Questions arising from the consultation process (1, 2, 5, 23 June 2020)

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1. It sounds like we are not happy with several aspects of the auditor's recommendations - can we negotiate on these?

No. Following several meetings where the corrective actions were debated, the corrective actions that appear in the final audit report from KPMG, plus the timelines and the areas responsible, are those that were agreed to by senior management. Return to Contents

2. Any deadline dates that were devised prior to the COVID-19 crisis must be revised.

We want to be working diligently towards the timeline allocated and do our best at completing the tasks. To date, there has been no indication that the timeline has been extended. Return to Contents

3. What are other universities doing?

Other universities are not going through this exercise. We are doing this as part of the corrective actions from an *internal* audit carried out by KPMG, that was commissioned by the University as a result of an incident. Return to Contents

4. Who is our contact person in the future for questions?

Kate Noble (k.noble@unsw.edu.au) is your main contact but you can also contact any of the faculty HSE advisors, or the Central WHS people (https://safety.unsw.edu.au/contacts) Return to Contents

5. Are you going to give this spreadsheet to everyone?

This is a UNSW-wide activity. It will be distributed via the Dean and Head of School. We are currently seeking feedback and comments on the spreadsheet. Return to Contents

6. Is it possible to send an email to the researchers about this? I am concerned about the backlash due to additional workload.

It will be coming from the Deans and the Heads of School and should replace the biological register you already have. Return to Contents

7. When will the message come out through the Deans?

Soon, but we are currently getting the register into the right format and socialising with users to give them the opportunity to provide feedback before rolling out Return to Contents

8. Would you get a better response if this was set up in Forms so that your answer then brings up the next appropriate question and they are not confronted with all the columns first. It may make it easier to capture the exclusions. Forms can then be exported into an excel spreadsheet. Can use power automate to then compile the Forms data into an excel sheet.

For some it may be better, especially areas that do not already have a register. For those who have a register, especially large ones, Forms may not be better. Return to Contents

9. I think we will additional functions to Jaggaer -we will need to link ethics and imports and approved people

We are looking at this function when we settle on a platform to host the register into the future. Meanwhile we are asking for the ethics & import permit numbers for this current register so that a manual check can be made if deemed necessary. Return to Contents

10. An inventory tracking database solution (recently proposed by Cold Storage Services, but canned due to an ability to source funding) should be implemented UNSW-wide

We are looking at several platforms that might achieve a solution, such as Jaggaer and the new WHS system. One outcome from the analysis of the data you are providing in this Biological Register is to ascertain whether additional resources are needed (!!) Return to Contents

11. Note that Kristin and MEDRIOS have developed two databases recently – one for medicine equipment and one for cold storage sample management.

These have both been useful and had positive feedback, maybe we could build off our knowledge and capabilities from these to build a separate biological sample database. These databases are not a "safesys" – they are simple databases without workflows that run quickly and efficiently and hold large quantities of data entries without issues – and take minimal development (not a whole lot more than generating the excel spreadsheet). They are based on Oracle that IT already have experience with. The MEDRIOS team have found them fantastic and I would urge consideration of this proposal.

It is possible that these management systems could be considered, but it will depend on what information the University decides should be routinely collected, and whether the system can be modified to accommodate these needs Return to Contents

12. Excel tool not sufficient for this -amount of data will crash excel

Tab 6 has been formatted to 800 lines, but you do not have to fill these before starting an additional Tab 6. If you have (as an example) 8 research groups in your school, you could have one Tab 6 for each group, or you could have one Tab 6 for each Chief Investigator within the group and only go down 10 or 150 lines or so. You would copy Tab 6 (see guideline) for however many groups or people you needed and then name each new Tab 6 with an identifier for the person or group, or school. Return to Contents

13. If each Principle Investigator(PI) was to fill this in -> estimate of 2-10hrs work per PI –> multiply by number of PIs with biological samples on campus –> ballpark figure 1000 -> 2000 – 10000 hours work - > who in Senior Management has authorised this effort?

The University commissioned this audit and the authorisation will come from the Deans/DVCR to the Heads of School/Units/Research Centres. How each area fills in the form is up to each School/Units/Research Centre and no additional resources have been allocated. Return to Contents

14. This is a huge task and resourcing will be an issue – time and personnel, without adding the complexity of the current working from home with the transition of safely returning to campus.

Areas having difficulty completing the requirements should escalate their concerns and direct comments to their Deans via their Head of School/Unit/Centre Return to Contents

15. There will be workload/resourcing concerns.

This should be brought up through the Dean/HoS Return to Contents

16. Schools must be able to source labour, funding and resources required to perform this new body of work.

Any difficulties should be brought up through the Dean/HoS Return to Contents

17. If you don't know the provenance of the material, is the sample or material still useful? What about historical materials that has lost this information over the years?

A decision is needed as to whether the material is still of any value. If it is, or possibly is, and it is to be retained, such as historical specimens, then it needs to be included with as much information as can be ascertained. If not considered to be of any potential value, then consider whether or not you need to keep it.

Historical specimens which may be used for teaching would need an assessment to clarify and document the risk associated with the materials and could have a one-line entry for each determined risk eg no determined risk, or possible allergens/toxins.

Fossils and skeletons (eg the bear in E26) do not need to be included in the register unless there is a risk that they might contain pathogenic microorganisms eg mummified remains. Return to Contents

18. I have a concern with legacy items - are we authorised to throw them out?

There may be legal requirements to keep them, or Grant conditions. If there is no information at all about a material, or who the material belonged to then they may be able to be discarded and you should seriously consider this. It can be escalated to Head of School if unsure. Return to Contents

19. Do all biological agents need to be included?

Yes – refer to definitions in Tab 3 of the Register, and in the Guide Return to Contents

20. Storage – what about materials stored in several sites

Storage locations in different buildings will need a separate line for each building. Storage in several different rooms in the one building should be able to go onto the single line entry for that building.
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21. What about materials purchased through the vending machine?

Once purchased, these need to be entered into the local register probably as a one-line item within a generic/group/class of materials. While in the vending machine, the materials do not need to be on a register. Return to Contents

22. What about toxins? They are chemicals.

Some microorganisms produce small molecules termed toxins that account for their pathogenicity (eg *Clostridium botulinum*). Some of the microorganisms that produce toxins are listed in Risk Groups 2 and 3. Toxins are also produced by certain plants and animals eg ricin from castor beans and saxitoxin from shell fish. Both poison and venom are toxins because a toxin simply describes a biologically produced chemical that alters the normal function of another organism. There is one quick way to remind you of the difference between poison and venom: If you bite it and you die, it's poison. If it bites you and you die, it is venom.
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23. Hi, will the register include when biological material is disposed/removed off site? So a material in and out register.

This particular register, no, as it a snapshot of what is in out buildings. Disposal may be required in future registers. Return to Contents

24. Column Q Primary Function (Research or Teaching) – one line for each, if relevant

If the intended function of the material is for both Research and Teaching, then a one-line entry is needed for each of these two functions. Return to Contents

25. Can there be a one-line entry to cover formal databases so that we don't have to duplicate the information?

25.1. Yes – example:

If you have a database that is a requirement of Legislation such as Department of Health, Biosecurity, or follows a specific Quality Assurance standard (eg NATA accreditation), then a one line entry to cover the database may be all that is required for the whole database.
A one line entry with columns B, D-F, I-Q (plus any other if relevant) completed, where K would a general description eg "Clinical samples from human cancer patients", L would give a rough range of cancers, *an indication of the number of samples*, and an indication of the relevant risk, M-O is the person responsible for the database, P – might be local and interstate hospitals, universities, other research establishments
Examples:

- CCI Biobank of patient disease samples.
- BEES BICON plant database
- Ramaciotti's NATA-accredited database Return to Contents

26. Can there be a one-line entry to cover bulk items, or generic/group/class of materials, such as common plants in the glasshouse, highly purified substances, commercially purchased substances, such as peptides, antibiotics, amino acids, monoclonal antibodies and such??

26.1. Yes – example: Soils

1. Plants required for Botany teaching classes can be a one line entry with the general description followed by the range of plants & approximate number. Fill in as many columns as you can. One entry if they are for teaching, one entry if they are for research.
    - Imported plants would need to be entered under individual import numbers
2. Soil purchased or acquired for the purpose of growing plants for the purpose of teaching or research then it doesn't need to included on this register.
3. If you are researching the soil or the soil is the subject of the teaching session, then these need to be included as a line item.
4. If you are isolating any organisms or microorganisms from the soil, or if you are growing these isolates, then these need to be listed and you would say that they were isolated from soil from [location].

NOTE 1: commercially purchased potting mix can contain pathogens such as *Legionella longbeachae bacteria*, which causes Legionella, and needs to be included in the risk management plan for the work.

NOTE 2: some soil microorganism, while not pathogenic to humans, may cause diseases in plants and be spread to new locations through poor work practices. Return to Contents

26.2. Yes – example: NON primary human cell lines IF they fall under the same HREC Approval number

- If a researcher/research group within the School/Unit/Centre each have their own range of NON primary human cell lines, then each researcher/research group would have a line where K would

say ‘non-primary human cell line’ and column L would provide the range of cell lines for the approval number.

- There would need to be an additional entry if the material is also used for teaching

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26.3. Yes – example: Animal cell lines or animal tissues,

- If a researcher/research group within the School/Unit/Centre each has their own range of animal cell lines, then each researcher/research group would have a line where K would say ‘animal cells’ and column L would provide the range of cell lines eg mouse cardiac muscle cells, sheep arterial endothelial cells. researcher/research group and if these are used for both teaching AND research then there will need to be a line entry for each. You will still need to provide the information into columns B-F, and K-Q

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26.4. Yes - example: Tissues/organs in preservatives

- A one line entry for human tissues/organ in preservative with a general description in column K eg human, animal, a description of the range (of animal) in column L,
  - *EXCEPT* for human brain, which will need a separate line entry.
  - There will need to be a line entry for each Teaching and Research purposes, if applicable.
- A separate line entry for non-human tissues/organs in preservative and a separate line entry for each Teaching and Research purposes, if applicable.

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26.5. Yes - example: Skeletons & bones

- A one line entry to cover whole or partial skeletons, individual bones and bone fragments with a general description in column K eg a description of the range, then in column L the range of species
- There will need to be a line entry for each Teaching and Research purposes, if applicable
- There will need a separate line entry for imported items

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26.6. Yes – example: Commonly available commercial products

Commonly available commercial kits and media (eg FBS) and commercially available human serum, so long as these are not needing any form of tracking. If an import permit is required, and the item doesn’t come under the Supplier’s import permit, then a line entry is needed. The risk group may still be important so these products should be grouped according to risk group.

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27. Animals, arthropods, reptiles and such, and their food

- A one line entry for each species, for wild-type or GMO, imported, an indication of quantity, risk group, whether for research or teaching.

NOTE: some microorganisms that infect arthropods can cause human disease. The arthropod is the vector eg mosquitoes may transmit arboviruses, lice may transmit rickettsiae.

- Basic food purchased or acquired for sustaining animals, reptiles, arthropods for the purpose of teaching or research doesn’t need to included on this register. If the food itself is part of the research, for example, testing different bacteria for specific health effects on the animal/reptile/arthropod, then this needs to be included. If you are growing the food for your species, such as live crickets to feed lizards, then these need to be a one-line entry.

NOTE: The dangers associated with house **crickets** are the **diseases** and parasites that they can carry in their bodies and in their waste, like E. coli and salmonella. They are also capable of carrying worms that can come out in their faeces.

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28. For antibodies do we need to list every one separably if produced in different animals against different antigens? or can we list just as antibody?

Antibodies are derived from biological materials and therefore need to be included. These can be a one line entry, with the range of antibodies provided in columns L. Return to Contents

29. Do we need to include antibodies, peptide extracts, yeast extracts, glycerol etc?

Scope for negotiation of where we draw the line, commercially made/produced products eg BSA may be able to be grouped as a one-line entry and reference Jaggaer, if it's already recorded on Jaggaer.

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30. Will antibiotics be included? Surely they are only a chemical risk not a biological risk.

If **you** are creating or altering *antibiotics*, these will need a separate entry describing the creation/alteration and but these should be able to be grouped into one entry if they are all similar and have no change in their effect or overall risk. Return to Contents

31. Antibiotics are extremely highly purified substances. Like-wise many chemicals of a biological source (eg amino acids, peptides)

These can be included in the entry for commercial/bulk materials UNLESS you are creating or altering antibiotics, amino acids, proteins and such. The creations/alterations will need a separate entry describing the creation/alteration and these could be grouped into one entry if they are all similar and have no change in their overall risk. Return to Contents

32. What about commercial bacteriophages used for plasmid transfection?

Commercial bacteriophages can be grouped as a one-line item, general descriptions, range, approx. numbers etc Return to Contents

33. What about biological materials purchased through Jaggaer? Aren't we duplicating items already in Jaggaer?

A one-line entry would be needed for the School/Unit/Centre with someone allocated as the responsible person. A reference needs to be made that the details of the item are available in Jaggaer. If the item is used for both teaching and researcher, then a one-line entry is needed for each.

Bulk-produced chemicals, eg ethanol, hydrogen peroxide and such, that are commercially purchased and are listed in Jaggaer, do not need to be included in the Biological register.

If you are creating these chemicals yourselves in the lab from biological material, as part of your research or teaching eg extracting these from cells & tissues, then these need to be included on the register.

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34. Do we need to register transient material (Flow Cytometry: samples brought into the lab for processing) or is it only for stored material, and if so, what time frame is something considered stored? Thanks

Generally speaking, transient materials do not need to be included on the register for the service/analytical facility as it should be included on the material owner's register. However, if there is a biological risk related with the material *and* it has to undergo any processing or preparation in the analytica lab in order to be able to use the equipment and which could expose people to that risk, then yes.

Storage of samples in these facilities needs to be included, as does any type of material that is being brought into the facility frequently or on a routine basis as these materials help to establish the risk profile for the facility.

Going forward, it is intended that all of these samples must be accompanied by some sort of tracking sheet that will provide the basic information that is being gathered on this register, especially so that managers of the area can check that the materials are appropriate to be brought into the facility.

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35. So for central facilities (eg EMU) we will need to collect tracking sheet, but not fill in the register? If sample is being brought to unit, analysed and then taken away?

Same as above.
For the purpose of this Corrective Action exercise, short term materials coming into these sorts of Facilities will not need to be included but anything stored does.

Going forward, these central facilities will need some form of tracking/traceability sheet to know what has been brought into the facility and as you will need to be checking that your facility is appropriate for the material that is coming in (especially imported materials that might need specific conditions). Tracking sheets should include - Is this imported? Is this a GMO? Etc to tick off the major triggers.

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36. Do these facilities have tracking sheets of what material came in and where from? and what do they do with the management of these sheets? Who owns it and is responsible?

These facilities should already be doing some sort of checks of the materials so that they can be assured that the facility is appropriate for receiving the materials.

Going forward, we will need to standardise the information that will need to be provided to the facility before the materials can be accepted. Tracking sheets will include things like: Is it a viable microorganism there what is the risk group? Is this imported? Is this a GMO? and such to tick off the major triggers. So the material owner will be responsible for providing accurate information to the facility. The facility manager is responsible for checking the information, that the material can be handled in the facility based on the information provided, and for the storage of the information sheets. What format the sheets will take on has not been decided. Format and content will need wide consultation.

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37. What If we have biological samples from collaborators to be imaged in the lab and will be disposed after use, not stored. Should we include them?

No. Transient materials do not need to be included on your register but you must ensure that your facility is of the correct containment level and has any of the certifications required for the sample. The materials do need to be on the register of the originating School/Unit/Centre this register, and must indicate that the materials are being taken to premises (Building, room etc) not managed by the originating area.

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38. What about biomaterials collected during field work, if it's discarded or not returned to UNSW?

If the materials include environmental samples, such as soil, leaves, water, that you can conduct analysis in the field before discarding/returning the sample to the field, then no.

Materials that are returned to a central point, shed, car, campsite, for further analysis/monitoring overnight or loner, then yes.

Materials collected from plants than are or might be toxic – yes.

If the materials are from wild or native animals, such as tissue, blood, stools, saliva, hair/fur, venom and such, and you have needed ACEC approval, then yes. Return to Contents

39. Import permits – we don't always know (or able to obtain) the import number

If you are importing the substance under an import permit where UNSW is the importer, or are collaborating with another research group/Institution where they are the importer, you need to include the import permit number.

If you are purchasing good through a distributor in Australia where you ae not the importer, you do not need to include an import permit number. Return to Contents

40. Can we get a record from the government about what import permits we have and what we have brought under it ?

The person listed on the Import Permit should be able to get the information related to that permit. It is not likely that other people would be given this information because DAWE would not be able to verify that the person is authorised to receive it. Before RECS came into existence, I was not able to get a list of all of the QC facilities listed under UNSW as my name was not on any of the documentation! Return to Contents

41. Will lab managers get access to ethics /GMO/import to check samples are documented on the register?

If the Lead Academic/Project supervisor/Chief Investigator is not entering the data themselves, they need to make the documents available to whoever is doing the data-input. Return to Contents

42. Exclusions from the register

- Commercially purchased soils specifically for the raising of plants, and not the focus of research or teaching
- Commercially purchased animal feed, specifically for feeding research and teaching animals, and not the focus of research or teaching
- Live HUMANS – as participants such as in clinical trials, PhD research projects, social research and such
- *Radio*-biologicals eg 14C-labelled amino acids
- Fixed microscope slides so long as the biological *cannot* be revived. Wax-embedded biologicals are not always non-viable.
- Fossils, but not mummified remains which might contain microorganisms
- RNA/DNA fragments Return to Contents

43. We will need transparency around ethics and import permits if we are moving biologicals around

Going forward there will need to be some sort of tracking sheet to help ensure that we are complying with various pieces of Legislation. Return to Contents

44. Attendees:

1 June 2020	2 June 2020	5 June 2020	
Adam Janssen	Adam Janssen	Adam Janssen	Joshua Peterson
Alex Tillman	Alex Tillman	Adam De Paoli	Kate Noble
Anthony Zhang	Anusha Hettiaratchi	Alfonso Goncalves Firmo	Adam Janssen
Balu Daniel	Ayad Anwar	Alex Tillman	Adam De Paoli
Celine Heu	Carl Power	Alex Symonds	Katherine Bryant
Christopher Brownlee	Christopher Brownlee	Anna Cessario	Katie Levick
Frank Hemming	David Lengel	Anthony Dever	Kristina Palmer
Giulia Oss	Dixie Papast	Anthony Zhang	Laarni Caluducan
Guy Taseski	JJ Chapman	Ayad Anwer	Leanne Howard
Helen Spiers	Jason Sercombe	Ballant Kojo Eyeson-Annan	Lucy Zhang
Jason Sercombe	Kate Noble	Camillo Taraborelli	Lynn Ferris
Kate Noble	Nancy martin La Rotta	Celine Heu	Michael Ferry
Lan Le	Rachel Manuel	Conan Long	Mikhail Farid
Lennard Martin	Theresa Kahwati	Corinne Payne	Nicholas Ariotti
Mira van der Ley	Toshna Singh	Denis O'Carroll	Owen Standard
Rachael Papa	Tracey Clay	Eldad Ben-Ishay	Paul Prammer
Shinoo Swapnil		Emilio Saliba	Phillip Doran
Shudi Tang		Eva Fiala-Beer	Rahmat Kartono
Theresa Kahwati		Ewa Goldys	Rahul Bajoria
Tom Sobey	**23 June 2020**	Gautam Chattopadhyay	Raymond Galway
Tracey Clay	Alex Tillman	Giulia Oss	Richard Li
Trung Tuong	Adam Janssen	Greg Harm	Ripon Bhattacharjee
	Kate Noble	Gregory Davis	Saurabh Attreya
	Laarni Caluducan	Guozhen Liu	Scott Cable
	Emilio Saliba	Ian Aldred	Shauna Simon
	Mikhail Farid	Iveta Slapetova	Stephen Cheng
	Joel Bennett	Jianqiang Zhang	Tamsin Peters
	Tresne Chesher	Jie Bao	Theresa Kahwati
	Katherine Bryant	Joanna Richmond	Toby Jackson
	Carmel Jaconelli	Joel Bennett	Tomas Kaiser
	Trung Tuong	John Starling	Tresne Chesher

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