A Call for Papers on Human Subjects

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Research on human subjects is currently represented in only a fraction of the papers published in the *JEM*, but the Editors and I would like that to change. Given recent advances, such as new techniques to precisely and quantitatively monitor human immune responses and new drugs that act on increasingly well-defined pathways, it is now more feasible to perform exciting research on human subjects.

Investigators who carry out research on humans often struggle to publish important findings in widely read journals. Everyone realizes that a researcher cannot typically achieve the same level of mechanistic depth and proof in human studies relative to more tractable animal and in vitro systems. Yet, there is a need to study human subjects to make discoveries that are directly applicable to the diagnosis, prevention, and treatment of human disease. It is clear that animal models of disease, where they exist, do not always reliably recapitulate the mechanisms and clinical features of human disease, and in many cases the pathology is quite different. Thus, the precision lost in human studies owing to limited subject number and uncontrollable variables is gained in relevance to human disease. The Editors of the *JEM* do not regard this research as translational in a literal sense, that is, extending lessons from mice to men. Rather, we view research on humans as de novo research on disease processes in man.

We would like to publish more research on human subjects in areas such as infection, hematopoiesis, malignancy, autoimmunity, and allergy, traditionally highlighted by the *Journal*. Two types of manuscripts are anticipated: (i) studies which identify new features of the disease process in humans and (ii) investigations of patient responses to approved experimental treatments or vaccines. Each paper will be judged in the context of human research, taking into account the significance of the problem that is being tackled and the challenges of the clinical setting. Studies involving a small number of subjects will be considered if they are of high quality and importance. As always, we will prioritize papers that provide new mechanistic insights.

The process of peer review will assess the suitability of the assays and the validity of the experimental design. We are pleased to welcome on board two new Consulting Biostatistics Editors, Drs. Glenn Heller and Madhu Mazumdar of the Memorial Sloan-Kettering Cancer Center, who will oversee expert statistical evaluations. As stated in our instructions to authors, all studies of human subjects must be conducted according to the principles expressed in the Helsinki Declaration (1) and be approved by an appropriate regulatory body, such as an institutional review board.

We are pleased that this issue of the *JEM* contains an example of the high caliber, high impact research on human subjects we would like to attract. Dhodapkar et al. (2) show that T cells can recognize and potentially control a precursor of multiple myeloma known as preneoplastic gammopathy. As Olivera Finn discusses in her commentary (3), the findings provide a strong rationale for premalignancy vaccines. The Editors and I look forward to receiving more experimental medicine of this caliber in the near future.

References

1. http://www.wma.net/e/policy/b3.htm
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3. Finn, O.J. 2003. Premalignant lesions as targets for cancer vaccines. *J. Exp. Med.* 198:1623–1626.

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