**GM Guidance document**

The form you require depends on whether you are modifying bacteria (*E.coli*, non-*E.coli*), viruses or plants. There is a separate form that involves the genetic modification of animals.

The following forms should be used:

Risk Assessment Form GM1 – use for contained use of genetically modified animals

Risk Assessment Form GM2 – use for Bacteria non E.coli

Risk Assessment Form GM3 – use for E.coli

Risk Assessment Form GM4 – use for plants

Risk Assessment Form GM5 – use for retrovirus

Amendment Form GM6 – For existing project holders only. Use for small changes such as a change of staff; this includes removals or additions of new members; or where the addition of a single vector or gene is required that does not alter the direction or aim of the project. If you wish to introduce a new part of the study or unrelated gene or vector you MUST complete a new submission.

Guidance for each section is given on the form to aid completion. In general, please be clear on vectors being used, this includes providing maps of vectors in the application; for in vitro expression in cells, please detail if primary or immortal and if human or other; any genes that are tumourigenic or may play a role in oncogenicity must be clearly described with references; lastly, methods of disposal must be documented to fully inactivate or degrade any organism.

If you are submitting a grant application and have indicated on the Health and Safety checklist that you are intending to use a GMO, then you must contact the GMSC Chair in order to confirm that your work is eligible to be carried out at GCU.

Please note that if your host organism is above Biosafety level 2, a noxious weed, is poisonous to humans or livestock, or presents other dangers either to the environment or to humans or animals, it is likely that your project will not fit into containment level 1, and more details of risk assessment will be required, and the proposal must be submitted for approval to HSE by the GM Safety Committee. Please complete HSE form CU2. Submission to HSE involves a fee of £981 (current at April 2016). The process takes approximately 4-6 weeks, and no work should be commenced until the proposal has been formally approved. A class 2 form is available on the webpage (<http://www.gcu.ac.uk/healthandsafety/proceduresandarrangements/hazardoussubstancesandbiologicalagents/geneticmodification/> ). If you are unsure how to class your organism, please refer to [Part 1 of the SACGM Compendium of Guidance](http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/part1.pdf) on the HSE website and the ADCP (<http://www.hse.gov.uk/pubns/misc208.pdf> ) in the first instance. If your organism requires Class 2 then please contact Prof Linda Scobie for advice on how to proceed (linda.scobie@gcu.ac.uk).

**Some Useful Key information when working with primary uncharacterised human cell lines *in vitro:***

The sections of import with respect to risk to human health in the SAGM are 2.1 (risk to human health), 2.2 and 2.5.

For cell culture, most cells are classed as GM activity class 1. The confusion arises due to the containment required to protect the user from the cells being manipulated as there is potential for biological contamination.  In this case, with human viruses in uncharacterised primary cells, containment level 2 is required to protect the user under normal COSHH risk assessment guidelines and is discussed in section 2.5, page 66 of the SAGM. For cells, there are a number of viruses that can be present which can be classified according to the ADCP pathogen hazard group list as hazard group 2 and 3.

Human tumour cells are also classified as GM activity 1 and do not require notification unless the modification increases risk, e.g., by increasing rate of tumour growth or metastatic potential.  The table below helps to classify the risk and is taken from the SACGM. So under the new regulations 2014 for classification of work, with respect to the genetic modification, as defined (***Class:*** *Contained uses are classified into one of four classes, as described in Schedule 1, based on the risk that the contained use presents to human health and the environment. These are referred to as class 1 (no or negligible risk), class 2 (low risk), class 3 (moderate risk) and class 4 (high risk). The contained use class is derived from the outcome of the risk assessment and is only applicable to GMMs and is not used for larger GMOs*) please note that now  a lot of class 1 practices have been elevated.

For example; level of risk for the inserted material is 1; level of risk for the recipient cells is 1, however, contained use requires level 2 to protect the individual. If we follow the guidelines as per table below it would assign the work to level 1; with the addition of measures from level 2 and under guidelines, this would require a risk classification of 2.

