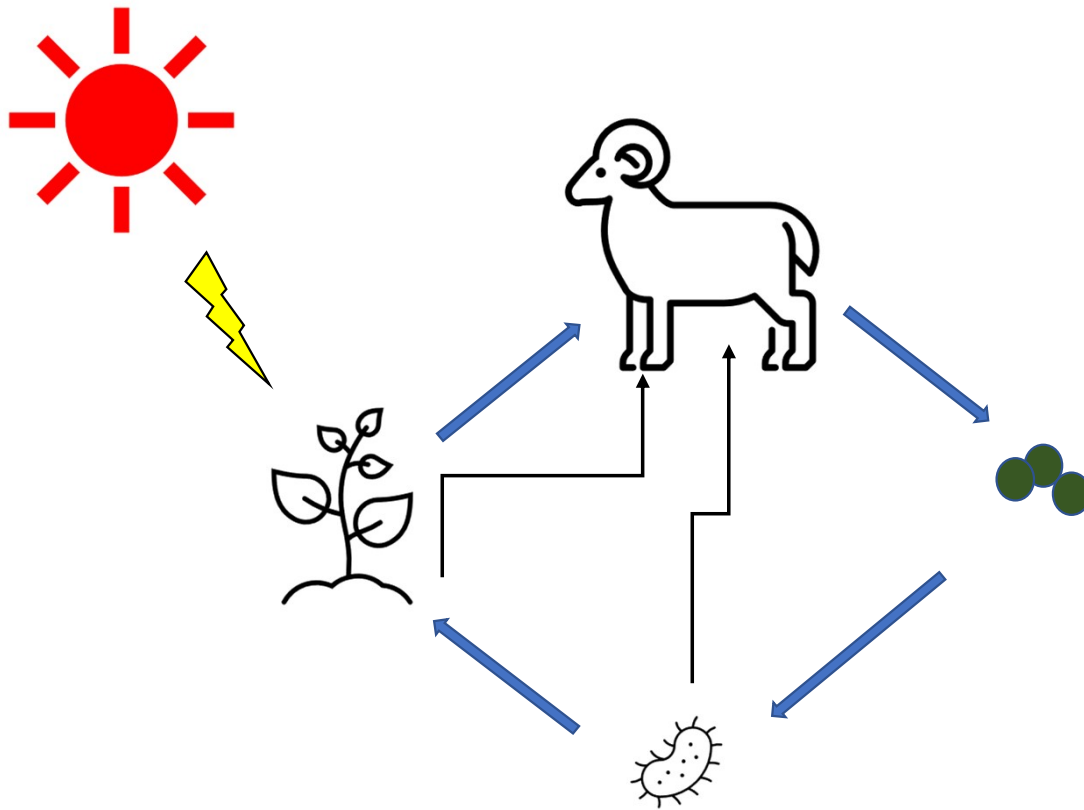


# Biosafety and other regulations in ISIS laboratories

Dr. Ludmila Mee, ISIS BioLab Manager

16 May 2023

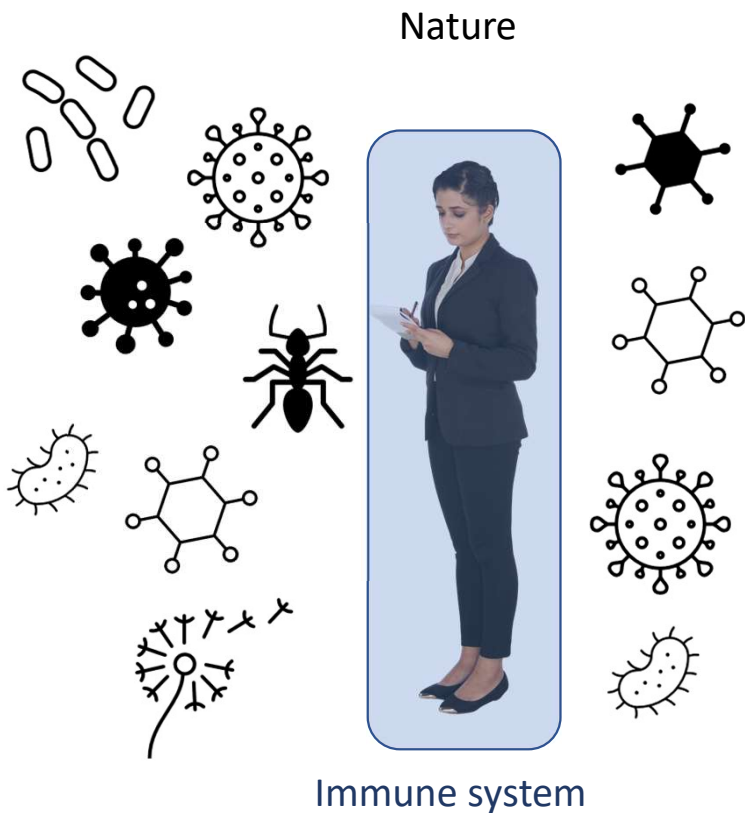
# Energy Transfer and the meaning of Life



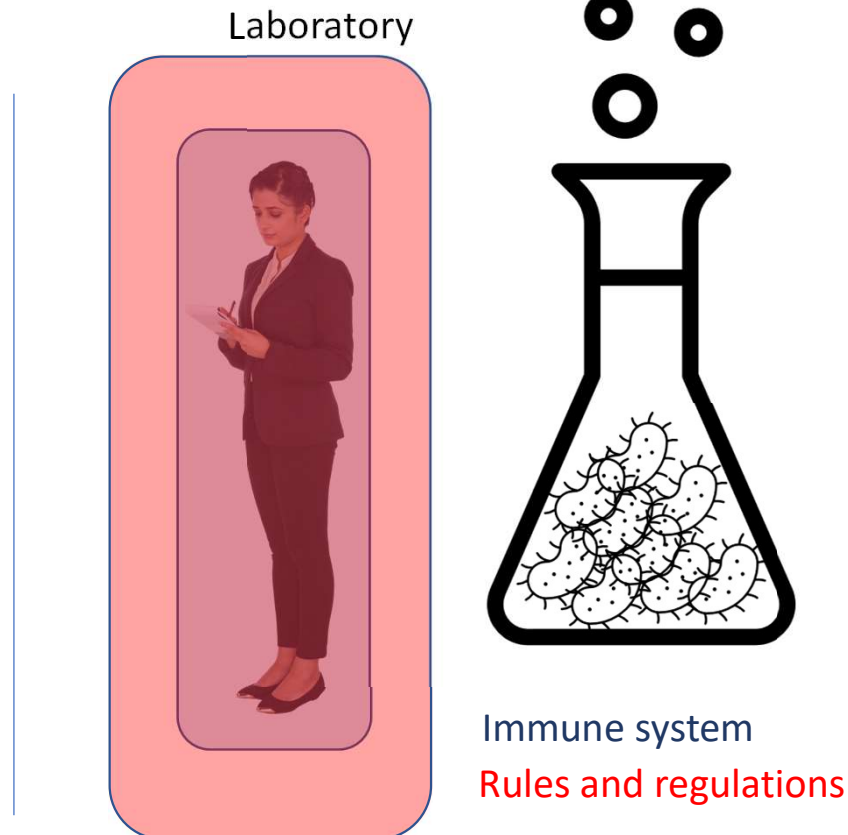
- Life = energy transfer between organisms
- Life is a **process**. Living organisms are dynamic systems
- The circle of life is brutal and unforgiving – either consume or be consumed
- From the nature point of view the meaning of life is to adapt and survive

Bacteria and plant will try to consume the animal as well (black arrows), and will ultimately succeed if it becomes weaker/dies

# Nature vs laboratory environment



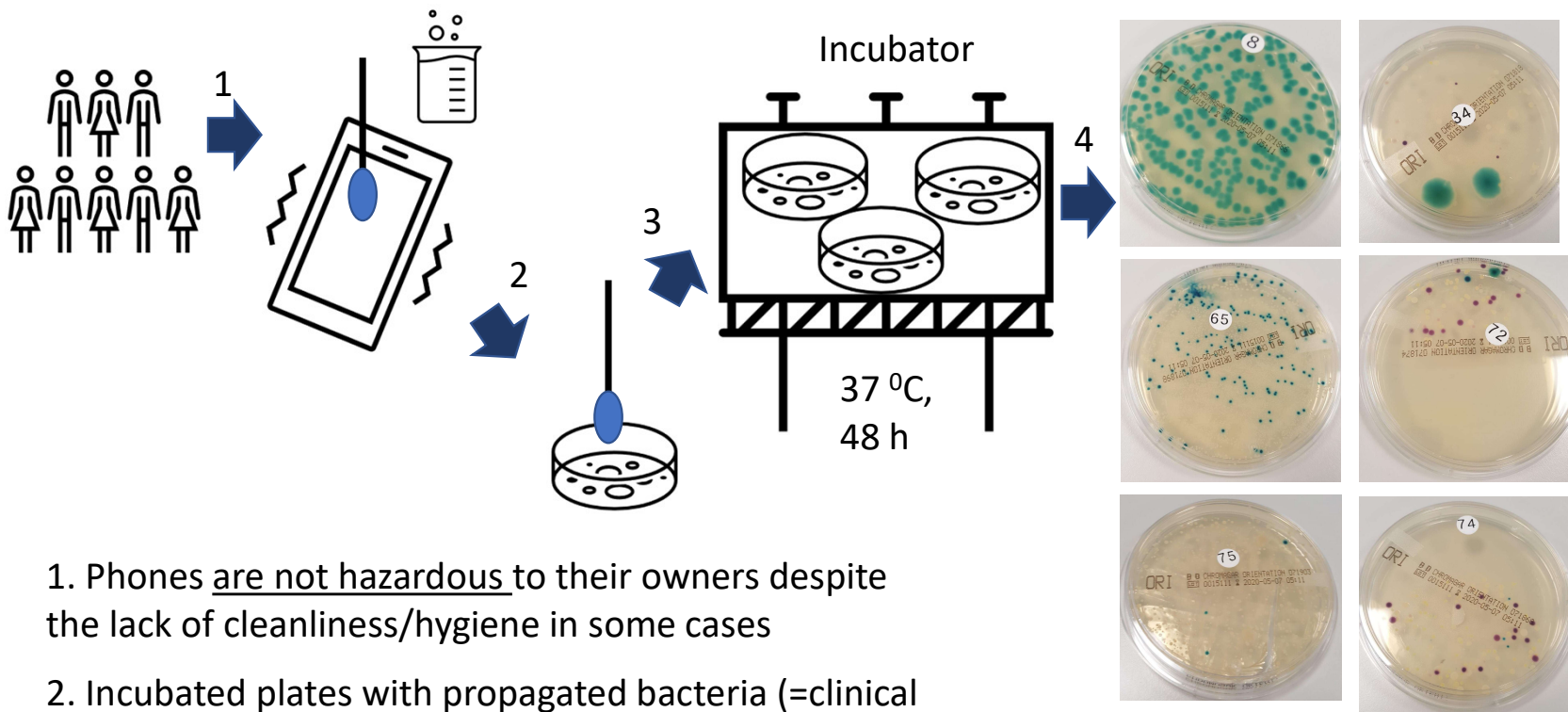
Regulated by brutal forces of nature:  
adapt and survive (or die...)



Regulated by the UK law (HSE, HTA, REC)

- *Life = energy transfer between organisms*
- *Life is a **process**. Living organisms are dynamic systems*
- *The circle of life is brutal and unforgiving – either consume or be consumed*
- *You are part of the life circle and subjected to other living organisms all the time*
- *This process is not regulated in the natural environment but heavily regulated in laboratories and does not depend on the safety of biosample.*

# Phone swab experiment: 100-300 participants



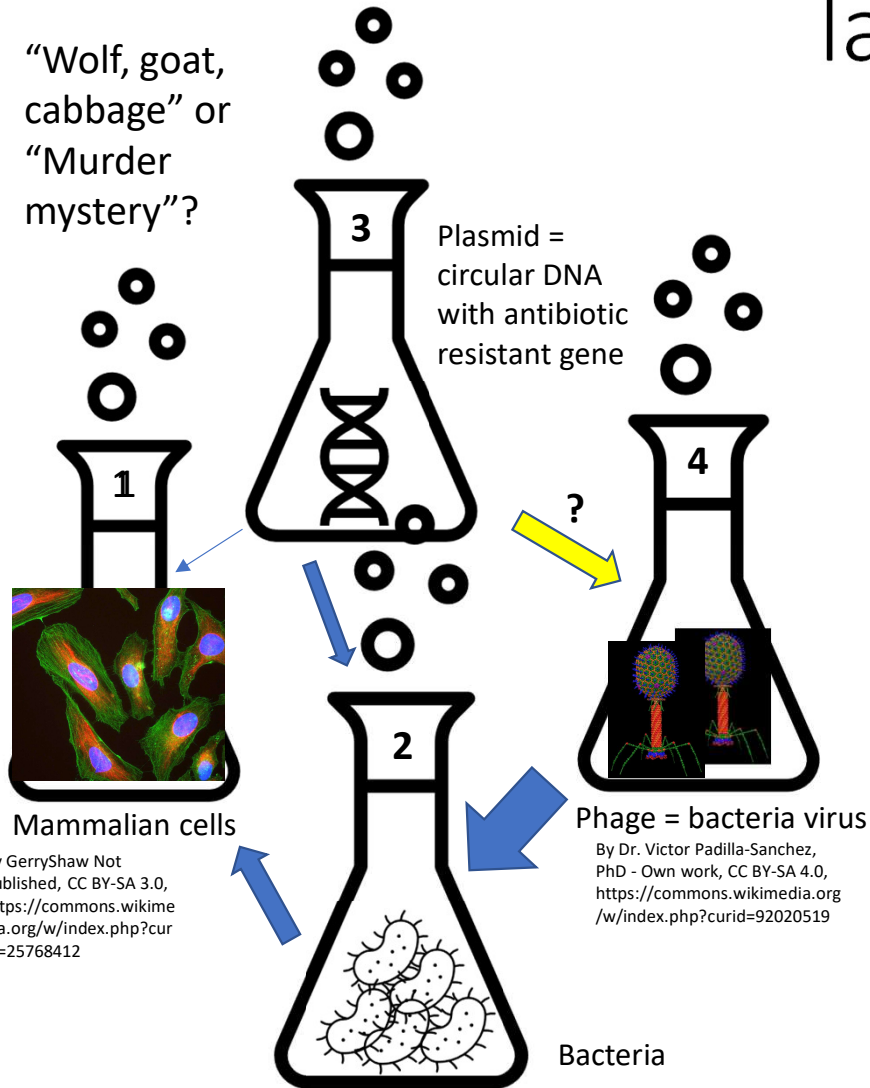
## Facebook close group



Blue/green – enterobacteria from the gut (= wash your hands...)  
Dark pink – E.coli from the gut (= wash your hands...)  
Colourless, white, yellow – bacteria and fungi present on skin

# Safety and ethics compliance in multi-user laboratories

“Wolf, goat, cabbage” or “Murder mystery”?



By GerryShaw Not published, CC BY-SA 3.0, <https://commons.wikimedia.org/w/index.php?curid=25768412>

- All live samples are playing “energy transfer” and “survival of the fittest” while we study them!
- **Compartmentalisation** (“a place for everything and everything in its place”) of each activity is required to mitigate potential biohazardous situations and sample contamination

# Biosafety, GMO and Research Ethics

BioCOSH RA via GSMC committee	Research Ethics via Research Ethics Committee (REC)
<ul style="list-style-type: none"><li>• BioCOSH RA is for assessing anything that is LIVE (or might be live) - bacteria, cells, etc.</li><li>• The GSMC committee is local and covers ISIS, Diamond, RCaH and RFI</li><li>• Applications are made via BioLab manager</li><li>• The BioCOSH RA form should be completed by the user with contribution from the BioLab manager</li><li>• The assessment takes into account source, quantity, proposed experimental steps, genetic modifications and suggests ways to mitigate possible biohazards</li><li>• Takes 2-6 weeks</li></ul>	<ul style="list-style-type: none"><li>• An application to REC is to assess the ethical implications of research involving human subject. That includes handling human tissues.</li><li>• The REC committee(s) reside within the NHS</li><li>• Applications are made online via IRAS system with BioLab Manager assistance</li><li>• The user is “Chief Investigator” and ISIS (Sarah R/Vicky/ other directors) is “Sponsor”</li><li>• The assessment is taken into account what human subjects will be studied, how data will be collected, how subjects will be notified of the results, what efforts will be made to publish the data, and whether experiments will be compliant with the established procedure for human tissue handling and accountability</li><li>• Can take a few months</li></ul>

Please let me know as soon as proposal is approved if you are to handle...

- live organisms (anything that can replicate itself including but not limited to phages, viruses, live cells, plants, animals, etc) and seeds/spores
- any genetically modified material (whether animals, plants, cells, seeds, spores or tissues)
- parts of human bodies / samples derived from a human – whether freshly obtained or fixed/stored (such as bodily fluids, hair, nail clippings, etc)

Do not believe your users when they say: “but it is totally safe...”, or “never had to do any paperwork for it before...”!

# We have a new BSO (BioSafety Officer)!

- Jon Gawn
- Virologist with extensive experience in Biosafety, including SAPO (specified animal pathogens order) licensing
- Short turn around time for BioCOSHH RAs
- Keen to help us to streamline the BioCOSHH RA paperwork
- Will visit ISIS on the 6<sup>th</sup> of June



# SUMMARY

- At ISIS we are very well equipped to process almost **any biosample up to Containment level 2** (and those above CL2 worth considering if mitigation down to CL2 is possible – **talk to me!**)
- The bio-paperwork is the BioLab manager and user responsibility – leave it down to us, but, please, **contact me in advance of your experiment**

