Ebola cDNA and the *NIH Guidelines*

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Research Involving DNA from a Risk Group 4 Agent (Ebola)

Cloning nucleic acid from a risk group 4 (RG4) agent into non-pathogenic bacteria or a lower eukaryote falls under Section III-D-2-a of the NIH Guidelines

- "…. Experiments in which DNA from Risk Group 4 agents is transferred to non-pathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment after demonstration that only a **totally and irreversible defective fraction** of the agent's genome is present in a given recombinant. **In the absence of such a demonstration, BL4 containment shall be used.** The Institutional Biosafety Committee may approve the specific lowering of containment for particular experiments to BL1. Many experiments in this category are exempt from the NIH Guidelines (see Section III-F, *Exempt Experiments*)."

NIH Guidelines

Section IV-C-1-b-(2). Minor Actions

NIH/OBA shall carry out certain functions as delegated to it by the NIH Director (see Section IV-C-3, *Office of Biotechnology Activities*). *Minor Actions* (as determined by NIH/OBA in consultation with the RAC Chair and one or more RAC members, as necessary) will be transmitted to RAC and Institutional Biosafety Committee Chairs:

Section IV-C-1-b-(2)-(a). Changing containment levels for experiments that are specified in Section III, *Experiments Covered by the NIH Guidelines* (except when a *Major Action* is involved);

Therefore, NIH OBA may lower containment for research falling under III-D, including research with RG4 agents that do not meet the conditions of Section III-D-2a.