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QUOTED. Nov. 16, 2018. Scott Gottlieb.

by

US FDA is proposing to amend its regulations to allow an institutional review board to waive or alter informed consent when a clinical investigation "poses no more than minimal risk" to human subjects and includes safeguards to protect their rights and safety. See what agency head Scott Gottlieb said about it here.

"Over the years, we've received feedback from sponsors and investigators that they were not able to move forward in conducting important clinical investigations where there would be minimal risk as these trials involved situations where obtaining informed consent wasn't possible, and the agency lacked the authority to permit a waiver of informed consent for that research. With the passage of the 21st Century Cures Act, the FDA's authorities were changed, allowing greater flexibility." –Scott Gottlieb, commissioner, US FDA

- Find out more: *US FDA Allows Waiver Of Informed Consent For Clinical Investigations With Minimal Risk*