Instructions to Deans/DVCR, and to Heads of Centres, Faculties, Schools, Units and Research Centres re: 2020 UNSW Biological and facility Register

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1. Important Notes:

1.1. Due date for return of list of areas

14 August 2020

1.2. Due date for return of registers

16 October 2020

1.3. UNSW Faculty/School restructures

For the purpose of fulfilling this audit corrective action the file names for the returning registers **will not be updated to meet any new structure or nomenclature.**

2. Instructions:

2.1. Deans/DVCR to communicate with:

- all Heads of Schools, Directors/Managers of Research Centres and Business Units in your areas, the findings from the KPMG internal Audit report (three moderate improvement findings, and two minor improvement findings)
- all Heads of Schools, Directors/Managers of Research Centres and Business Units in your areas, that they are required to:
    - compile a list of each area that is using biological materials and/or agent as part of their teaching and/or research, (See Definitions) and the nominated contact person for each. This list is to be returned to their Dean/DVCR who will then compile all the lists for their area, and send to Kate Noble (k.noble@unsw.edu.au) by14 August 2020.
    - Ensure that this biological register is completed and returned to the UNSW WHS Coordinator for Biosafety, Kate Noble (k.noble@unsw.edu.au) by 16 October 2020

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2.2. Heads of Schools, Directors/Managers of Research Centres and Business Units To ensure that:

- *Before* the 14th August 2020, you provide to your Dean/DVCR, confirmation of the use of biological materials and agents in your School/Centre/Unit for teaching and/or research (See Definitions - excluding living humans), with the name of a person who will act as the contact with the UNSW Biosafety Coordinator
- One register per School/Centre/Unit is completed. The register can have as many Tabs as needed to accommodate different teams/groups within Schools.
- A person is allocated the responsibility for ensuring that the register is completed and returned to the UNSW WHS Coordinator for Biosafety, Kate Noble (k.noble@unsw.edu.au) by the due date, which is 16 October 2020.

2.2.1. About the register:

- One register per School/Centre/Unit to be returned with a file name that uses the naming convention documented on the website.
- Please ensure that the following are identified *for every line entry* to enable future collating and sorting of all combined 2020 UNSW Biological and Facility Registers:
    - use the naming convention document to complete Tab 6 Columns B, C & D of the Register on Tab 6
    - use the list of campuses and buildings (Tab 5) for columns E & F
- Research schools that use large varieties and quantities (such as SOMS & BABS) can send one register back per floor.
- Please ensure that a list of any acronyms used to identify the Tab 6, is provided to the UNSW WHS Coordinator for Biosafety.
- Direct enquiries to the UNSW WHS Coordinator for Biosafety, Kate Noble (k.noble@unsw.edu.au), or your WHS Contact.

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3. Link to the site for the Register and Guidance documents

The following documents are found on the 2020 UNSW Biological and Facility Register webpage:

- Instructions for Deans/DVCR, Heads of Schools, Directors/Managers of Business Units and Research Centres (pdf) - *this* instruction document.
- Definitions and Abbreviations (pdf) – biological materials and agents
- Material flow diagram (pdf)
- The template for the UNSW Biological and Facility Register (xlsx)
- The Guide for the UNSW Biological and Facility (pdf) – how to fill in the register
- Register Naming Convention (pdf) - for the completion of Register columns B, C, D plus for the return of completed Registers
- Q&A June 2020 Consultation (pdf) – answers to questions brought to the consultation sessions
- Risk Group Category (pdf) – a summary of the risk group ratings and corresponding containment facility levels taken from AS/NZS2243.3:2010
- KPMG Internal Audit final report

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4. Summary Audit report findings (UNSW KPMG Internal Audit final report)

4.1. Section 2: Five improvement findings:

Finding 2.1 - Moderate:

- The University is currently unable to confirm the extent of non-GMO biological agents on-site

Finding 2.2 - Moderate:

- Controls for the acquisition of non-GMO biological agents including review and approval processes are not consistently in line with UNSW policies and procedures

Finding 2.3 - Moderate:

- Storage and Registers of non-GMO biological agents are not consistently in line with UNSW policies and procedures

Finding 2.4 - Minor:

- The current Biosafety Procedure does not define responsibilities for all processes and is not in line with legislation, regulations and standards

Finding 2.5 - Minor:

- Biosafety training and awareness is not standardised and is incomplete, increasing the risk of incidents and inappropriate use of equipment and materials

4.2. Summary of the six resulting Agreed management actions:

R1 - Moderate

- R1A: UNSW Safety and Wellbeing will update current policy and procedural requirements to ensure all materials are registered (excluding SSBA's monitored by RECS) and communicate to Heads of School the responsibility of all laboratories to regularly undertake inventory checks and to maintain a complete register of all substances stored within each laboratory.
- R1B: Develop a plan to undertake a University wide risk based inventory exercise to take stock of all the biological materials (and related import permits, where applicable) being stored within each laboratory.
  HOS will be required to coordinate the undertaking of an inventory exercise with relevant laboratory registers updated. Outcomes of this stocktake will be endorsed by HOS & will be provided to the Biosafety Coordinator for central storage. Findings and exposures are to be reported to relevant areas for inclusion in their respective risk profiles.
  Inventory stocktake guidelines will be developed to ensure consistency across facilities
- R1C: The outcomes of the stocktake (Refer to R1B) the risk profiles of DVCR, RECS, WHS and schools will be verified to ensure they reflect the level of risk exposure as informed by the outcomes of the inventory exercise.

R2 - Moderate

- R2A: The current review and approval processes will be reviewed, amended and documented to ensure a holistic, practical, risk based approval approach for all research and teaching involving the use and management of non-GMO biological material is undertaken as part of the updated of the policies and procedures
- R2B: Communicate the revised review and approval process requirements to all HoS
- R2C: Following the undertaking of the inventory exercise (Ref to R1B), UNSW will conduct and review to determine if a new governance mechanism is required to provide oversight over research and teaching relating to the use of biological materials and compliance with relevant policies and processes.

R3 - Moderate

- R3: As part of the revised procedure (refer to Finding 2.2), the HOS will be required to ensure up-to-date registers are provided to the Biosafety Coordinator on a half-yearly basis (risk based).

R4 - Moderate

- R4: Management will define, as part of the process updated in Finding 2.3, the requirement for risk based, regular and/or periodic inspections on facilities to ensure compliance with WH&S legislation and AS/NZS Standard 2243.3 requirements. The process will require the following:
    - Audits to be conducted on non OGTR certified and DAWE regulated facilities within a defined time period, based on risk, including the consideration of different audit types, for example, self declaration, health check or full detailed inspection; and
    - Outcomes of audits will be articulated in a report which includes root cause analysis and presented to an appropriate governance mechanism (including reporting on the closure of actions as a standing agenda item of the Committee).

  In determining a three-year audit plan, resource requirements, consideration of responsible stakeholders and potential constraints will be articulated and presented to the Division of Research and WH&S leadership to ensure adequate resourcing is allocated to the undertaking of the audit plan. Additionally, where facilities will not be included as part of the audit plan, reasoning will be documented

R5 - Minor

- R5A: University Compliance Owners assigned under the Biosecurity Act 2015 (Cth) (as agreed in action R5B) to update existing internal controls (eg Biosafety Procedure) & establish new internal controls necessary to effectively manage the obligation and give assurance under the existing legislative compliance certification program (in accordance with the Legislative Compliance Procedure). This will include the requirements for annual compliance declarations to be completed for key roles within the revised procedure (ie Principle researchers, HoS etc) to specify compliance with biosecurity and biosafety responsibilities to the relevant Compliance owner.
  Review and ensure the appropriateness of the current compliance officer for the Biosecurity Act and confirm that all requirements within the Act are addressed through compliance activities.
- R5B: Highlight specific obligations that arise under the Biosecurity Act 2015 (Cth) to ensure that the appropriate University Compliance Owner is assigned to each obligation (in accordance with the Legislative Compliance Procedure), & ensure that each obligation is recorded in the University legislation Register
- R5C: University Compliance Owners assigned under the Biosecurity Act 2015 (Cth) (as agreed in action R5B) to update existing internal controls (eg Biosafety Procedure) & establish new internal controls necessary to effectively manage the obligation and give assurance under the existing legislative compliance certification program (in accordance with the Legislative Compliance Procedure). This will include the requirements for annual compliance declarations to be completed for key roles within the revised procedure (ie Principle researchers, HoS etc) to specify compliance with biosecurity and biosafety responsibilities to the relevant Compliance owner.
  Review and ensure the appropriateness of the current compliance officer for the Biosecurity Act and confirm that all requirements within the Act are addressed through compliance activities.

R6 - Minor

- R6: Following the establishment of the revised procedure and process (Refer to R5), the University will undertake a training needs analysis and develop a training matrix which identifies role specific and risk based mandatory research related training requirements to be completed by all staff and students. It will be the responsibility of all HOS to ensure training delivery is in accordance with the developed training matrix.
  The training analysis should require certification of successful completion to be provided to an appropriate governance mechanism once staff and students have received a 100% pass on the competency assessment.
  As part of establishing training requirements consideration will be given to laboratory access restrictions based on the completion of training requirements.

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