

# The Representative Studies Rubric: 12 Steps to Address Underrepresentation in HIV Clinical Research



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## BACKGROUND

Women and other underrepresented populations suffer the consequences of exclusion from HIV research.

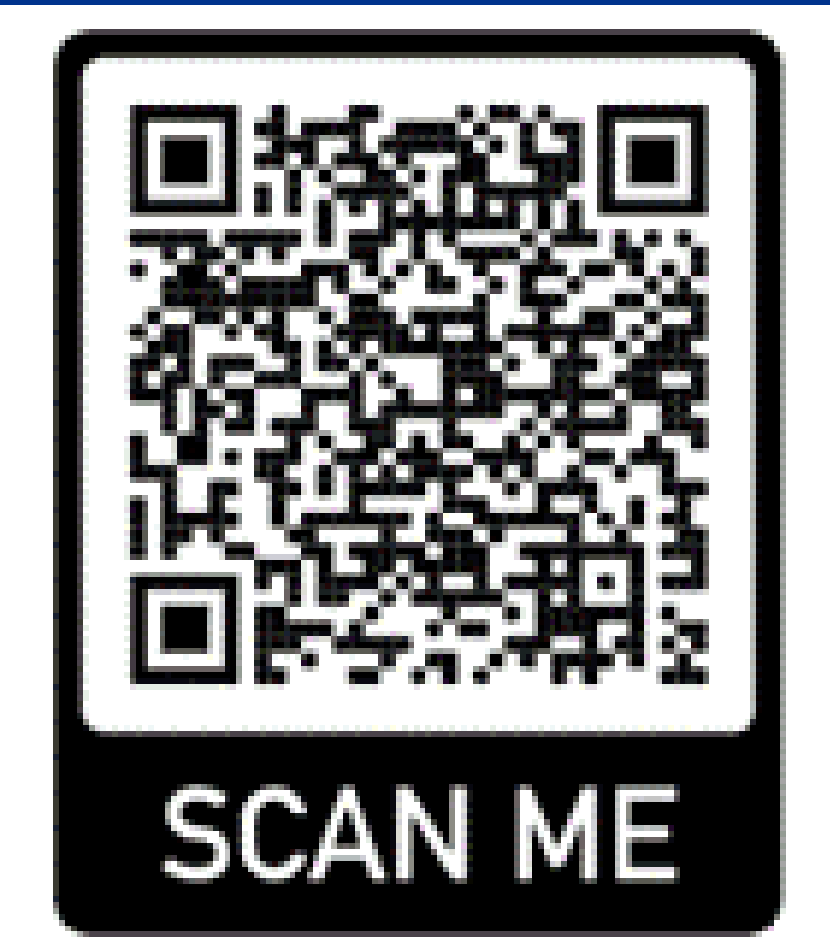
## METHODS

The Legacy Project designed and applied a 12-item questionnaire (the RSR) to assess 47 HIV clinical research protocols for inclusiveness in the following categories: **Age, Ethnicity, Gender, Drug use, Pregnancy, Race, and Sex assigned at birth.**

## CONCLUSION

A simple screening tool (the RSR) helps identify and rectify components of HIV research protocols that unnecessarily exclude women and other underrepresented populations.

The RSR should be implemented proactively as a protocol development tool to ensure that clinical trials are designed to enroll representative study populations.



## RESULTS

A significant number of study protocols were found to exclude women and gender minorities with no justification for exclusion provided. Only 12 studies (26%) correctly defined the study population by gender identity and sex assigned at birth. Over half of the studies required participants to actively avoid pregnancy.

