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Problem Statement: The concept of “vulnerability” has been connected to the Belmont Report in question of the justice in the selection of research participants. More recently, the use of vulnerability is more expansive; according to the Council for International Organizations of Medical Sciences, guidelines include, as vulnerable, “junior or subordinate members of a hierarchical group,” “residents of nursing homes; people receiving welfare benefits or social assistance, and other poor people and the unemployed,” “ethnic and racial minority groups,” and “homeless persons, nomads, refugees or displaced persons.” With an even more specific list, the National Bioethics Advisory Commission classifies for identifying “vulnerability” in research participants as five different types. However, under one or another of these rubrics, nearly everyone who wants to participate in human research can be vulnerable since the benefit of research cannot be guaranteed in advance. In this schema of “vulnerability,” virtually all potential human participants are included so that the premise, which the vulnerable groups are to provide additional protections, cannot be satisfied in reality.

Description of the Research: We believe that it is time to rethink the present concept of vulnerability and its justification. In other words, if everyone is potentially vulnerable, then the concept becomes meaningless; we view that it is not possible to additionally protect the vulnerable groups and to give special consideration to research in which these groups may be included. In this paper, we first review regulations and guidelines related to the vulnerability in human research. We show the reasons that the concept of vulnerability is overbroad. In order to prove the evidence, we briefly survey potential participants in human research. Then, we identify the theory (guidelines and regulations) is not consistent with the practice (reality). Finally, we consider implications for policy of making vulnerability explicit.

Additional Information: We always emphasize vulnerable groups in human research, but there was little attention on the concept of vulnerability in research. We will share both the literature review and results of the survey in order to reduce the gap between the theory and reality. The research is useful to reestablish the concept of vulnerability based on the reality in order to actually additionally protect vulnerable groups.