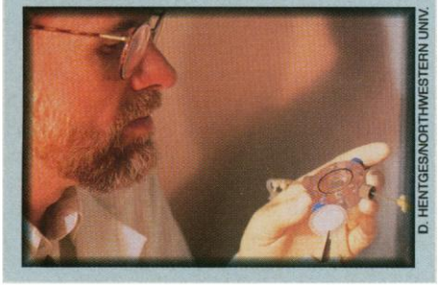
LETTERS

On closer inspection

U.S. Army researchers are said to be required to follow the "Common Rule" when conducting studies on humans. Concerns are expressed by New Zealanders about exterminating rabbits with the use of a viral disease. Some in vitro alternatives (below) to the Draize rabbit eye test are said to be making progress. And the response of the immune system to tuberculin vaccination is discussed.



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Human Subject Research

In the ScienceScope item "Broader oversight for research on humans?" (31 Jan., p. 605) it is stated that for "Army scientists doing classified studies . . . following the Common Rule is voluntary." On the contrary, it is mandatory for the Army and all other Department of Defense researchers to follow the regulations set forth in the Common Rule "which requires that researchers obtain approval for human experiments from an institutional review board, fully inform test subjects about the risks, and obtain subjects' written consent."

As a federal agency and as part of the Department of Defense, the Army is (i) one of the 16 agencies to work for adoption of the Common Rule, and (ii) one of the agencies that adopted the Common Rule in 1991. Title 32, *Code of Federal Regulations*, Part 219, is the Common Rule for the Department of Defense. All Army and Department of Defense biomedical human subject research, whether classified or nonclassified, intramural or extramural, is subject to the Common Rule. The Army and Department of Defense are also subject to the Food and Drug Administration's oversight of investigational medical product research and use involving humans.

While it is correct that " 'there is no law saying that all research involving human subjects must have informed consent,' " the implication cannot be made that informed consent is therefore not required or obtained. In the mid-1970s, both the National Institutes of Health and the Army instituted major changes in regulations governing the oversight of human subject research. The changes, including requirements for informed consent, are enforced, and they continue to be strengthened and clarified in response to concerns of the scientific and lay community.

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Atopic Disease and Immunologic Response

In their report "The inverse association between tuberculin responses and atopic disorder" (3 Jan., p. 77), Taro Shirakawa *et al.* suggest that their findings are the result of a protective effect of early exposure to mycobacteria. A number of older studies of atopic dermatitis documented the same correlation, but derived an alternative conclusion—that atopic disease alters delayed hypersensitivity (*1*). Uehara (*2*) found that size of tuberculin reaction decreased and then increased in individuals as they underwent aggravation and then remission of atopic dermatitis. Although the idea that early childhood infections (and perhaps vaccination) can protect against the increasingly more common diseases of asthma and hay fever is attractive, the evidence admits of other interpretations.

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References

1. H. Gudjonsson, A. Lodin, J. Modee, *Acta Dermatovena* **46**, 159 (1966); G. Rajka, *ibid.* **47**, 158 (1967); M. Forsbeck, A. Hovmark, E. Skog. *ibid.* **56**, 135 (1976).
2. M. Uehara, *Arch. Dermatol.* **113**, 1226 (1977).

In their report, Shirakawa *et al.* state (p. 77) that, in immunized schoolchildren, "[p]ositive tuberculin responses predicted