

# OBA News

## News from the NIH Office of Biotechnology Activities

September 29, 2009

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**NIH Guidelines Revised to Include Biosafety and Containment Standards for Research with Certain Influenza Strains** - The [NIH Guidelines for Research Involving Recombinant DNA Molecules](#) have been revised to address appropriate containment and biosafety practices for research involving certain strains of influenza that have either caused pandemics in the past or are highly pathogenic in humans and thought to be a potential source of a future pandemic. Previously, [Appendix B](#) of the *NIH Guidelines* classified influenza viruses A, B, and C as Risk Group 2 agents. No distinction was made between potentially pandemic strains of influenza and other lower risk influenza viruses.

After consultation with the NIH Recombinant DNA Advisory Committee, experts in biosafety and influenza, the Centers for Disease Control and Prevention, and the U.S. Department of Agriculture, the NIH Office of Biotechnology Activities concluded that more specific guidance in the *NIH Guidelines* was warranted to promote uniform biosafety practices for recombinant research with human H2N2 virus, which circulated from 1957-1968, the 1918-1919 H1N1, which caused the deadliest pandemic in the past century, and the Highly Pathogenic Avian Influenza (HPAI) H5N1 virus that is thought to have pandemic potential.

These viruses are now classified as [Risk Group 3](#) agents. Risk Group 3 agents have the potential to cause serious or lethal disease in humans for which preventative and therapeutic measures may be available. For research with the designated influenza strains, the *NIH Guidelines* now include requirements for enhanced biosafety practices, including the use of powered air purifying respirators (PAPRs) and other personal protective equipment to prevent laboratory worker exposure and minimize the risk of spread outside of the laboratory. The *NIH Guidelines* also specify containment standards for research with influenza viruses that are generated by recombinant methods (e.g., generation by reverse genetics of chimeric viruses with reassorted segments, introduction of specific mutations) and contain one or more genes and/or segments from human H2N2, 1918 H1N1 or HPAI H5N1. In addition, the *NIH Guidelines* now require Biosafety Level 3 enhanced containment for all influenza viruses that contain one or more genes and/or segments from 1918 H1N1 because of the uncertainty about the virulence factors for this agent. The *NIH Guidelines* also detail occupational health practices for work with these viruses, including policies regarding the use of prophylactic antiviral agents and isolation of laboratory workers who are exposed to one of these viruses.

The revisions are detailed in a September 22, 2009 *Federal Register* [notice](#). Because the revisions are considered Minor Actions as defined in [Section IV-C-1-b-\(2\)](#) of the *NIH Guidelines*, public and Federal agency comment is not required and the changes are to be implemented immediately. However, in order to promote transparency and to gather ongoing input from scientific community, OBA is encouraging the public to submit written comments, in particular on the following question regarding containment for 1918 H1N1:

- What data can be used to confidently predict that an influenza virus containing one or more genes from the 1918 H1N1 virus can be worked with safely at a biosafety containment level lower than Biosafety level 3-enhanced? Are there animal models of infection that are consistent and predictive of attenuation or loss of virulence in humans? What data should be used to assess attenuation in animal model(s)? What criteria should be used to evaluate a request for reduction of containment?

Comments may be submitted to OBA by email at [oba@od.nih.gov](mailto:oba@od.nih.gov) or to the following address: Suite 750, 6705 Rockledge Drive, Bethesda, Maryland 20892-7985. The [revised NIH Guidelines](#) may be downloaded off of the [OBA Web site](#).