# Policy on reporting incidents involving rDNA to the NIH Office of Science Policy (OSP)

Researchers are responsible for immediately reporting any spill and/or accident involving recombinant or synthetic nucleic acid molecules research resulting in an overt or possible exposure, or that otherwise could lead to personal injury or illness, or to a breach of containment to their PI, the Biosafety Officer (BSO), the IBC Coordinator and, when applicable, the Animal and/or Greenhouse Facility Director. These kinds of events may include, but or not limited to, skin punctures with needles containing recombinant or synthetic nucleic acid molecules, the escape or improper disposal of transgenic animals, plants, or their reproductive materials, or spills of recombinant or synthetic nucleic acid molecules agents/materials occurring outside of primary containment. Failure to adhere to the containment and biosafety practices articulated in the NIH Guidelines must also be reported to the BSO and IBC Coordinator. Researchers should consult with the BSO and/or the IBC if there is any doubt about reporting.

The BSO is responsible for following up on incident reports and ensuring all incidents involving recombinant or synthetic nucleic acid molecules are reported to the IBC Coordinator. The IBC Coordinator will relay the information to the IBC and the Institutional Official (IO). The IBC Coordinator is responsible for reporting incidents involving recombinant or synthetic nucleic acid molecules to the NIH OSP on the behalf of the IBC. The IBC Coordinator will draft the incident report in coordination with the BSO and the PI. The incident report should include sufficient information to allow for an understanding of the nature and consequences of the incident, as well as its cause. A detailed report should also include the measures that the institution took in response to mitigate the problem and to prevent its reoccurrence.

## **CSU’S TIMELINE FOR REPORTING TO NIH OSP**

As per Section IV-B-2-b-(7) of the NIH Guidelines, registered IBCs are obligated to report “…any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses” to NIH OSP within 30 days. However, as outlined in Appendix G of the NIH Guidelines, certain types of accidents must be reported on a more expedited basis. Incidents involving recombinant or synthetic nucleic acid molecules which result in an **overt exposure**, and occur **in a BSL2 or BSL3 laboratory** must be immediately reported to NIH OSP. In addition, incidents involving recombinant or synthetic nucleic acid molecules which result in a **potential exposure**, and occur in a **BSL3 laboratory** must also be immediately reported to NIH OSP. However, incidents which result in a potential exposure, and occur in BSL2 labs do not require immediate reporting to NIH OSP, but must be reported within the 30-day timeframe.

Upon receiving the incident report, the IBC Coordinator will determine whether or not immediate reporting is required (based on the NIH Guidelines). If immediate reporting is required, the IBC Coordinator will make an initial report to NIH OSP via email. The IBC Coordinator will draft the formal incident report using the NIH OSP Incident Reporting Template. Prior to submission, the report will be reviewed by the PI, the IBC, and IO.

*\*This policy does not include adverse events experienced by participants in human gene transfer trials, which are subject to a separate set of reporting requirements. Please refer to Appendices M-I-C-3 and M-l-C-4 of the NIH Guidelines for more information on those reporting requirements.*

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