



Guidance on work with tissues, blood and samples obtained from COVID-19 patients or with the novel coronavirus SARS-CoV-2

This guidance is provided for research work involving the novel coronavirus SARS-CoV-2 which is the causative agent of the infectious disease called COVID-19. The guidance is focused on the hazards, risks and controls related to work involving human tissues, blood and samples but it also applies to relevant animal tissues and materials. The Health & Safety Executive (HSE) Microbiology & Biotechnology Unit has provided specific advice about the containment and control measures required for work involving COVID-19 samples and SARS-CoV-2 virus in research work. Public Health Scotland (PHS) and Public Health England (PHE) / UK Health Security Agency (UKHSA) have also produced important information and guidance about this novel disease and virus which may be relevant to your work in relation to the control of risks from work related activities.

1. Law

Health and safety and environmental protection laws are not suspended or weakened during emergencies like the current coronavirus pandemic although the authorities may make additional special requirements or temporary variations if they determine they are needed. The COSHH and GMO (Contained Use) Regulations are the main laws relevant to biological safety and must be complied with and HSE provides extensive guidance to help us ensure safety and compliance.

2. Guidance

General guidance on safe working with biological agents and genetically modified organisms, BA / GM risk assessment, and containment and control measures is provided on the Biosafety Unit (BSU) website. HSE has produced detailed guidance on biological safety which can be found on their website.

- [HSE Control of substances hazardous to health](#)
- [HSE ACDP Approved list of biological agents](#)
- [HSE ACDP Management and operation of microbiological containment laboratories](#)
- [HSE Genetically modified organisms contained use](#)
- [HSE SACGM Compendium of guidance](#)

In addition PHE (UKHSA) in collaboration with HSE has produced guidance which is applicable throughout the UK which covers certain types of work in laboratories with human tissues, blood and samples obtained from COVID-19 patients and to work with the SARS-CoV-2 virus.



- [Public Health England \(PHE\) COVID-19: Safe handling and processing for samples in laboratories](#)

This PHE (UKHSA) guidance is designed primarily for activities in clinical diagnostic laboratories. The university does mostly research work although we do also carry out specialist human and veterinary clinical diagnostic laboratory work. However, HSE have agreed that the PHE (UKHSA) guidance is applicable to research laboratories as well as diagnostic laboratories as long as the work is consistent with the activities described in the guidance and subject of course to risk assessment and compliance with the relevant safety regulations.

Therefore, the PHE (UKHSA) guidance can be used by Schools and researchers when doing risk assessments for our work and to help determine the appropriate containment and control measures for work conducted in the University with human tissues, blood and samples obtained from COVID-19 patient sources and the SARS-CoV-2 virus.

3. ACDP Classification of SARS-CoV-2

The Advisory Committee on Dangerous Pathogens (ACDP) has formally decided that the approved classification under COSHH of the SARS-CoV-2 virus is hazard group 3 (HG 3). HSE has published this information and it will in due course be added to the ACDP Approved list of biological agents. If this classification changes at any point in future then they will issue further advice at the time.

4. Risk Assessment, Containment and Control

The specific work related hazards and risks and which containment and control measures will be required for any research work involving human tissues, blood or other samples obtained from COVID-19 patient sources or the SARS-CoV-2 virus itself must be determined in suitable and sufficient BA / GM risk assessments. The risk assessments, containment and control measures must follow the principles and requirements set out in the COSHH and GMOCU Regulations and HSE guidance as well as University and School policies and guidance. There is also the additional PHE (UKHSA) guidance on laboratory work involving samples from COVID-19 patients or the SARS-CoV-2 virus which is relevant to certain types of our work. Please note that there is no change to the established University and School systems for the review and approval of BA and GM risk assessments which is done through your School GMBSC and following local safety arrangements. BA and GM risk assessments must be reviewed and approved by your School GMBSC and where relevant projects must be notified to HSE and consent obtained for the work and any permitted derogations.

Generally COSHH specifies that any work with human tissues, samples, blood and related materials normally requires containment level 2 and the associated control



measures for the incidental risks of adventitious pathogens which have the potential to be present in any of these materials. In addition, if there is a known, presumptive or likely presence of any specific pathogen hazard in any type of tissue, samples or other material then the containment and controls required will depend on the hazard group. Therefore, any work with a hazard group 3 pathogen requires containment level 3 and the associated control measures. Human tissues and samples which are handled at containment level 2 would typically involve using control measures like microbiological safety cabinets (MSC), suitable containment of samples, personal protective equipment (PPE), sharps controls, safe transport, disinfection, disinfection and cleaning, waste inactivation and disposal, emergency procedures and good microbiological practice etc. Schools and researchers should already be doing this for work with human or animal tissues, blood, samples and other related materials since this is required to protect workers from potential risks related to incidental exposure to adventitious pathogens.

HSE has confirmed that the PHE (UKHSA) guidance COVID-19 Safe handling and processing for samples in laboratories can also be applied to those handling specimens from patients with suspected or laboratory-confirmed COVID-19 in non-clinical diagnostic laboratories, for example in laboratories undertaking research, or developing diagnostic assays with such samples. The processes that can be undertaken at containment level 2 should be based on a suitable and sufficient assessment of the risks and be consistent with those activities described in the laboratory guidance. Note that what is referred to above is the confirmation of disease in the patients and not of SARS-CoV-2 virus in the specific tissues, samples or other related materials which are not necessarily the same in terms of the hazards and risks. Note that if any samples are confirmed or likely to contain the SARS-CoV-2 virus then they are HG3 and must be handled at containment level 3.

The PHE (UKHSA) guidance specifies that where it is applicable, certain types of work with blood and other very low risk samples obtained from COVID-19 patients can be done at containment level 2, subject as stated above to compliance with COSHH, risk assessment and following the PHE (UKHSA) laboratory guidance. So work with human blood or other very low risk samples and activities may generally be conducted at containment level 2. The PHE (UKHSA) guidance specifies the types of control measures that are expected to be implemented including that blood and other relevant low risk samples from COVID-19 patients must be handled using an MSC and appropriate methods of containment.

However, it is important to note that any work involving SARS-CoV-2 virus must not be conducted at containment level 2. Any research or diagnostic work activities with the SARS-CoV-2 virus in any form (eg pure virus, culture, concentrated virus samples, infectious materials etc) or involving a known, presumptive or significant likelihood of SARS-CoV-2 virus being present in any tissues, samples or other materials must be treated according to the relevant requirements for hazard group 3 biological agents and must only be handled at full containment level 3 with all the associated control measures.



In the case of existing work with human tissues, samples and related materials, if there is any new information that the work may be potentially more hazardous than originally intended or if a change to the hazards, risks, containment level or controls might be required then the local risk assessments should be reviewed and any advice taken from your safety advisers and GMBSC where needed.

Briefly in addition any work involving the genetically modified SARS-CoV-2 virus would generally be class 3 genetically modified microorganisms (GMM) work. This work would require review and permission to be obtained for the GM risk assessment from your School GMBSC, HSE notification and consent to be obtained and the use of full containment level 3 (CL3) and robust control measures to protect people and the environment. Also any work with infectious nucleic acids or infectious clones of the SARS-CoV-2 virus would generally need to be treated the same way as the infectious virus itself so they would be hazard group 3 biological agents or class 3 genetically modified microorganisms (GMM) unless for example they were not independently infectious or highly attenuated. Note that many types of work with lower risk GMM might of course only be class 1 or 2 and require containment level 1 or 2. The precise risks and controls for work involving genetically modified organisms and genetic modification activities of this virus would of course be determined in GM risk assessments.

5. HSE Notification of Projects

There is a requirement under the COSHH or GMOCU Regulations to notify the HSE when conducting certain work activities involving pathogens or genetically modified organisms at containment level 2 and 3. For example, any work conducted with SARS-CoV-2 virus at containment level 3 requires notification to HSE and consent to be obtained. But in addition any work conducted with human blood or very low risk samples from COVID-19 patients at containment level 2 also requires notification to HSE and consent. Class 2 or 3 GMO work at containment level 2 and 3 also requires notification to HSE and consent to be obtained.

6. Further Information and Guidance

Further information and guidance on safe working with biological agents and genetically modified organisms, BA / GM risk assessment, and containment and control measures can be found on the Biosafety Unit (BSU) website. Your School should provide you with local guidance about the biological safety arrangements for coronavirus projects. Please contact your School Biological Safety Adviser if you need advice on any aspect of biological safety.



Document version

Version number	Summary of change	Date and by whom
V1.0	New template	June 2023 HE
V1.1	Minor updates to text and links.	January 2024 PW

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