

## “Informed Consent in the Refugees and Immigrants Mental Health Researches - A Qualitative Systematic Review and Recommendations”

### Researcher:

**Fatemah Samir Alghamdi**

PhD. NCC. CCTP

Assistance Professor of Psychology, Department of Psychology,

Faculty of Arts and Humanities, King Abdulaziz University,

Jeddah, Saudi Arabia



## Abstract:

The refugee and migration crisis is at its most critical consideration in history. Millions of people fled their countries to save their lives from armed conflicts or natural disasters that impacted their mental and physical health. This article aimed to map out the body of published articles in the refugees' and immigrants' researches to highlight the method of informed consent process that is crucial for the Institutional Review Boards. This research systematically reviewed published literature between 2010 and 2020 on acquiring informed consent among refugees and immigrants. This systematic review was conducted in the Association of Computing Machinery (ACM), PschInfo, EBSCO, and PubMed using Preferred Reporting Items of Systematic Review and Meta-Analyses (PRISMA) framework to identify the process of informed consent in researches that addressed mental health and related issues among refugees and immigrants. A total of 32 qualitative and quantitative research genres were reviewed to highlight the informed consent procedure in refugees and immigrants researches between 2010 to 2020. The current research found out three themes: a third party involvement, participants' educational level, and ethical violation in the informed consent process. Also, this research suggested the multifaceted informed consent to maximize the research outcomes and elude ethical violations.

**Keywords:** Mental health, Informed consent, Refugees, Immigrants, Multi-phased, IRB.

## Introduction

Refugees and immigrants are vulnerable populations who experienced pre-migration traumatic events and post-migration acculturation stress. It is required to provide an in-depth understanding of their experiences to be able to provide appropriate support by designing research studies that aim to highlight their issues and needs. The number of studies that refugees and immigrants participated in is limited. This paper aims to highlight the obstacles that refugees and immigrants experience when contributing as subjects for a study. Besides, this paper illustrates the multifaceted informed consent that considers refugees and immigrants language limitation, promotes accurate understanding, and reduce their anxiety that is increased by signing traditional informed consent forms.

In general, several obstacles that hinder mental health professionals to conduct studies on refugees and immigrants. One of the significant reasons is the refugees' and immigrants' legal and political status. Those individuals have fewer humanitarian rights to protect and advocate for them compared to the mainstream citizens because of their homeland's political and financial issues (Leaning, 2001). The political regulations impede researchers from recruiting sample from those populations which are going to impact the research process and data collection.

Another challenge is to identify refugee and immigrants populations. Birman (2005) stated that some agencies detected less effort to keep their documents of specific data to be used in research. Meaning, after refugees get resettled, most refugee's agencies do not track their status and demographic information, which make it difficult to estimate the accurate statistic of refugees and immigrants numbers for recruiting participants for research.

Further, the subgroups within an ethnic background add another challenge to identify refugees and immigrants participants in a research project. According to Gay, Mills & Airasian (2012), the sufficient data depend on the sample's representation of the general population. The significant diverse refugees' and immigrant's background increase the difficulty in classifying their demographic information. In this case, researchers could ignore specific cultural differences or use broader categories to categorize participants such as calcify them with a larger group (Birman, 2005). Therefore, merging subgroups into broader ethnic groups marginalizes the cultural role and social influence on a phenomenon.

Another issue is the multicultural guidelines and regulations of the refugee's research is not clear. The United Nations Convention on Refugees (1951) established the refugees' protection framework that illustrates necessary standers for treatment of refugees that allowing the host country to apply their law. With the guidelines inadequacy, underestimating refugees' cultural backgrounds causes an ethical dilemma. For an instant, one of the fundamental ethical and research issue in the research is obtaining refugees' signature on the informed consent form. Therefore, there is a limited technical international framework for obtaining informed consent that considers the refugees' cultural background (Leaning, 2001).

### Informed consent

The root of Informed consent has developed in the medical field that emphasized on the shared-decision-making procedure that a researcher provides sufficient information about their project to participants. Also, It is defined as the process of sharing information with a patient that is essential to make a decision (Beahrs & Gutheil, 2001). The American Counseling Association ACA (2014) elaborated that informed consent promotes clients to decide to enter the counseling relationship and remain in service and counselors have an obligation to clarify the responsibility of the counselor and client in writing.

The informed consent is a legal document that is required to establish a professional relationship. It promotes a client's autonomy, boosts understanding, improves decision-making, reduces risk, and enhances the therapeutic relationship (Snyder & Barnett, 2006). Informed consent has been viewed as a fundamental factor to establish a trustworthy, respectful, and non-judgmental therapeutic alliance (Barnett, Wise, Johnson-Greene, & Bucky, 2007).

### Issues in the refugees and immigrants research

Studying a phenomenon among vulnerable populations, such as refugees and immigrants, may develop obstacles related to getting the participants' signature on informed consent. In the first place, researchers should concentrate on asking questions that related to the process of the informed consent in order to consider the participants' cultural background. For instance, could the informed consent unintentionally "harm" those whom the researchers hope to assist? Whom do informed consent forms protect? What should the researchers do to solve the ethical and cultural dilemma? How can the researcher integrate the refugees' cultural background and the western code of ethics? Would the modified informed consent improve the quality of the participants' understanding?

Several barriers that prevent refugees and immigrants from involving in studies. Barnett, Wise, Johnson-Greene, & Bucky (2007) reported that the age range, cultural background, and language level are factors that influence the informed consent process. Leaning (2001) emphasized that acquiring genuinely informed and voluntary consent is a challenging process because of cultural consideration, language and educational limitation, and diverse social norms. Consequently, it is insufficient to provide paper-based informed consent documents for the vulnerable sample with language limitation and traumatic experiences.

The fear of signing on legal documents appears to be a theme among refugees who experienced complex trauma. Yu & Liu (1986) contacted Vietnamese refugee participants to collect data for research purposes. Although the participants were willing to participate, they refused to sign the informed consent forms. Some participants were anxious and broke off the interview; others reported that they should not sign the documents for the researcher who is a "stranger", and some of them were afraid the communist spies would come after them.

Furthermore, several researchers have questioned the validity of obtaining reliable informed consent from a vulnerable population with limited rights and support. The researcher's power may influence the feasibility to achieve a genuinely informed consent (Gehlert & Mozersky, 2018). Thus, innovating a new method to sign the informed consent forms and protect the vulnerable participants' autonomy has been a demand in our technical era, because the traditional informed consent style has harmed the refugees rather than getting benefitted.

English language limitation and miscommunication is another issue that the researcher should contemplate during the informed consent process. Gross (2001) described three evaluation criteria that must be accomplished for valid informed consent, including the client's ability to understand the information presented, the consent must be given voluntarily, and the client must be competent to give consent. Also, Researchers in the mental health field must intentionally develop the informed consent readable and easy to comprehend (Barnett, Wise, Johnson-Greene, & Bucky, 2007). Therefore, traditional informed consent is not valid in refugees and immigrants studies, because of English language limitation which leads to lack of understanding and communication with the research team.

It has been proposed to shorten informed consent forms for refugees and immigrants and decrease the English language complexity because of the language barrier among refugees and immigrants (Beskow, Friedman, Hardy, Lin, & Weinfurt, 2010). Paasche-Orlow, Taylor, & Brancati (2003) found that the Institutional Review Boards provided informed consent that was written at advanced reading levels than the national reading average. Therefore, ambiguous and difficult of comprehending informed consent overwhelms a refugee with a massive amount of information that inappropriate for his/her reading level and shorten it is one of the solutions to reduce harm in this process.

It has been argued that refugees and immigrants should be avoided as a research subjects based on “do no harm” code of ethics. Obtaining a signature on informed consent in the clinical studies that focus on vulnerable populations has become an ethical dilemma. Gehlert & Mozersky (2018) asserted that this issue contributes to underestimate the risk that misleads professionals to improve the vulnerable individuals’ health. Policy remains unnotified about the effectiveness of the medical and psychological interventions that have been provided to the refugees (Birman, 2005).

Moreover, excluding refugees and immigrant would affect the research validity. Meaning, the research sample became skewed and failed to represent the population averages (Gehlert & Mozersky, 2018). Hence, excluding refugees and immigrants from participating in research causes more harms, adds to the loop of being underserved, limit understanding of their acculturation issues, and generates ungeneralizable or trustworthy result because of the sampling issues. Finding solutions for the ethical and cultural issues related to the informed consent process is essential rather than excluding those populations.

### Methodology

To analyze the existing literature regarding the process of informed consent among refugees and immigrants, I conducted a literature review in the following databases: Association of Computing Machinery (ACM), PschInfo, EBSCO, and PubMed. To maximize the validity and standardization of the methods, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines was utilized (Liberati, et al., 2009).

### Search strategy

The review considered qualitative and quantitative English language on refugees and immigrants mental health and related issues published between 2010 to 2020 in the peer-reviewed literature from three main databases: Association of Computing Machinery (ACM), PschInfo, EBSCO, and PubMed. The databases were selected because they were comprehensive of the research topic and covered the researchers related to mental health and social sciences. Boolean Methodology was utilized to search query for the databased. Table 1 illustrated the search queries for each journal.

### Inclusion and Exclusion Criteria

The inclusion criteria for the articles were: a) research should be conducted on refugees and immigrants; b) sample of the study speak a different language than the host country; C) the research conducted between 2010 to 2020; and d) the research highlight mental health issues and related topics. The review excluded studies that focused on professional personals who worked with refugees and immigrants organizations and centers; and those published before 2010.

### Data Extraction

To extract data, I created a spreadsheet to maintain extracting information about the articles including the research title, year of publication, country of research, research design: qualitative or quantitative, disciplinary field, sample size, participants: sample size, language or country of origin, the language of the informed consent, informed consent method: paper-based form, including a third party, and multifaceted, and violation of IRB. The current research reviewed 32 published articles and purposely included studies from several countries and several refugees and immigrants backgrounds to provide an overview of the informed consent. Figure 1. illustrate the PRISMA procedure for the systematic review.

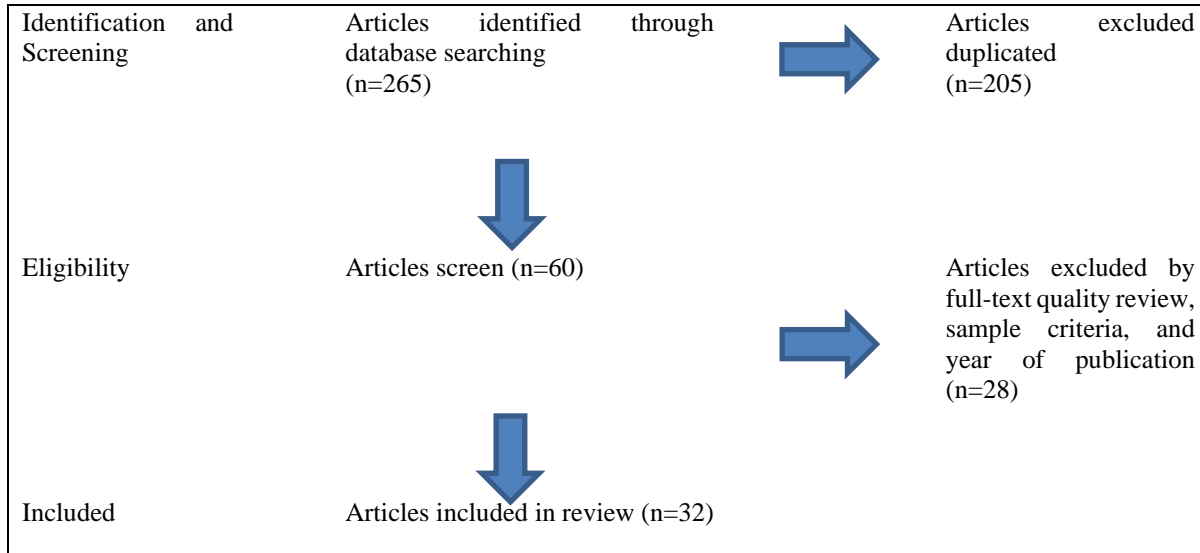


Figure 1. PRISMA Flow Diagram of Review Process

## Results

This research included 32 articles that met the inclusion criteria. All of the articles were in English, and conducted in a host country that admitted refugees and immigrants: 9 is from Australia and New Zealand, 10 from the United States and Canada, 7 from Europe, 5 from Asia, and 1 from Africa. Additionally, the disciplinary field of the articles was related to mental health issues among refugees and immigrants. Seventeen studies were conducted on mental health, three mental health and educational issues, six educational issues, one mental health and nursing, two family studies, one behavioral science, and two public health.

The studies that were included in this review addressed a range of refugees and immigrants country of origin, such as the Middle East, Asia, Africa, South America, and East Europe and Russia (Table 1). The age range of the participants in those studies was vary: four studies focused on children, nine on youths, and nineteen on adults. Gender factor was included in the current article. There were four studies focused on women refugees, and one study focused on men.

Furthermore, The focus of the present study was the informed consent process in refugees and immigrants research. Included articles reported language used in informed consent. Twenty two researches used English only to inquire about the informed consent, five were bilingual (English-Arabic, English-Amharic, English-French), four were in first language of the participants' language, and one was waived by the IRB. Moreover, the methods to inquire informed consent from the participants were mainly paper-based formed (eight studies); including a third party such as interpreters, teachers, community leaders, community workers, international office workers, and local organizations (twelves studies); paper-based forms and third party including an official translator (three studies); and utilizing multifaceted (one studies). **Appendix A** illustrates detailed information about the processed studies.

**Table 1 the Researchers Participants' Countries of Origin**

Region	Country	Number of Articles*	Region	Country	Number of Articles*	
Middle East	Iraq	9	Africa	Nigeria	1	
	Iran	4		Zimbabwe	2	
	Syria	4		Sudan	3	
	Palestine	1		Ghana	2	
	Yemen	2		Somalia	1	
				Ethiopia	2	
Asia	Afghanistan	6	South America		3	
	Bhutan	2		Other	East Europe and Russia	4
	Burma	12				
	Nepal	1				
	India	2				
	Siri Lanka	2				
	Bangladesh	1				
	China	1				
	Korea	1				

\*Research may focus on more than one country of origin

## Discussion

The present systematic review on the process of informed consent in the refugees and immigrants who fled their home country because of armed conflicts or natural disasters. The major findings of this systematic review was a third party involvement, participant's reading level, ethical violation in the process of informed consent. Moreover, I recommended the usage of multifaceted informed consent.

### A third party involvement in the informed consent process

The preferred informed consent method among the included articles (seventeen articles) was to be facilitated by a third party. The third party could be interpreters, teachers, friends, community leaders, community workers, international office workers, and local organizations. The involvement of a third party was supported by Barnett, Wise, Johnson-Greene, & Bucky (2007) who suggested that researchers protect their participant's rights by involving a third-party in the informed consent process. Another study recommended to contact a third party, such as healthcare providers and immigrants advocates, to obtain information about the refugees to avoid violating their rights by the research process ( Zion, Briskman, & Loff, 2010). Moreover, involving a native-speaking researcher in a research team (four articles) facilitated not only the informed consent process, but also promoted meaning understanding and themes analyzing in qualitative researches (twenty one qualitative studies).

Moreover, Leaning (2001) Highlighted that researcher should use multilabel informed consent techniques with the individual documents that are culturally appropriate, such as contacting the community leaders and heads of the household would solve this dilemma. Involving a third party to obtain a signed informed consent face a debate that this procedure does not allow participants to make their own decisions and takes their autonomy. Autonomy is one of the ACA code of ethics that professional should consider in the therapeutic relationship (ACA, 2014). However, responsibility and familial loyalties are more valued over autonomy in many collective cultures comparing to Western cultures (Jotkowiz, 2004).

### Participants reading level and paper-based informed consent

I found eight articles in this systematic review have given the participants paper-based informed consent regardless of their reading levels and educational backgrounds. This finding was supported by Beskow, Friedman, Hardy, Lin, & Weinfurt (2010) that the researcher should consider the reading complexity when writing informed consent. I also found that quantitative studies (eleven studies) utilized paper-based informed consent in the surveys that have been written in English. However, the sample's understanding of the research was questionable because the sample size was large which hindered the direct interaction between researchers and participants. As it mentioned previously in this paper, the complexity of the informed consent and the language barrier interferes with participants fully understanding of the form and researchers should consider the language limitations. Therefore, researchers should consider the participants reading level to not violate research ethics.

### Ethical Violations in the informed consent process

Refugees and immigrants are vulnerable populations because of the pre-migration traumatic events and post-migration stressors. Refugees and immigrants have to complete and sign several official documents to get admitted to the host country. One of the major ethical violations that I found in this systematic review was to include the informed consent form with the visa application. This violated the refugees' and immigrants' autonomy for three main reasons: first, the new comers may not understand the language of the form. Second, even if the form was given in bilingual matter, the new comers could be illiteracy or significantly low reading levels which impacts their understanding of the research nature. Third, new comers' fear of rejection and send back home could force them to sign the forms against their will.

Another ethical violation I found in this systematic review was sending informed consent to the family. Researches that focused on school aged refugees and immigrants sent informed consent to parents. Most of the new comers depend on their children reading to help them translate forms and communicate with others. Therefore, it is not ethical to get a parent's signature without being informed. Moreover, parents of school aged students feel obligated to sign because of fear of their children could be expelled from the education system if they did not consent to participate in the research. Therefore, multifaceted informed consent is recommended.

### Multifaceted informed consent

Providing translated informed consent to refugees and immigrants does not guarantee that they fully understood the research process. Therefore, I recommend the multifaceted informed consent that promotes reliable understandings of the research and avoids potential research ethical violations. Multifaceted informed consent was utilized in two articles of the current systematic review. In the first article, the researcher utilized a paper-based and oral explanation in native language explaining informed consent. The second article utilized prior recorded informed consent in the participants' native languages that facilitate informed the consent process. Therefore, the use of technology in the multifaceted informed consent is recommended.

Creating visual and explicit informed consent forms in refugees' and immigrants' studies is fundamental to ensure visual reminder of the information. Wilbanks (2018) is considered a pioneer who developed the online informed consent and called it the "e-consent". He included standardized iconography in the electronic informed consent that creates a visual language which describes the informed consent. Simon, Klein, & Schartz (2014) suggested that the systematic combination of multimedia interactive approach and the researcher involvement in designing of the electronic informed consent to improve the participants' understanding. Moreover, Gehlert & Mozersky (2018) highly emphasized on obtaining informed consent by using technology such as social media and smartphone apps.

The electronic informed consent has the potential to increase effective communication and understanding than the paper-based informed consent by using several types of media, such as photographs, videos, audio narration and graphs (Simon, Schartz, Rosenthal, Eisenstein, & Klein, 2018). Thus, participant receive information in their houses, which provide more time to participants to review information, and the usage of smartphones and iPads with a simple user interface guarantee to attain effective and vivid signed informed consent the participants truly comprehend.

The age of technology has encouraged us to think about alternative ways to assure that refugees and immigrants rational the information that has been provided. Herman, White, and Barkin (2015) used a creative multifaceted approach of informed consent among low socioeconomic status and racial minority groups. They found that visual aids avoided jargonning,

and provided readable and comprehensible informed consent to the underserved sample. Therefore, the e-consent and the smartphone apps are new instruments that have been designed to upgrade the paper-based informed consent. Evaluation is highly needed for assessing the instrument's effectiveness and protecting participants.

The main criteria to measure the effectiveness of the electronic informed consent is by assessing the comprehension and remembering ratio of the information that was presented. This imperial evaluation methodology was supported by Doerr, Suver, & Wilbanks (2016) that concluded to provide a quiz at the end of the electronic informed consent to quantitatively measure the participants' understanding. Another study has used the mixed-methods multilabel steps to promote the informed consent rational, such as reading the form individually, reviewing the information with the research assistant, giving a four-question multiple choice assessment, and finally revisiting the wrong answers until the instructions and information have become evident (Rounsaville, Hunkele, Easton, Nich, & Carroll, 2008). Thus, a research with electronic informed consent provides a clear understanding of the form by applying qualitative and quantitative multilabel levels methodology for information illustrating, and including a quiz after reading, watching, and listening to the information in the informed consent.

### Conclusion

To sum up, refugees and immigrants studies are developing because of several political legislation and the vulnerable populations' characteristics. English language limitation is one of the primary considerations in the informed consent process that impacts the understanding and communication style between the researcher and the participant. Also, the refugee's cultural background concerns, such as trusting the research team and fear of signing documents, that hinder them from participating in a study. Informed consent that is trustworthily, confidential, and convenient leads to more participants enrollments which provide further data and extra grants for refugees' and immigrants studies. It has been recommended to use the individual paper-based informed consent and involve a third-party to moderate the refugee's fear of signing informed consent documents. Moreover, using the interactive electronic informed consent, that illustrates graphs, videos, and photos, enhances the participants' comprehension and consider their English language limitation. Those strategies promote in-depth understanding and prevent cultural clash between the participant's background and the western code of ethics. Designing electronic informed consent and evaluating its effectiveness is developing and has promising future in the human service fields.

### Availability of data and materials:

All data generated or analyzed during this study are included in this published article, please review the file (appendix A)

Funding: This research did not receive funding.

### Acknowledgements

The author acknowledge with thank to King Abdulaziz University library for the research website accessibility, and to Dr. David Delmonico at Duquesne University, Pittsburgh, PA. USA for his feedback on the process of the research.

### References

- American Counseling Association. (2014). ACA code of ethics. American Counseling Association. <https://www.counseling.org/resources/aca-code-of-ethics.pdf>
- Barnett, J. E., Wise, E. H., Johnson-Greene, D., & Bucky, S. F. (2007). Informed consent: Too much of a good thing or not enough? *American Psychological Association*, 38(2), 179-186. <https://doi.org/10.1037/0735-7028.38.2.179>
- Beahrs, J. O., & Gutheil, T. G. (2001). Informed consent in psychotherapy. *American Journal of Psychiatry*, 158, 4-10.
- Beskow, L. M., Friedman, J. Y., Hardy, N. C., Lin, L., & Weinfurt, K. P. (2010). Developing a simplified consent form for biobanking. *PLoS One*, 5(10). <https://doi.org/10.1371/journal.pone.0013302>
- Birman, D. (2005). Ethical issues in research with immigrants and refugees. In *Research ethics challenges involving diverse ethnocultural groups* (pp. 155-177).



- Doerr, M., Suver, C., & Wilbanks, J. (2016). Developing a transparent, participant-navigated electronic informed consent for mobile-mediated research. *SSRN Electronic Journal*. <https://doi.org/10.2139/ssrn.2769129>
- Gay, L. R., Mills, G. E., & Airasian, P. (2012). *Educational research competencies for analysis and applications* (10th ed.). New York: Pearson. <https://doi.org/13.978-0132613170>
- Gehlert, S., & Mozersky, J. (2018). Seeing beyond the margins: Challenges to informed inclusion of vulnerable populations in research. *The Journal of Law, Medicine & Ethics*, 46, 30-43.
- Gross, B. H. (2001). Informed consent. *Annals of the American Psychotherapy Association*, 4(5), 24.
- Heerman, W. J., White, R. O., & Barkin, S. L. (2015). Advancing informed consent for vulnerable populations. *Journal of Pediatrics*, 135(3), e562-e564.
- Jotkowitz, A. (2004). Vulnerability from a global medicine perspective. *American Journal of Bioethics*, 4(3), 62-63.
- Leaning, J. (2001). Ethics of research in refugee populations. *The Lancet*, 357, 1432.
- Liberati, A., Altman, D., Tetzla, J., Mulrow, C., Gotzsche, P., Ioannidis, J., . . . Moher, D. (2009). The prisma statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: Explanation and elaboration. *Clin. Epidemiol*, 62, 1-34.
- Paasche-Orlow, M. K., Taylor, H. A., & Brancati, F. L. (2003). Readability standards for informed-consent forms as compared with actual readability. *New England Journal of Medicine*, 348(8), 721-726.
- Rounsaville, D. B., Hunkele, K., Easton, C. J., Nich, C., & Carroll, K. M. (2008). Making consent more informed: Preliminary results from a multiple-choice test among probation-referred marijuana users entering a randomized clinical trial. *Journal of the American Academy of Psychiatry and the Law*, 36(3), 354-359.
- Simon, C. M., Klein, D. W., & Schartz, H. A. (2014). Traditional and electronic informed consent for biobanking: A survey of US biobanks. *Biopreservation and Biobanking*, 12(6), 423-429.
- Snyder, T. A., & Barnett, J. E. (2006). Informed consent and the process of psychotherapy. *Psychotherapy Bulletin*, 41, 37-42.
- The United Nations High Commissioner for Refugees. (2018). *Figures at a glance*. The United Nation Statistical Yearbook. <http://www.unhcr.org/en-us/figures-at-a-glance.html>
- Wilbanks, J. (2018). Design issues in e-consent. *Journal of Law, Medicine & Ethics*, 46(1), 110-118.
- Yu, E. S., & Liu, W. T. (1986). Methodological problems and policy implications in Vietnamese refugee research. *The International Migration Review*, 20(2). <https://www.jstor.org/stable/2546045>