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Injection drug users (IDUs) at high risk for human immunodeficiency virus (HIV) infection are being identified as a population for HIV vaccine trials. We studied willingness of drug users to enroll and their comprehension of consent procedures in the context of a Phase II trial at one site. Of 175 people screened for enrollment and whose data sets were complete, 119 (68%) were IDUs. Of the 71 who were eligible, 39 (55%) were IDUs. Exclusion of IDUs was usually for medical reasons. Using a 17-item true/false test, comprehension of the informed consent procedure was high (median score, 16 of 17 for IDUs and non-IDUs); only three subjects (all of whom were IDUs) were excluded from enrollment due to lack of comprehension. Follow-up rates were similar for IDUs and non-IDUs. These data suggest that recruitment of IDUs into HIV vaccine trials is feasible, that IDUs can comprehend and complete the informed consent procedures, and that they return for follow-up visits.

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