



STATEMENT

IFPMA statement on research with vulnerable populations within the scope of the World Medical Association (WMA) Declaration of Helsinki revision

On 14-15 May 2024, IFPMA was represented at [a targeted interdisciplinary discussion](#) within the scope of the WMA Declaration of Helsinki revision. The aim of the meeting was to foster discussion with experts on the paragraphs in the Declaration of Helsinki focused on vulnerable people in research, with a view to contribute the findings to the revision process.

The statement was delivered by Karla Childers, Head, Bioethics-based Science and Technology Policy at Johnson & Johnson, on behalf of IFPMA.

At the foundation of modern-day research ethics is the concept that vulnerable people deserve special protection. These protections are formalized in guidelines, like the Declaration of Helsinki, and can be found in local laws. The list of groups considered vulnerable is long and includes intrinsic vulnerability, as well as episodic vulnerability, such as accidents or trauma.

The requirements associated with conducting research with vulnerable populations are well intended and important – and yet the culture of protection has often resulted in people being excluded from research to the detriment of that population. We must remember that being vulnerable does not necessarily mean an individual does not have the capacity to make their own decisions about participation in research.

The research ecosystem has at times failed to advance treatments and solutions for their unique conditions or did not gather the data critical to safely administer existing treatments.

Over time, though, we have seen a shift in the mindset from protecting people *from* research to protecting them *through* research. As IFPMA, we are increasing efforts to broaden access to clinical trials and ensure more diverse and equitable inclusion, often engaging with vulnerable populations and finding that delicate balance between inclusion and protection, while ensuring voluntary and informed consent.

Furthermore, the increasing use of novel, complex technology has required new and evolving thinking around vulnerability as we attempt to provide appropriate and understandable information about these new modalities to facilitate informed consent of all research participants.

We are also seeing new conceptions of vulnerability or changes in vulnerability, such as with impacts of war, climate change, and global health emergencies. It may be a productive exercise for this group to challenge ourselves with better describing what we mean by vulnerable and the shifting nature it can assume to be better prepared to manage that in research.

IFPMA has been making important inroads into including vulnerable and historically excluded populations in critical research, such as paediatrics, neurologically debilitating diseases, research

with pregnant persons, to name a few. We believe there is a great depth of experience in industry to draw upon in engaging with these populations and those who care for them.

As we sit together and contemplate potential changes to the Declaration of Helsinki regarding vulnerability, there are three things that are top of mind: balancing protection, inclusivity, and the potential unintended consequences of adding specificity.

Currently, the language makes no distinction for sicker or sometimes more desperate populations who may have a greater tolerance to accept a higher level of risk for the potential benefit. We think there is the opportunity to encourage engagement with vulnerable populations to better understand their preferences and personal willingness to participate in research.

IFPMA is also striving to encourage greater diversity and broader inclusion in research to enable access for populations previously not represented in clinical trials. We are committed to doing this in a fair and transparent manner, as articulated in the [Ethos](#) of IFPMA. In doing this, we appreciate that many of these populations are also considered vulnerable, sometimes across multiple dimensions.

Finally, as we contemplate any potential changes to add clarity, we must be disciplined with engaging in too much specificity and effectively creating a position that neither serves patients nor the research ecosystem or uses language that is relevant only during a snapshot in time.

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