

## The Diversity Study: Factors Influencing Clinical Research

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# The Diversity Study: Factors Influencing Clinical Research A Focus on Women Participants

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## OVERVIEW

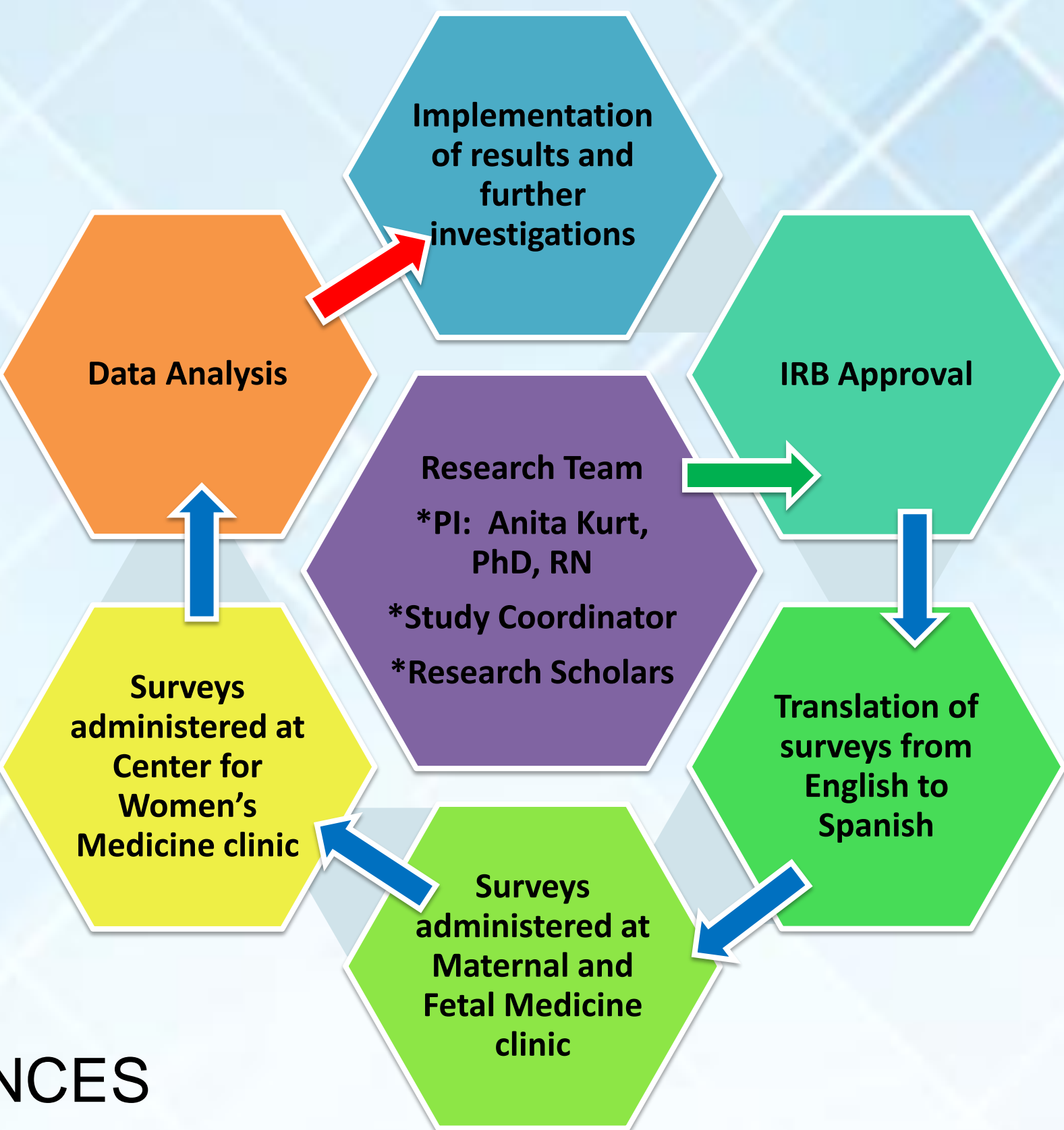
The Diversity Study is a two-pronged study which aims evaluate both clinical research professionals and **patient populations eligible to participate in studies**. This segment is focused on **women** surveyed in Obstetrics clinics, Center for Women's Medicine and Maternal and Fetal Medicine, in the Lehigh Valley Health Network (LVHN).

### SPECIFIC AIMS:

- Identify the extent of participation of the LVHN community in clinical studies
- Gauge opinions regarding promotional tools which may more effectively prompt women to participate in clinical research using a 0-4 Likert scale
- Improve diversity in research (aligns with LVHN triple aim) and community involvement

Outcomes indicate that women in Obstetrics clinics of all races and cultures are open to participation in clinical studies given the right approach and resources.

## METHODS

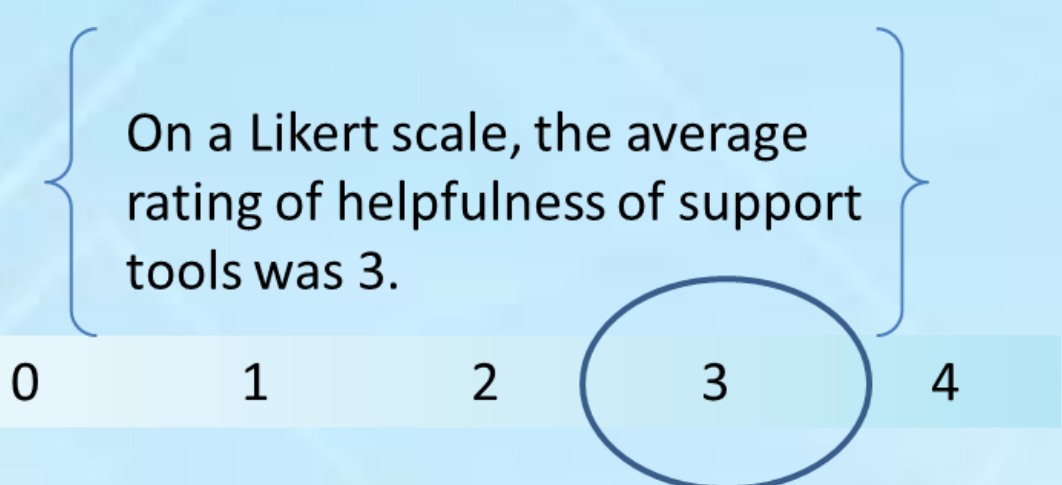


## RESEARCH QUESTIONS

- Are women open to promotional and support tools to encourage them to participate in clinical studies?  
[YES]
- How do ethnicity and socioeconomic status influence openness to participation?  
[SEE CONCLUSIONS]
- Does participation vary if the subject speaks a language other than English at home?  
[NO]

## RESULTS

Participant Information	Average Response
Age	25-34
Percent with Children	76.80%
Previously Participated in Research Study	8.35%
Rating of Tools For Understanding Research Studies	3



TOP HELPFUL RESOURCES		
RESPONSE	AVERAGE RATING	P-VALUE
"Having all material provided in my own language"	3.21 Median=4	0.055
"Having opportunity to speak to a patient who has participated in a clinical research study"	3.06	0.0039
"Written material explaining the research study"	2.97	0.0018

Table 2: the average rating and statistical significance of the top three helpful resources from all survey participants.

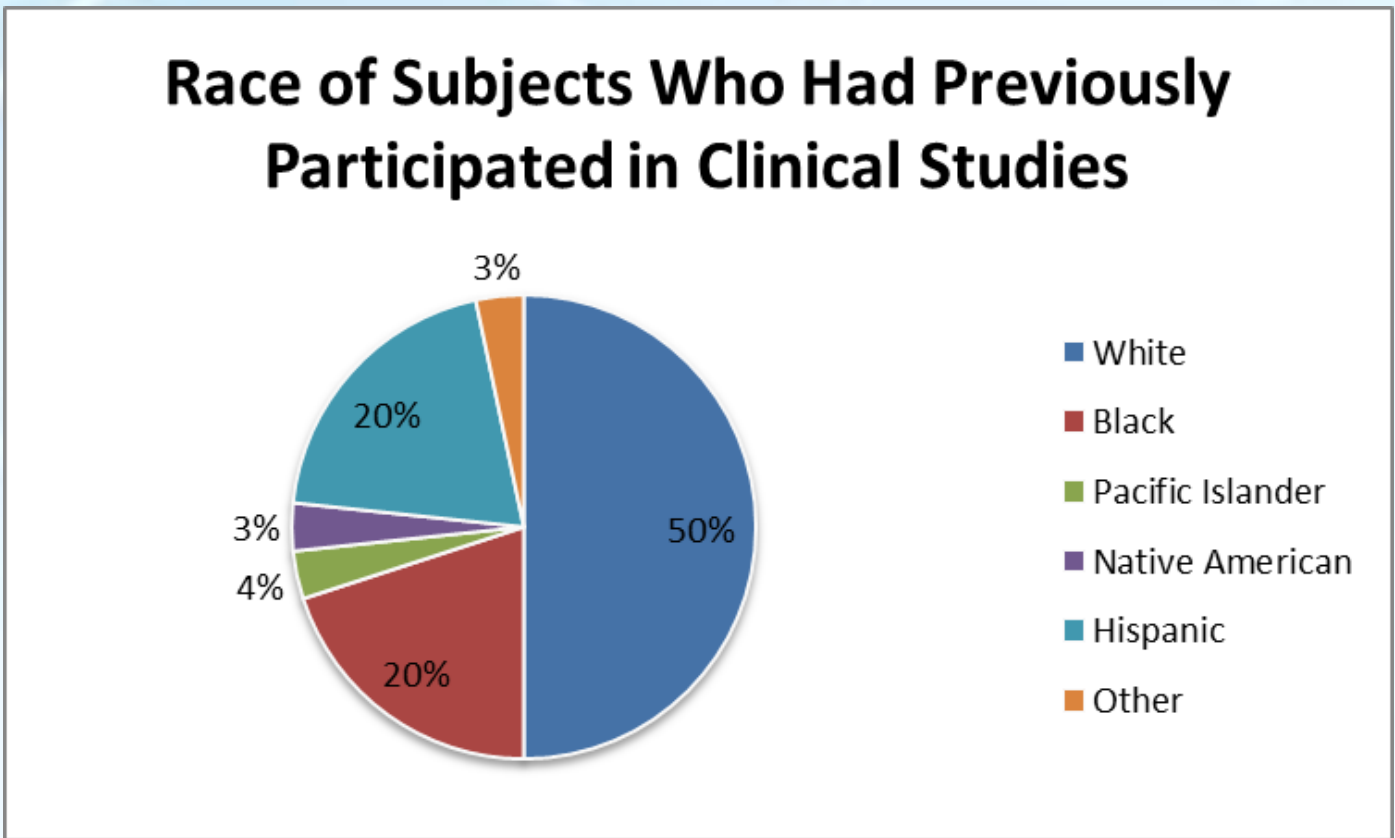


Figure 1 displays the percentage of women who had previously participated in clinical studies by race.

Figure 2 shows the inverse relationship between ratings of tools (lower income subjects rated tools as more helpful).

## DISCUSSION AND CONCLUSIONS

Table 1 provides a sample of descriptive statistics of the 400 women surveyed. Average education was "some college or 2 year degree" ( $p=0.014$ ), average English spoken was self-rated "very well" ( $p=0.016$ ), 42.27% described themselves as Hispanic, and the average language spoken at home was Spanish ( $p=0.014$ ).

- The average rated helpfulness of supportive tools was 3 on a Likert scale, indicating openness to participation in clinical studies.
- Ethnicity and language preference was diverse among the participants in clinical research. The lower the income of the participant, the more likely they were to prefer helpful resources such as materials in the subject's own language. Less educated and the most educated participants rated helpfulness of resources lower than those who had graduated high school/GED, attended some college, or had a 2 year degree.
- Of the 8.35% who had previously participated in clinical research, 84.85% of those subjects spoke a language other than English at home. Language did not prevent these patients from participating.

**Outcomes suggest that women are in fact open to educational and supportive resources which may increase openness to participation in clinical studies. The largest factor which may improve openness to clinical studies may lie in the approach and provision of support to patients.**

## IMPACT AND FUTURE DIRECTIONS

- Women of childbearing potential were banned** from phase 1 and early phase 2 clinical trials in 1977.<sup>2</sup> This guideline has generalized to exclude women from most phases of clinical study.
- To avoid skewed conclusions from trials, **the presence of women in clinical studies must be increased.**
- Use of each tool at discrete enrollment sites, followed by comparison of success, could better identify which resources are best for the women and minority populations at LVHN in future studies.

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## REFERENCES

- Kurt, Anita. (2014) Protocol, Factors influencing participation in clinical research.
- Sherman, Linda A., Robert Temple, and Ruth Merkat. "Women in Clinical Trials: An FDA Perspective." *Science* 269 (1995): 793-95.