ABSA
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June 12, 2013

NIH Office of Biotechnology Activities
National Institute of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD, 20892-7985
Fax: 301-496-9839
oba@od.nih.gov

Re: Request for Comments on proposal to revise the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid* Molecules – Streamlining Review of Certain Human Gene Transfer Trials that Pose a Low Biosafety Risk

Ladies and Gentlemen;

The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. ABSA reviewed the Federal Register Notice (Vol. 78, No. 92/ Monday May 13, 2013/Notices) requesting comments on proposed changes to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid* Molecules by streamlining the review of certain human gene transfer trials that pose a low biosafety risk. ABSA would like to submit the following comments and questions.

Overall, ABSA supports the proposal as written. However, ABSA believes there will be many questions about how to interpret these changes and ensure compliance at participant locations and recommends that the Office of Biotechnology Activities create training modules, frequently asked questions and guidance documents for posting on its website. Below is a list of what we believe will be the most likely asked questions and concerns:

- What is the definition of "initial trial"?
- If a Serious Adverse Event (SAE) occurs at a single trial site during a multi-site trial, would all participant sites be required to receive a report of the event?
- If an initial human gene transfer clinical trial is conducted at another clinical site and reviewed by another IBC that uses different standards of review, would the site where the later trials
- are conducted be required to use their safety data to verify whether the particular use can be exempt from IBC review?
- Will IBCs involved in multi-site trials be able to access data from the Data Safety Monitoring Board?

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- If a human gene transfer trial is exempted from IBC review, is the IBC required to report an SAE that occurs during the trial to NIH/OBA?
- A study site is part of a multi-site trial and all work at that site is determined to be exempt from IBC review. Later, the initial site makes changes to the clinical application. What types of changes to a trial would warrant a re-evaluation of the exemption?

ABSA appreciates the opportunity to provide comments on the proposed changes.

Sincerely,

Barbara Fox Nellis, SM(NRCM), RBP, CBSP
President
American Biological Safety Association