# Standard Operating Procedure for Data61 Environmental and Ecological Risk Assessment Team

#### The CSIRO’s Data61 Environmental and Ecological Risk Assessment (DEERA) team is a specialist team led by Dr Keith Hayes, who perform probabilistic risk assessments in a range of application domains, including gene technology products and their application. The purpose of this document is to convey the standard operating procedures (SOP) that the DEERA team operates under when performing risk analysis for external or internally funded projects. The SOP is to ensure that the team maintains a sufficient barrier from the gene technology research team, whether such team is within CSIRO, collaborating with CSIRO or independent, to prevent a conflict of interest.

The core DEERA team and their skills are identified in the Appendix. The skills of the team relate to statistical and mathematical modelling, hazard analysis, risk-benefit assessments. The team is based in the CSIRO Data61 Business Unit, located in CSIRO Battery Point site in Hobart, Tasmania. Projects are typically delivered through different business units. The DEERA team currently conduct assessments to the Land & Water Business Unit in the Synthetic Biology Program and the Health & Biosecurity Business Unit in the Risk, Evaluation and Preparedness program. The Research Delegate for the respective Program is responsible for overseeing project delivery. The relevant Research Delegate is identified in the Appendix.

## CSIRO Organisational Principles and Governance

CSIRO is a Federal research organisation and requires the ability to disclose its work to its Minister and respond appropriately to different Government Ministers and Government Agencies. Fundamental to all CSIRO activity is our role of being and remaining a trusted advisor to governments, businesses, our community and our partners. Underpinning this role CSIRO has policies and procedures to govern the work we do, who we partner with, and practises to ensure proper handling of information, intellectual property, records and declaration and avoidance of real or perceived conflicts of interest. CSIRO's employees are subject to contractual confidentiality obligations under their employment agreements and the general law, as well as statutory and internal CSIRO policy requirements governing the handling of information. Specific behaviours required from all CSIRO officers include to:

1. not improperly use information (including commercial and technical information of CSIRO and its customers) which is gained in the course of employment to obtain an advantage for himself or herself or someone else or cause detriment to CSIRO or another person;
2. maintain the confidentiality of such information and only disclose such information (including by way of publication) with the approval of a senior manager;
3. respect the intellectual property of others;
4. appropriately attribute authorship to staff, students and collaborators to acknowledge and recognise contributions;
5. properly record, handle and store information and records, such as research data and materials; and
6. avoid any real or apparent conflicts of interest, including in relation to the handling of information.

All new CSIRO employees are required to sign an Intellectual Property Acknowledgement and Undertaking upon commencement, which reinforces the obligations of CSIRO employees regarding the handling of information.

## Standard operating procedure for DEERA team

In this document the ‘WE’ refers to the members of the DEERA team identified in any contract or project scope of work.

1. **Conflict of Interests:** As per CSIRO’s Conflict of Interests Procedure, when a member of the DEERA team or a member of their immediate family has interests which conflict, or appear to conflict, with the requirements of the team member's CSIRO job or the affairs of CSIRO, the team member will declare details of the interest to the responsible CSIRO Research Delegate. 'Interest' includes both pecuniary and non-pecuniary interests, whether possessed directly or indirectly by a member of the DEERA team. The Research Delegate will discuss the interest with the Team Leader and agree on a suitable action to avoid the conflict.
   1. An action to avoid a conflict of interest may include (i) altering the duties of the staff member to the extent possible to avoid the conflict of interest or (ii) removing the CSIRO staff member from the project.
   2. Any potential conflict of interest will be identified at the project scoping phase or kick off meeting and responses will be recorded in a register for each project and monitored every quarter by the Project Leader.
   3. Conflicts of interest that are unable to be avoided should be disclosed to the funder.
   4. At the date of this version the DEERA Team have disclosed no vested interest in development or application of gene technologies.
2. The CSIRO strives to increase impact by collaborating with others and increasing the funding available to the organisation through external businesses, funding bodies and philanthropic organisations. To minimise bias the DEERA Team are on indefinite employment contracts.
3. **Independence:** Independence from internal CSIRO gene technology research is formed by deploying to the DEERA team individuals that are not contributing to the technical development, application or adoption of gene technologies or derived products. The Team Leader will maintain a register of the DEERA Team. Independent external experts will be requested to declare involvement on current projects and identify and avoid potential conflict of interests. The Team Leader will maintain a register of the Independent external experts for the project term.
4. **Independent Technical Experts for domain knowledge:** To deliver risk assessment projects the DEERA team may involve independent technical experts on the specific gene technology under evaluation, such as gene drives, for assisting in understanding of the technical approach. WE recognise that CSIRO has experts in these same gene technologies. To mitigate the effects of motivational bias, maintain an information barrier and maintain an arm’s length risk assessment, WE may also consult or contract independent, external qualified technical experts that are not employed by CSIRO and are not part of the external teams whose products WE are assessing the risk of. If it is necessary to share confidential information, a non-disclosure agreement or terms and conditions included in the consultancy agreement would be entered into with the relevant expert.
5. **Independent Technical Experts for elicitation exercises:** When WE undertake formal elicitation exercises, as part of our probabilistic risk assessment or hazard analysis exercises, WE involve independent technology domain experts. To maintain the transparency of our analysis and independence of the experts WE do not require these experts to sign non-disclosure agreements and WE do not share confidential client or collaborator information with experts in the elicitation exercises.
6. **Confidential Information:** According to usual CSIRO business practise, third party information that is shared with CSIRO for the purposes of a risk assessment and identified as confidential by the discloser is only shared with CSIRO personnel and project subcontractors on a strict “need to know” basis for delivering the project under appropriate use conditions, as agreed with our clients or collaborators.
7. **Trusted Advisor:** WE require that all risk assessment reports and outputs are available publicly. WE may negotiate with clients and funders a publication procedure that enables publication with minimal delay, and that aside from seeking permission to incorporate data generated by third parties or removing client confidential information as relevant, the authors determine the content of such articles. CSIRO's contractual arrangements also require that we respond to information requests from our Minister or the Australian Parliament in a manner that respects confidentiality arrangements where appropriate.
8. **Peer Review:** All risk assessment reports are subject to internal peer review as part of CSIRO’s science integrity assurance processes. In addition we seek to publish our work in scientific journals and book chapters that are subject to external peer review processes.
9. **Progress Reports**: In delivering a project WE routinely provide project progress reports to the funding organisation and request information and data from project team members that are developing the gene technology products. For data integrity and testing WE maintain freedom to independently source information from any other source.
10. **Implementation of this SOP**: Implementation and governance of this SOP will be the responsibility of the Team Leader and Research Delegate. To acknowledge the importance of the DEERA Team’s ability to maintain arm’s length unbiased assessment it is intended that external and internal customers include this SOP as part of the project documentation.

**Appendix**

**DEERA Team members**

Keith Hayes – Team Leader, probabilistic risk assessment, Bayesian statistics

Jessica Ford - Statistics, data analysis, direct elicitation and hazard analysis

Geoffrey Hosack - Bayesian statistics, direct and indirect elicitation and spatio-temporal modelling

Jeffrey Dambacher - Qualitative mathematical modelling, monitoring design and hazard analysis

Scott Foster - Statistics, spatio-temporal modelling and monitoring design

Dave Peel - Statistics, data analysis and risk assessment software

Adrien Ickowicz - Bayesian statistics, indirect elicitation and spatio-temporal modelling

Nicholas Beeton – Spatio-temporal modelling

*Please note that in addition we also currently working with:*

Andy Wilkins (Energy BU) - Spatio-temporal modelling and numerical simulation

**Research Director**

Dr Paul De Barro, for *Risk, Evaluation and Preparedness* in Health & Biosecurity Business Unit

Dr Claudia Vickers, for *Synthetic Biology* the Future Science Platform in Land & Water Business Unit

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| Version | Authors/Edited by | Date |
| Version 2 | Keith Hayes, Vicki Locke | 16 October 2017 |
| Version 3 | Keith Hayes, Vanessa Leaman | 28 February 2018 |
| Version 4 | Keith Hayes | 20 March 2019 |