

## Introduction to: *Considerations for the Use of Human Participants in Vector Biology Research: A Tool for Investigators and Regulators* by Achee et al.

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**I**N 2003, *VECTOR-BORNE AND ZOO NOTIC DISEASES* (VBZD) published the landmark special issue entitled, “Arthropod Containment Guidelines.” This was conceived in 1999 at the annual meeting of the American Society of Tropical Medicine and Hygiene (ASTMH), was based on input from many experts in the field, and was endorsed by the American Committee for Medical Entomology (ACME). These guidelines have been utilized by researchers and institutes in many countries. The Publisher of VBZD, Mary Ann Liebert, Inc, publishers, recognized the importance of the work and provided free downloads at a time before ‘open access’ was an everyday term. It is still available from the website at [www.liebertpub.com/overview/vector-borne-and-zoonotic-diseases/67/](http://www.liebertpub.com/overview/vector-borne-and-zoonotic-diseases/67/)

A second guidance document “Guidance for Contained Field Trials of Vector Mosquitoes Engineered to Contain a Gene Drive System: Recommendations of a Scientific Working Group” was released in 2008, and can be freely accessed at the same website.

I was involved in many discussions related to the “Arthropod Containment Guidelines” and briefly described its history in my editorial in the 2003 issue. Every effort was made to ensure that it was comprehensive, however, as one may imagine there were some contentious issues, not the least being the use of human subjects in work related to vectors. Ultimately this topic was omitted from the guidelines.

I am therefore delighted to introduce this issue of the journal that features an article “Considerations for the Use of Human Participants in Vector Biology Research: A Tool for Investigators and Regulators.” The current ACME president, Nicole L. Achee, is the lead author and I know that the National Institutes for Health (NIH) and the Foundation for the National Institutes of Health (FNIH) were very supportive in facilitating discussions that have resulted in this publication. This is the first known publication that interprets U.S. regulations on human subject use in vector biology research. Although, like the *Arthropod Containment Guidelines*, it has a U.S. focus it nevertheless has applicability for investigators and regulators around the globe. One reason is that the U.S. regulations not only apply to research in the U.S., but can also apply to U.S. federally funded projects overseas. However, even for research that is not covered by these regulations, this document will be of great value in understanding standard techniques used in vector biology research for the planning and execution of a

wide variety of studies. Human participants, often local volunteers play a variety of important roles in vector-related work. The best known is probably the human landing catch (HLC) technique for surveillance or vector collection. Host preference can be extremely specific, with no viable substitute for using humans to collect some species of vector that are strictly anthropophilic. It is possible that in the future exact formulations of chemicals that perfectly mimic humans may become available, but we are not at that stage yet. Being fed upon by uninfected vectors may be regarded as relatively low risk, but when collecting in areas with ongoing transmission of human pathogens, the risks to the participants must be carefully considered.

A developing scenario, not covered in this paper relates to release of genetically modified (GM) vectors or release of vectors harboring symbionts. With ongoing releases in several countries and proposals to release GM mosquitoes in Florida this will inevitably become a subject of public discussion. Were only males released, then human exposure either deliberate for HLC or natural, would not be an issue. However, if females are released, especially if they are of a species such as *Aedes aegypti*, which preferentially feeds on humans, then it seems inevitable that people will be fed upon by these mosquitoes. Fortunately, since the integrated genetic elements seem to be non-transmissible and the symbionts seem not to be transmitted in a functional form between different species, exposure would seem to be a low risk activity for humans, equivalent to being fed upon by uninfected arthropods.

Due to human host preference, some laboratory studies including colony maintenance may require feeding on people, because even human blood presented in artificial feeders does not work. These colonies are critical to support a variety of studies on attractants, repellents, basic biology and pathogen transmission. I remember many years ago maintaining a colony of *Sabethes (cyaneus* I believe) that would only feed on human blood and then only feed on the knuckles. If three out of 25 fed during a whole afternoon, it was considered as a successful day. Other laboratory-based use of human subjects may include vector-delivery of pathogens, for example to test vaccine efficacy. The increasing body of evidence demonstrating that inoculation by needle does not accurately represent natural arthropod-borne transmission may actually increase interest in this mode of challenging human subjects.

In order to develop a better understanding of vector-borne diseases, to generate predictive models and approaches that will ultimately reduce the impact of these diseases, the need for human subjects is clear. What needed clarification, were the rules, regulations, recommendations and sometimes ambiguous language that investigators, members of Institutional Review Boards (IRBs), and others were expected to interpret when planning field and laboratory work with vectors. This seminal article, lays out for the first time, a clear description of what is and is not regarded as research, a definition of what constitutes research on human subjects, and how rules and regulations should be applied. Even if technically not covered by the U.S. regulations, this paper is an invaluable resource to ensure that the people involved in vector-related work, whether defined as

human subjects or not, are treated ethically, and have sufficient understanding of the risks and benefits of their participation, so that their consent is based on complete information. This does not imply that this has not been the case in the past, but we now live in a more regulated, better informed and more connected society and this manuscript will ensure that we get the maximum value with minimal risk from the dedicated people that patiently present arms for research.

The paper can be freely obtained from the following link [www.liebertpub.com/doi/full/10.1089/vbz.2014.1628](http://www.liebertpub.com/doi/full/10.1089/vbz.2014.1628)

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