

> -----Original Message-----

> From: KLEIN, Jan [mailto:JKLEIN@fpm.wisc.edu]

> Sent: Friday, July 28, 2006 1:04 PM

> To: Office of Biotechnology Activities (NIH/OD)

> Subject: Request for Guidance

>

> Hello,

>

>

>

> The Institutional Biosafety Committee of the University of Wisconsin ?
Madison seeks your guidance about the appropriate containment level for
handling full-length Ebola virus cDNA. Since this construct is not
infectious, it seems reasonable to conclude that it could be handled
safely under BSL-2 containment. When we review section III of the NIH
Guidelines, we do not find language that supports this conclusion. The
qualifier in III-D-2-a allows BSL-2 for a construct that is an
irreversibly defective fraction of the genome. This construct, however,
is neither a fraction of the genome, nor is it irreversibly defective
since infectious virus can be produced when it is combined with plasmids
encoding necessary proteins, a procedure that would be attempted only in
a BSL-4 facility.

>

>

>

> Please provide your assessment on the appropriate containment for the
full-length Ebola virus cDNA and the relevant reference to the NIH
Guidelines.

>

>

>

> Thanking you in advance for your attention to this issue,

>

> Jan

>

> //

>

> Jan Klein

>

> Biological Safety Officer

>

> UW-Madison

>
> From: Whitney, Bruce (NIH/OD) [C] [mailto:whitneyb@mail.nih.gov]
> Sent: Friday, October 20, 2006 2:37 PM
> To: KLEIN, Jan
> Cc: Shipp, Allan (NIH/OD) [E]
> Subject: RE: Request for Guidance

>
> Dear Dr. Klein,

>
>
> Thank you for your query regarding the appropriate containment level
> for research involving full-length Ebola virus cDNA.

>
>
> Section III-D-2 of the NIH Guidelines For Research Involving
> Recombinant DNA Molecules (NIH Guidelines) applies to "Experiments in
> Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted
> Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic
> Host-Vector Systems." Section III-D-2-a states "experiments in which
> DNA from Risk Group 4 agents is transferred into nonpathogenic
> prokaryotes or lower eukaryotes may be performed under BL2 containment
> after demonstration that only a totally and irreversibly 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."

>
>
> It is the opinion of OBA that a recombinant containing full-length
> Ebola virus cDNA is not a "totally and irreversibly defective fraction
> of the agent's genome" and that BL4 containment must be used for
> experiments with full-length Ebola virus cDNA.

>
>
> If I can be of any further assistance, please do not hesitate to
> contact me.

>
>
> Sincerely,

>
>
> Bruce Whitney, Ph.D.

> Senior Biosafety and Outreach Specialist (contractor)

> NIH Office of Biotechnology Activities

> 6705 Rockledge Drive, Suite 750

> Bethesda, Maryland 20892-7985

> Tel: (301) 435-2149

> Fax: (301) 496-9839