pathogenicity, biological effects and toxicity of the host organism, foreign gene insert / product and the attenuation / virulence properties of the vector and mobility of plasmid(s). Therefore, consider host, vector, final GMO / GMM and survivability. Also severity of effects if an accident or exposure was to occur.*

# 9. IDENTIFICATION OF POTENTIAL HARMFUL EFFECTS AND HAZARDS TO THE ENVIRONMENT

*This section considers the possible harmful effects / hazards to the environment (in particular to environmental species that could be affected). What is the likelihood of release / escape of organism from the containment laboratory? Consider host, vector, final GMO / GMM, scale and survivability. Also severity / consequences if an accident or release was to occur.*

**10. ASSIGNMENT OF PROVISIONAL CONTAINMENT LEVEL**

*This considers the Containment Level necessary to control risk of host and by making a judgment about whether the modification(s) carried out will result in a GMO / GMM, which is more / less hazardous, or about the same.*

# *(Select)* Containment Level 1 / 2 / 3

*(For assignment of a Containment Level see section 22 below ‘Assignment of a Containment Level to control the risk’ and for a summary table of Containment Levels Requirements, see Table 6.4.2 in Part 6 of the SACGM Compendium of Guidance:* <http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part6.pdf>)

If certain parts of the work (e.g. gene cloning) can be conducted at a lower Containment Level than that selected above, clearly identify those parts of the work here:

# 11. POSSIBILITY (LIKELIHOOD) OF THE ABOVE EFFECTS OCCURING: RISK TO HUMANS

*Consider the scale of cultures used and their frequency, production of aerosols, use of sharps, any other hazardous procedures.*

*Use the risk estimation table in Section 22(e) ‘notes for guidance’:*

Likelihood …….. X Consequence……Overall Risk to human health =…….

# 12. POSSIBILITY (LIKELIHOOD) OF THE ABOVE EFFECTS OCCURING: ENVIRONMENTAL CONSIDERATIONS

*Consider theoretical modes of transmission (e.g. drains, air), can the environment support the survival of the GMO / GMM, are there species in the environment which are susceptible to infection by the GMO / GMM; Use the risk estimation table under ‘notes for guidance’.*

*Use the risk estimation table in Section 22(e) ‘notes for guidance’:*

Likelihood …….. X Consequence……Overall Risk to the Environment =…….

13. DOES THE LABORATORY / FACILITY MEET THE REQUIREMENTS FOR SMALL SCALE ACTIVITIES INVOLVING GMO / GMM CONTAINED USE? *(select)* Yes / No

*To be validated by an inspection conducted by the Biological Safety Adviser / Officer.*

*If ‘Yes’ is selected, you are attesting that the laboratory / facility (ward / pharmacy) and work arrangements meet the requirements for the appropriate Containment Level as noted in the Regulations.*

*(For a summary of Containment Level Requirements for clinical gene therapy trials, see Table 6.4.2 in Part 6 of the SACGM Compendium of Guidance:* <http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part6.pdf>*)*

# 14. WASTE CONTROL

*GMO / GMM contaminated waste (Class 2 and above) must be rendered non-viable (autoclaving for solid, validated disinfectant treatment for liquid* ***before*** *removal or disposal from the premises); Class 1 waste can be disposed directly into an authorised clinical waste stream or disposed after validated disinfectant inactivation. This ensures that any contact between GMOs / GMMs and the environment is limited to an extent commensurate with the risks identified in the risk assessment and provides a high level of protection for humans and the environment. Consider the degree of kill offered by the inactivation method (e.g. disinfectant inactivates to 5 log of GMO / GMM) and any proposed testing / monitoring measures that may be required. Further information on the site’s clinical / GMO waste arrangements should be in the site’s GM Policy.*

15. ARE ALL WORKERS FAMILIAR WITH LOCAL RULES AND GM REGULATIONS ON SAFE WORKING AND WASTE DISPOSAL METHODS?

 *Specific worker training records for GM work at Class 2 and above must be kept.*

*(Select)* Yes / No

**16. ASSIGNMENT OF CONTAINMENT LEVEL AND CLASS**

*After considering that all the activity and environmental considerations have been taken into account revise, if necessary, the provisional containment level so that all risks are controlled. Please note that work classified as GM Class 1 cannot start until approval from the GMSC has been granted; additionally, work assessed as GM Class 2 or above will need specific HSE notification AND approval / consent, and also may require additional information and laboratory / facility inspections.*

Containment level…………… Class……………

*All projects must be reviewed regularly to ensure that the risk assessment is still valid and that the work has not changed significantly – If this is the case, the project must be re-assessed – see section 23.*

# 17. ADDITIONAL ASSESSMENTS

***Select*** *the appropriate answer, and enclose / attach appropriate documents:*

1. *Completion of an Environmental Risk Assessment (enclose with draft GM risk assessment (where increased environmental risk is foreseeable))*

***Yes / No / Not Applicable***

1. *Has the above project been assessed under the COSHH regulations in terms of hazardous chemicals, wild type pathogen or other biological hazards; and for any other H&S risks?*

***Yes / No / Not Applicable***

1. *If using radioactivity, has this been assessed and approved?* ***Yes / No / Not Applicable***
2. *Have all health surveillance requirements for individuals relevant to the GM and associated project work been assessed? (see section 22 below for further assistance)* ***Yes / No / Not Applicable***
3. *Any other regulatory notifications relevant to this work have been made and received? (e.g. Human Tissue Act (2004), Research Ethics - Gene Therapy Advisory Committee (GTAC) / HRA, MHRA, CQC approvals):* ***Yes / No / Not Applicable***
4. *Any other relevant information not covered above.* ***Yes / No / Not Applicable***

# 18. COMMENTS OF THE GMSC *(Biological Safety Adviser / Officer Use Only)*

*E.g. Biological Safety Adviser / Officer review comments, GMSC members Peer Review comments, amendments to be made, updates required.*

# *INFORMATION ON THIS PAGE IS CONFIDENTIAL*

**19. RISK ASSESSMENT PREPARED BY:**

*(To include Principal Investigator sign off)*

**Name**  ………………………………………

*(In signing this you agree that work will not commence until GMSC approval and where required, HSE acknowledgement or approval / consent has been granted)*

**Date** ………………………………………

**Signature** ………………………………………

**Name**  ………………………………………

*(In signing this you agree that work will not commence until GMSC approval and where required, HSE acknowledgement or approval / consent has been granted)*

**Date** ………………………………………

**Signature** ………………………………………

**20. APPROVED BY GMSC** *(Biological Safety Adviser / Officer Use Only)*

**TRUST PROJECT REFERENCE NUMBER:**

**Name**  ………………………………………

**Date** ………………………………………

**Signature** ………………………………………

**21. HSE APPROVAL** *(Biological Safety Adviser / Officer Use Only)*

**HSE ACKNOWLDEGEMENT PROJECT REFERENCE AND DATE:**

**HSE APPROVAL DATE (for Class 2):**

**HSE CONSENT DATE (for Class 3 or 4):**

**CONNECTED PROGRAM OF WORK DETAILS:**

**22 *NOTES FOR GUIDANCE, AND WHERE TO OBTAIN FURTHER HELP***

1. ***Risk Assessment Completion***

*This form can be obtained as a word file from the*

***Key Contacts:***

***First point of assistance*** *- Biological Safety Adviser / Officer (add name, email and telephone number)*

***Further assistance -***

*GMSC Chair: (add name, email and telephone number)*

*GMSC Deputy Chair: (add name, email and telephone number))*

*GMSC members: names and contact details at (provide Trust’s link)*

*This form can be obtained as a word file from the ATTC Website Knowledge hub (*[*https://www.theattcnetwork.co.uk/knowledge*](https://www.theattcnetwork.co.uk/knowledge)*). Separate GM risk assessment forms are available for Deliberate Release GM projects, at this webpage(s).*

***In the first instance, the completed form should be sent as an attachment by e‑mail to the Biological Safety Adviser / Officer****. The form can be lengthened / shortened as required. Members of the GMSC can also provide guidance on the completion of this form. See the flowchart below and the sites GMO Policy for guidance and information on the risk assessment and approval process.*

1. ***Flowchart for the GMO Contained Use Risk Assessment and Regulatory Notification Process:***



1. *The following documents / resources provide guidance for completion of the risk assessment:*
2. *The Genetically Modified Organisms (Contained Use) Regulations 2014:*[*https://www.legislation.gov.uk/uksi/2014/1663/contents*](https://www.legislation.gov.uk/uksi/2014/1663/contents)
3. *The Scientific Advisory Committee on Genetic Modification (SACGM) Compendium of Guidance:* [*http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/*](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/)

*(In particular see* [*Part 2: Risk assessment of genetically modified microorganisms (other than those associated with plants) *](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part2.pdf) *and* [*Part 3: Containment and control of activities involving genetically modified microorganisms *](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part3.pdf)*) and Part 6:* [*Guidance on the use of genetically modified microorganisms in a clinical setting*](https://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part6.pdf)

1. *Significant changes to a GM Contained Use Notification [Institute of Safety in Technology and Research (ISTR) guidance document]* [*https://istr.org.uk/groups/biosafety/documents*](https://istr.org.uk/groups/biosafety/documents)
2. *Additional HSE / SACGM GMO documents and resources* [*http://www.hse.gov.uk/biosafety/gmo/information.htm*](http://www.hse.gov.uk/biosafety/gmo/information.htm)
3. *HSE / ACDP biological agents documents and resources* [*http://www.hse.gov.uk/biosafety/information.htm*](http://www.hse.gov.uk/biosafety/information.htm)
4. ***Health Surveillance requirements***

*To determine GM worker Health Surveillance requirements (where the risk assessment determines), contact the Biological Safety Adviser / Officer for initial advice on requirements and the Occupational Health Department for registration and monitoring. Part 1, Pages 17-20 of the SACGM Compendium of Guidance details instances where Health Surveillance may be required for GM work (*[*http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part1.pdf*](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part1.pdf)*).*

1. ***Risk Estimation Table:***

|  |  |  |
| --- | --- | --- |
| **Consequences of hazard** |  | Likelihood of Hazard |
| **High** | **Medium** | **Low** | **Negligible** |
| **Severe** | High | High | Medium | Effectively zero |
| **Modest** | High | Medium | M/L | Effectively zero |
| **Low / Minor** | M/L | Low | Low | Effectively zero |
| **Negligible** | Effectively zero | Effectively zero | Effectively zero | Effectively zero |

1. ***Assignment of a Containment Level to control the risk:***

|  |  |  |
| --- | --- | --- |
| **GMO / GMM Contained Use - Final Risk Evaluation** | **Containment necessary to control the Risk** | **Risk Classification** |
| Effectively zero risk to humans and/or the environment | Level 1 | Class 1 |
| Low to medium risk to humans and/or the environment | Level 1 with the addition of measures from Level 2 *or*Level 2 (without additional measures) | Class 2 |
| Medium risk to humans and/or the environment | Level 2 with the addition of measures from Level 3 *or*Level 3 (without additional measures) | Class 3\* |
| High risk to humans and/or the environment | Level 3 with the addition of measures from Level 4 *or*Level 4 (without additional measures) | Class 4\* |

*\*Note: Class 3 and 4 gene therapy trials are unlikely due to inherent infectious / fatality risks at this level.*

***PAGES INCLUDING SECTIONS 23-25 CAN BE REMOVED AND ATTACHED TO A NEW VERSION OF THE ASSESSMENT TO ENABLE WORKER RECORD TRANSFER AND RETENTION***

# *INFORMATION PROVIDED IN SECTIONS 23-25*

# *IS CONFIDENTIAL*

**23** **PROJECT RISK ASSESSMENT REVIEW**

*This assessment should be periodically reviewed and updated as necessary over the active life of the project as per site Policy.* ***Reviews should be conducted at least once every 3 years****, unless specified otherwise by the GMSC. Where medium to high residual risk exists, the assessment must be reviewed* ***annually*** *as per site Policy. Forward the Biological Safety Adviser / Officer, the new version of the assessment and keep a copy of the old version for* ***at least 10 years*** *after work has ceased (‘work’ includes storage of GM material). Significant amendments require consideration and approval by the GMSC; GM Class 2 and above activities also require HSE approval. Cessation or move of a Project to another Institution requires notification to the Biological Safety Adviser / Officer and for GM Class 2 or above, also to the HSE (via the Biological Safety Adviser / Officer).*

|  |  |  |
| --- | --- | --- |
| VERSION | DATE OF LAST REVIEW: | SIGNATURE OF GM PROJECT SUPERVISOR |
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**24 GM PROJECT WORKERS**

*To include qualifications, training and experience with GM work. All GM workers (and any others who may be significantly impacted by the work) should* ***sign below in section 24*** *to indicate that the assessment has been read and understood.* ***Updates in Project Workers should be notified to the Biological Safety Adviser / Officer by sending the updated pages for sections 23 - 25****.*

*Some GM workers (where the risk assessment determines) may require Health Surveillance and the sites Occupational Health Service must be contacted to ensure adequate monitoring. See the sites GM Policy for further information and section 22 above for further information.*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FULL NAME** | **QUALIFICATIONS** *(academic / clinical)* | **GMO work experience** *(e.g. length of time, type of GMOs / vectors / micro-organisms handled)* | **GM Training** *(e.g. Bio/GM safety courses at current and / or previous Institutions, local /in house and external training)* | **SIGNATURE and DATE** |
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**25 ASSOCIATED STAFF / STUDENTS / OTHERS**

*This risk assessment should be easily available (e.g. in the laboratory) and where it can be read by others who may be* ***significantly impacted*** *by the work (e.g. those not on the project but working in close proximity in the same laboratory).**All those working or significantly impacted by this project should read the assessment before beginning work and/or obtain a briefing on the significant findings and required risk controls.* ***Sign below to indicate that you have read and understood the latest version of the assessment and/or obtained a briefing.*** *If required****,*** *please extend the table to include more names.* ***Updates should be notified to the Biological Safety Adviser / Officer by sending the updated pages for sections 23 - 25****.*

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