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On behalf of the Environmental Protection Network

I am a former AA of ORD and chair of CASAC under Ronald Reagan, and am an elected member of both the National Academy of Medicine and the American Society for Clinical Investigation.

In addition to my 3 minutes, I humbly ask you to please review my written submission.

First, let's be practical. There are no guarantees. Personal information from a study of Alaskan Native populations related to the Valdez oil spill was judicially required to be released to Exxon.

Consider a study by Zhang et al. that had much impact on the 2010 IARC vote in favor of formaldehyde being a cause of human leukemia. Industry has resolutely refused to repeat the study, instead funding consultants to reanalyze data in many questionable ways.

This study had 34 co-authors from 7 institutions and 3 countries. What if just one co-author decided not to make raw data available for industry to continue the nit-picking defamation that has been central to the formaldehyde story? Would both IRBs, one US, one China, give permission? Would the Dutch IRB have deferred to the other two if the data could end up being used by anyone? Isn't an inevitable outcome of EPA's proposal a cumbersome barrier to putting together teams of international or multi-university investigators?

How about NIEHS not being able to get into the field until about 8 months after the Gulf oil spill, largely due to HIPAA issues. This delay contributed to confounding by recall bias. Will EPA's new requirements further delay responses to environmental disasters?

What about the ethical constructs central to IRB decisions? IRBs often consider whether the proposed study is scientifically valid to justify any risk – including the disclosure of personal information. They also turn down requests that are inherently biased.

The potential for bias exists because of the near certainty, based upon past behavior, that the regulated industry would hire consultants whose future success depended on finding and exaggerating possible confounders. These are inherent in any study that cannot be done in a random double-blind fashion –

which is true for virtually all environmental health studies (I emphasize that not all consultants are inherently biased).

An IRB might also refuse because reanalysis does not constitute replication of an environmental health study, which is claimed to be the rationale to request IRB permission. Bias also can be an issue in that industry is more likely than at-risk communities to afford paying consultants.

Finally, although I am familiar with IRBs, I do not consider myself an expert. But neither are you. This complicated issue deserves in-depth analysis, perhaps by the National Academy of Medicine.

But once again, this EPA leadership has seen fit to rush headlong into making major changes without enlisting the help of the scientific advisory processes that have characterized EPA's first 50 years. Please do not be complicit in their doing so.

Let me conclude by thanking you for serving on the SAB.