Policy 347 Version 8 09/08/015

**Policy Change Cover Sheet**

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| **This form must be attached to each policy presented. All areas in red, including the header, must be completed; if not, it will be sent back to you for completion.** |
|  | *I****f the changes you are requesting include housekeeping, please submit those changes to*** ***ndsu.policy.manual@ndsu.edu*** ***first so that a clean policy can be presented to the committees.*** |
| **SECTION**:  | 347 Institutional Biosafety Committee |
| 1. **Effect of policy addition or change (explain the important changes in the policy or effect of this policy). Briefly describe the changes that are being made to the policy and the reasoning behind the requested change(s).**
 |
| * Is this a federal or state mandate? [x]  Yes [ ]  No
* Describe change: The new section 3 is proposed to meet the requirements set forth in the U.S. Governmental Policy for Oversight of Life Sciences Dual Use Research of Concern and the U.S. Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern
 |
| 1. **This policy change was originated by (individual, office or committee/organization):**
 |
| * Office/Department/Name and the date submitted
* Office of the Vice President for Research and Creative Activity
* September 8, 2015
* Email address of the person who should be contacted with revisions
* Jolynne.Tschetter@ndsu.edu
 |
| ***This portion will be completed by Mary Asheim.***Note: Items routed as information by SCC will have date that policy was routed listed below. |
| 1. **This policy has been reviewed/passed by the following (include dates of official action):**
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| **Senate Coordinating Committee:** |  |
| **Faculty Senate:** |  |
| **Staff Senate:** |  |
| **Student Government:** |  |
| **President’s Cabinet:** |  |

The formatting of this policy will be updated on the website once the **content** has final approval. Please do not make formatting changes on this copy. If you have suggestions on formatting, please route them to ndsu.policy.manual@ndsu.edu. All suggestions will be considered, however due to policy format guidelines, they may not be possible. Thank you for your understanding!

**North Dakota State University
Policy Manual
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**SECTION 347
INSTITUTIONAL BIOSAFETY COMMITTEE**

SOURCE: NDSU President

1. The National Institute of Health (NIH) Guidelines require that each institution conducting or sponsoring recombinant DNA research is responsible for ensuring that research is conducted in accordance with NIH Guidelines. In addition, institutions must establish an Institutional Biosafety Committee (IBC) composed of no fewer than five members collectively having experience and expertise in recombinant DNA research.

North Dakota State University endorses this regulation and has an established Institutional Biosafety Committee. The NDSU IBC's purpose is to assure the safe use of recombinant DNA, infectious agents, and human blood, bodily fluids, or tissues, in research and teaching, and to maintain compliance with NIH Guidelines and additional federal regulations.
2. All project directors of research and teachers of courses involving recombinant DNA, infectious agents, or human blood, bodily fluids or tissue at NDSU, or conducted by representatives of NDSU, are responsible for submitting the protocol forms required for review and approval by the NDSU Institutional Biosafety Committee.
3. As part of its commitment to ensuring that life science research is being conducted according to federal regulations, North Dakota State University has established an Institutional Review Entity (IRE) and an Institutional Contact for Dual Use Research (ICDUR).

The purpose of the IRE is to determine if life science research meets the federal definition of Dual Use Research of Concern and to, as needed, work with the PI and others to draft a Risk Mitigation Plan. The IRE shall be an *ad hoc* subcommittee of the IBC comprised of 5 members from the IBC with the Biological Safety Officer and ICDUR acting as consultants. On a case by case basis, other individuals with specific expertise may be added to the IRE as members or called on to act as consultants.

The responsibilities of the ICDUR shall reside with the Vice President for Research and Creative Activity or designee and minimally shall include to serve as an institutional point of contact for questions regarding compliance with and implementation of the requirements for the oversight of Dual Use Research of Concern as well act as the liaison between the institution and relevant federal funding agencies.

1. Further information about the IBC can be obtained from the Office of Sponsored Programs Administration (Research 1, Rm 132, phone 701.231.8114, email: ndsu.ibc@ndsu.edu).

The NDSU Institutional Biosafety Committee is administered by the Office of Sponsored Programs Administration (Division of the Vice President for Research and Creative Activity).

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HISTORY:

New July 31, 2001

Housekeeping March 16, 2015