

# Informed Consent Mistake, Not Science, Trips Up 'Golden Rice' Research

By ACSH Staff — September 10, 2015



Surely one of the most hotly contested foods in the world is

golden rice. This genetically engineered rice variety has been altered by adding genes from other plants such as marigolds, so that its grains contain beta-carotene, which the body can use to make vitamin A. The beta-carotene colors the rice (as it does sweet potatoes, and other foods), hence the name "golden rice." This rice was devised to help stem the tide of vitamin-A deficiency, which, according to the [WHO](#) <sup>[1]</sup>, has caused blindness in 250,000 to 500,000 children, half of whom die within a year of becoming blind.

Besides the fact that it's genetically engineered, anti-GMO activists have complained for years that golden rice wouldn't help with vitamin A deficiency, because it wouldn't produce enough vitamin A to address the problem. However, a recent paper (published in 2012 in the *American Journal of Clinical Nutrition*) tested that issue and found that when fed to vitamin A deficient children, golden rice raised the levels of vitamin A in their blood as well as did supplements of vitamin A itself.

So this is good news, no? Not exactly, because sadly, the paper that explained that study has since been [retracted](#) <sup>[2]</sup> by that journal.

The sad part is that there was nothing wrong with the science. There was no data-fudging or improper statistical analyses. What brought the journal to retract the paper was an ethical, rather than a scientific, breach.

As noted in the article referenced above, as well as in the [Boston Globe](#) <sup>[3]</sup>, the researchers apparently used Chinese children in their study without completing the required notification of their parents and acquiring their informed consent for their children's participation in the trial. Any such use of human subjects *absolutely* requires their informed consent about the manipulations to be used in the study and of course for children, the parents must agree.

As a result of this infraction, the researcher who ran the study was prohibited from the use of human subjects in her research for a period of two years. And once an article has been retracted, other researchers in that scientific area won't be citing it. This means that valuable data are essentially negated.

ACSH's senior nutrition fellow, Dr. Ruth Kava had these comments: "This is a truly unfortunate situation because an easily accessible source of beta-carotene, which could save both the eyesight and lives of many children is still vulnerable to attacks by anti-GMO activists. It's doubtful that even this demonstration would have stopped their misplaced mistrust of golden rice, however it could have encouraged the further testing and acceptance of this grain by both consumers and governments. This incident should make it clear to all researchers who want to use human subjects that shortcuts in obtaining ethical approvals must be avoided at all costs."

Scientifically accurate information about the use of genetic engineering in agriculture can be found in the ACSH publication *Food and You*. [4]

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**Links**

[1] <http://www.who.int/nutrition/topics/vad/en/>

[2] <http://retractionwatch.com/2015/07/30/golden-rice-paper-pulled-after-judge-rules-for-journal/#more-30806>

[3] <http://www.bostonglobe.com/metro/2015/08/17/medical-journal-retracts-paper-tufts-researcher-over-questions-ethical-breach/K7UQwnJITLE6sfo6C9TQ8l/story.html>

[4] <http://acsh.org/2014/03/food-guide-modern-agricultural-biotechnology/>