

From: [Schatz Gerald](#)
To: [ACF OPREInfoCollection](#)
Cc: [Kalinowski Carol A.](#)
Subject: Department of Health and Human Services, Administration for Children and Families, Proposed Information Collection Activity: Descriptive Study of the Unaccompanied Refugee Minors Program (New Collection), Request for public comment, 83 Fed. Reg. 46,956...
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TO:

Administration for Children and Families
Office of Planning, Research, and Evaluation
ATTN: OPRE Reports Clearance Officer
330 C Street SW
Washington, DC 20201

VIA: OPREinfocollection@acf.hhs.gov

FROM:

Gerald S. Schatz, Esq.
(Of the Bars of the District of Columbia and Pennsylvania)
Post Office Box 178
505 North Mill Street
Northport, Michigan 49670
geraldschatz@charter.net
231.386.5936
231.632.0328

Carol A. Kalinoski, Esq.
(Of the Bars of the District of Columbia, Pennsylvania, and New Jersey)
2505 Hayes Street
Alexandria, Virginia 22302
kalinowski2003@yahoo.com
703-548-4652
202.360.1555

IN RE: Department of Health and Human Services, Administration for Children and Families, Proposed Information Collection Activity: Descriptive Study of the Unaccompanied Refugee Minors Program (New Collection), Request for public comment, 83 Fed. Reg. 46,956 (Sept. 17, 2018),

These comments and recommendations respond to the above-captioned Administration for Children and Families (ACF) Notice. We take into account copies of the proposed information collection materials, which we requested. We received no copies of supporting materials, which we also requested, but supporting materials would not cure self-evident problems in the proposal.

OUR PERSPECTIVE:

We are lawyers and legal educators in administrative, immigration, and international law and in the ethics and law of research on human subjects. As lawyers, we are officers of the court; hence our joint response stems from our responsibilities to the law and is not submitted on behalf of any client or employer.

THIS PROJECT AS PROPOSED WOULD VIOLATE BOTH THE PAPERWORK REDUCTION ACT AND EXISTING LAW FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH.

As proposed, the project would violate the Paperwork Reduction Act (PRA), the National Research Act, the Department of Health and Human Services' (DHHS'S) own regulations for the protection of human subjects of research, and international norms for the protection of refugees.

This information collection would include two sets of respondents especially vulnerable both to inordinate persuasion, if not coercion, and to severe consequences of unwanted disclosures--not only for themselves but for identifiable third parties. The two respondent groups at risk are "Unaccompanied Refugee Minors" and "Foster Parents" of "Unaccompanied Refugee Minors." The third parties at risk would be persons who might be mentioned in that process. Vulnerabilities stem not only from immigration status issues, but also from intrafamilial and interfamilial dynamics, from educational, cultural, religious, and language disparities, and from psychological and emotional turmoil.

The proposal does not make clear who the "Unaccompanied Refugee Minors" and "Foster Parents" of "Unaccompanied Refugee Minors" actually are and where they are. Neither does the proposal show the immigration status and custodial status of the "Unaccompanied Refugee Minors." Nor is the actual, legal "foster parent" status of the "Foster Parents" shown. Nor does the proposal show the custodial relationships between the proposed child respondents and adult respondents; to do so would not fix the problems here, but it would indicate, at least, some knowledge of why these individuals were chosen as prospective research subjects.

The project is proposed as research, submitted to and apparently approved as by an Institutional Review Board (IRB), the mechanism for vetting research pursuant to human subjects protection regulations. But the proposal does not meet regulatory requirements for IRB approval.

The use of research subjects who are especially vulnerable, both to coercion and to the consequences of unwanted or inadvertent disclosure, would violate the PRA by unnecessary imposition of undue burdens and by violation of existing law for the protection of human subjects of research.

If this information collection is deemed instead a social program evaluation, and thus not covered by the specifics of the human subjects regulations, the proposal nonetheless would impose undue burdens on the "Unaccompanied Refugee Minors" and "Foster Parent" respondents and third parties and thus violate the PRA.

THE PROJECT AS PROPOSED FAILS TO MEET PAPERWORK REDUCTION ACT CRITERIA FOR APPROVAL.

Contrary to the Paperwork Reduction Act, this information collection is proposed without regard for how it would burden two sets of intended respondents--"Unaccompanied Refugee Minors" and "Foster Parents" of "Unaccompanied Refugee Minors"--and third parties who might be damaged by disclosures--whether by research subjects or by researchers.

The likely burden, even for seemingly innocuous questions or lead-ins to discussions, has to be considered in terms of who the respondents would be and how free they are. Our experience tells us that people who have been displaced by social violence, extreme poverty, and wars and other conflicts are psychologically and physically vulnerable, and are intimidated by, and suspicious of, authority, and that even within the same families, villains may move alongside their victims. Reprisal and retribution for statements in focus groups, for statements in interviews, and for failures of document security cannot be ruled out. Similarly, "foster parents" in these situations may be harmed because of disclosure of problematic family relationships, some of which may have immigration consequences. Mandatory reporting of abuse or neglect under state laws may also lead to disclosures that could result in deportation and death.

The proposed information collection would risk hard consequences for what is basically an impressionistic collection of opinions and is unrelated to individual resettlement. This proposed would provide no new and actionable information, but instead would violate the purposes and substance not only of U.S. law, but also of international humanitarian and human rights law and ethical norms for the protection of refugees and other displaced persons.

The agency thus fails to comply with the Act, which has as principal purposes the reduction of burdens imposed on individuals by Federal agency requests for information; agency compliance with concurrent law; protection of individual privacy; enhancement of Federal agency economy and efficiency; and enhancement of Federal statistical quality. 44 U.S.C. sec. 3501.

For failure to assess risk and protect respondents, this activity would be unlawful whether this is or is not research. The project imposes but relieves no burdens on respondents. It does not comply with concurrent law for protection of human subjects of research. Its focus groups are inherently non-private, non-confidential. It would yield no useful information that the agency cannot surmise easily from the circumstances. Nor does it even pretend to compliance with or enhancement of Federal statistical standards.

The proposed use of focus groups of "Unaccompanied Refugee Minors" and "Foster Parents" of "Unaccompanied Refugee Minors" would comply with neither the intent nor the letter of human research protections law. Whether the remainder of the project would comply warrants new scrutiny, as evidently insufficient regard was paid for context and confidentiality, let alone vulnerability of research subjects.

OUR RECOMMENDATION:

At least eliminate the use of focus groups of "Unaccompanied Refugee Minors" and "Foster Parents" of "Unaccompanied Refugee Minors" from this proposed project, in light of:

- (1) Failure to understand and specify who these prospective focus-group targets are, their immigration status, their custodial status, their vulnerability to intimidation, their vulnerability to consequences of disclosures;
- (2) Failure to understand and account for vulnerabilities of third parties who might be mentioned in focus groups;
- (3) Inability to protect privacy and confidentiality especially as "focus groups" are by definition un-private and non-confidential;
- (5) Meaninglessness of consent or assent in these circumstances, whether respondents are in detention or not;
- (6) Violation of the National Research Act and human subjects research protection regulations, by lack of subjects specification, lack of concern for their vulnerabilities, lack of circumstances conducive to knowing and voluntary consent, lack of special protections for children, lack of consent from parents or legally authorized representatives, and lack of prospect of direct benefit to these individual subject;
- (7) Methodological deficiencies; and
- (8) Violations of U.S. international legal obligations.

ANALYZED WITHIN THE PAPERWORK REDUCTION ACT FRAMEWORK:

This proposed activity is contrary to the purposes and substance of the Paperwork Reduction Act, 44 U.S.C. sec. 3501.

This information collection and over-all project do not comply with the Act itself. A principal purpose of the Act is to minimize burdens on the public. 44 U.S.C. sec. 3501(1). The burden would include the direct and indirect consequences of disclosures within focus groups and the emotional strains imposed on already traumatized focus group respondents. Neither does the project comply with 44 U.S.C. secs. 3501(8) & 3501(9) approval criteria: "ensure that the creation, collection, maintenance, use, dissemination, and disposition of information by or for the Federal Government is consistent with applicable laws, including laws relating to" privacy and confidentiality, and security of information, and "ensure the integrity, quality, and utility of the Federal statistical system."

-- WHETHER THE PROPOSED COLLECTION IS NECESSARY FOR THE PROPER PERFORMANCE OF THE FUNCTIONS OF THE AGENCY, INCLUDING WHETHER THE INFORMATION SHALL HAVE PRACTICAL UTILITY.

Necessity?

This activity is not mandated in law.

The focus groups would yield opinions and personal anecdotes, but no actionable information.

Practical utility?

Practical utility is questionable on these grounds:

Analytical method: Focus groups do not satisfy Federal statistical standards. U.S. Census Bureau, Methodology and Standards Council, Statistical Quality Standards (rev. 2013) at 154 (https://www.census.gov/quality/standards/Quality_Standards.pdf). Neither is this project justifiable as a qualitative study; it does not lend itself to extrapolation.

Reliability: Seeking psychological disclosures from individuals who are not free and safe, and who are already traumatized or intimidated, will not elicit assuredly credible information, whether in ostensibly private sessions or in focus groups, which are proposed here and are non-private by definition. See Tricia Hynes, The issue of 'trust' or 'mistrust' in research with refugees: choices, caveats and considerations for researchers, Working Paper No. 98, <http://www.unhcr.org/3fcb5cee1.html> (Nov. 30, 2003).

-- ACCURACY OF THE AGENCY'S ESTIMATE OF THE BURDEN OF THE PROPOSED COLLECTION OF INFORMATION.

Without knowing who the respondents are or what their circumstances are, researchers can neither adequately propose their research nor estimate the extent and kinds of burdens that it would impose.

The proposal does not recognize either the vulnerabilities of intended focus group respondents or the implications of their vulnerability. It does not even adequately describe who these intended focus-group respondents (study populations) are or what their circumstances are. It has not considered the actual potential burden of the proposed collection on these respondents.

As announced in the ACF Notice, the focus group respondents would be "unaccompanied refugee minors" and "foster parents" of "unaccompanied refugee minors."

"Refugee" is a particular legal status recognized in U.S. and international law. Refugees so designated must be given special legal protections, including privacy. It is unclear from the ACF Notice whether the "unaccompanied refugee minors" to be studied are actual refugees or have some other legal status or no immigration status at all. Apparently they are migrant children and youth who have come into the United States, and, either before or after entering the United State have become separated from their parents. These children have been traumatized and are not free. What they say can get themselves or others into further trouble.

Neither is it clear who the "foster parents" are in this study. If they are truly "foster" parents as recognized in U.S. law, they have been appointed as such by courts of competent jurisdiction, the children who are fostered are wards of and under the protection of cognizant state courts, and all parties would be represented by counsel and as necessary guardians ad litem. The decision-making authority in each custodial or guardianship case varies from case to case, although the default general position usually is what is adjudicated by the court to be in the best interests of the child. These matters are reserved to the several states. For purposes of Federally sponsored research on children: "*Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care." 45 C.F.R. sec. 46.402(e). Additional restrictions, depending on the nature of the research, apply to children who are wards, i.e., children "who are wards of the state or any other agency, institution, or entity . . ." 45 C.F.R. sec. 46.409(a). Any of these prospective focus-group subjects who are detained come under yet more protections applicable to prisoners. 45 C.F.R. sec.46.303(c).

Regardless of whether this kind of activity is designated officially as research, it raises serious, long-recognized challenges. As reported by the (U.S.) National Research Council:

"[R]esearcher and the sponsoring organization have a duty to make a safety assessment: Are the research subjects still vulnerable to coercion or retribution? . . . [C]onfidentiality and security of the original research records cannot be ensured, despite . . . good intentions. . .

". . . There are many reasons to collect data in an emergency setting (administrative data collection, physician interviews, surveillance, to name a few), but not all of these are . . . research. However, they may still involve potential risks and benefits for research subjects, depending on the future use of such data.

"The dangerous and extreme circumstances that accompany conflict and forced migration can make it very difficult to conduct ethical research. For example, . . . public health workers crossed . . . accompanied by armed insurgents as security guards . . . to conduct public health surveys. Can one ethically make use of the data they collected? Many nongovernmental organizations (NGOs) collect program data that are meant to be internal, but are later used by researchers: Is it ethical to use these found data? If they are individual case notes, is the answer different than if they are macro-level data? Also, it may not be known whether or not the data were collected in an ethical manner. All of these issues are real dilemmas in the field when data are precious, but may be fraught with ethical concerns."

National Research Council, Roundtable on the Demography of Forced Migration, in Research Ethics in Complex Humanitarian Emergencies, <http://www.nap.edu/catalog/10481.html> (2002) at 2-3.

Here we are dealing with migration forced not by governmental directive, but by variously intentional governmental neglect and by direct governmental complicity in societal violence and appalling poverty. The implications for the ethics of research on the people thus hurt and displaced are the same.

The effort of response poses an inescapable burden in the potential for opening or re-opening of emotional wounds despite ethical obligations. Nicholas Howen, Fundamental Protection Function of the Human Rights Field Operation, in Human Rights Field Operation: Law, Theory and Practice, supra (Michael O'Flaherty ed., 2007) at 43.

-- WAYS TO ENHANCE THE QUALITY, UTILITY, AND CLARITY OF THE INFORMATION TO BE COLLECTED.

For planning purposes, but not for research purposes to which subjects have not consented freely, use qualitative information already identified, non-identifiable, and available from documentation adduced in pending litigation and from reliable, independent refugee service organizations who, unlike the research performers in this matter, are not regularly contractors for the sponsoring Federal agency.

-- WAYS TO MINIMIZE THE BURDEN OF THE COLLECTION OF INFORMATION ON RESPONDENTS.

Cancel the focus-group portions of this project.

-- ESTIMATES OF CAPITAL OR START-UP COSTS AND COSTS OF OPERATION, MAINTENANCE, AND PURCHASE OF SERVICES TO PROVIDE INFORMATION.

This query may be referred to the Office of the Inspector General of the Department of Health and Human Services.

-- WHETHER THE PROPOSED ACTIVITY IS CONSISTENT WITH APPLICABLE LAWS, INCLUDING LAWS RELATING TO PRIVACY AND CONFIDENTIALITY AND SECURITY OF INFORMATION.

Research subject protection:

The focus-group portions of this proposed project violate the Department of Health and Human Services' human subjects research protection rule, 45 C.F.R. part 46, as it stood before its current revision, as it now stands, and as it is scheduled to change after its current transition period. Citations to 45 C.F.R. part 46 herein are to the updated text at 45 e-C.F.R. part 46 (Nov. 1, 2018), https://www.ecfr.gov/cgi-bin/text-idx?SID=f30c3534f32b50ee8c3e545944ab2e79&mc=true&node=pt45.1.46&rgn=div5#se45.1.46_1101. For applicability and effective dates of the revised regulations, see 45 e-C.F.R. sec. 46.101(l).

The apparent Institutional Review Board approval of this project flouts the National Research Act mandate "to protect the rights of the human subjects of such [behavioral and/or biomedical] research." 42 U.S.C. sec. 289. The IRB's approval is not dispositive. The Secretary or his or her delegate may overrule an IRB's approval, and that judgment whether to overrule "shall be exercised consistent with the ethical provisions [autonomy, justice, beneficence; fairness of selection of research population; absence of coercion; absence of coercive circumstances; special protection for vulnerable subjects; freedom for knowing, voluntary, consent or refusal] of the Belmont Report [The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.- Belmont Report. Washington, DC: U.S. Department of Health and Human Services. 1979.]." 46 C.F.R. sec. 46.101(c). Specific requirements may be waived only if the project is essential and no less consistent with the Belmont Report and even then the proposed exception must be especially noticed in the Federal Register with opportunity for public comment. 45 C.F.R. sec. 46.101(h).

Among the legally and ethically consequential facts here are that these children, some of them very young, are separated from their parents; inhere to detention if not already detained, and to removal from the United States unless they found legally to be refugees or asylees; survivors of physical and emotional trauma; culturally, linguistically, and socially displaced; intimidated by authority; in circumstances are not conducive to voluntariness; and unrepresented by counsel. Their families are similarly vulnerable, and their care-givers may be at least indirectly vulnerable as well.

This project is not a Federal public benefit or public service program research-and-demonstration project within the scope of the DHHS human subjects research protection regulation's exemption provisions. See 45 C.F.R. sec. 46.104(a), (b), & (d)(5). To hold otherwise would violate the protective mandate of the National Research Act, 42 U.S.C. sec. 289.

Institutional Review Board's questionable independence and knowledge:

Whether the IRB that reviewed this project was constituted and operated properly is questionable; the reviewing IRB was that of the project contractors, who have not made public its membership composition and consultant(s) for this review. It is not apparent that the reviewing IRB included any member who was without conflict of interest but who was familiar with immigration law and "knowledgeable about and experienced in working with" these prospective focus group respondents, who are "vulnerable to coercion or undue influence"; see 45 C.F.R. sec. 46.107(a); or that the IRB consulted with anyone without conflict of interest but familiar with immigration law and the diverse cultural, social, linguistic, and emotional circumstances of the prospective focus group respondents; see 45 C.F.R. sec. 46.107(e).

Problems with consent:

Children lack legal capacity to consent to research but have the opportunity, in the terminology of the regulation, to "assent" or decline; absence of refusal is not to be taken as agreeing to be a subject of the research. See 45 C.F.R. sec. 46.402. But their legally effective permission for participation as a research subject must come from their parents or lawfully appointed guardian (a state court matter) or "legally authorized representative . . . an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in . . . the research." 45 C.F.R. sec. 46.102(j). The applicable law here is state law, which varies as to the authority granted to guardians, custodians, foster parents, public and private child welfare agencies, and others who may be care-givers, including relatives other than parents. 45 C.F.R. sec. 46.402. For wards and for children in some family court proceedings, the court itself may be the only "legally authorized representative."

Moreover, the even if satisfied, standard elements of consent, 45 C.F.R. sec. 46.116, are legally insufficient in these circumstances. When or where prospective subjects are especially vulnerable--as are these focus group subjects--the regulation encourages supplementing the standard elements with additional information on possible adverse consequences of their participation. 45 C.F.R. sec. 46.109(b). In this situation, the planned consent-or-decline procedure would not inform prospective focus group respondents that their disclosures may get themselves or others into deep trouble.

Detainees:

The regulation prohibits this research on detainees. 46 C.F.R. sec. 306, consent notwithstanding.

Children:

Research on these children would in any event require parental or guardian permission. 45 C.F.R. sec. 46 subpt. D. But parents are not available here, and legal guardianship is not established. but the proposal does not take into account the quest. Because of the legal jeopardy faced by child participants, the research here poses more than minimal risk, defined as the ordinary risks of daily life. 45 C.F.R. sec. 46.102(j). These children are not living "ordinary" lives. But even if this were deemed "minimal risk" research, the issue of who could consent legally would remain, as would the "best interests of the child" criterion for their decision. There is no direct benefit here to the child.

If the research were deemed only a minor increase above minimal risk with no direct benefit to subjects, such research would not be approvable unless "of vital importance" to ameliorating the subjects' condition. 45 C.F.R. sec. 46.406(c).

For wards "of the state or any other agency, institution, or entity, 45 C.F.R. sec 46.409(a), which may be the case here, the research must relate to their status as wards, 45 C.F.R. sec. 409(a)(1), must be otherwise approvable, and: "If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One

individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization." 45 C.F.R. sec. 46.409(b). This proposal does not meet these requirements.

Privacy, confidentiality, security, and vulnerability:

The proposed focus group respondents are in this situation because of immigration irregularities, law enforcement, and ever-changing administrative agency actions. For good, bad, and in-between, these individuals are emotionally stressed, and uncertain of the future. They are easily intimidated by authority figures and are vulnerable to the consequences of disclosure, by themselves or others, relating to family and others. Researchers might try to keep secrets, but other focus group participants and their contacts may not. Warnings to that effect do not help. An inadvertent or even purposeful disclosure could result in adverse interpersonal, intrafamilial, or immigration consequences. Despite promises of researcher confidentiality, the research personnel are subject to subpoena, as are the focus group participants. A departmental Certificate of Confidentiality (not in place or applicable here) would not protect against voluntary disclosure by research personnel. Focus groups, we reiterate, are inherently non-confidential, and the lack of CDC legal authority and actual ability to guarantee confidentiality add up to a violation of the several confidentiality provisions of the human subjects protection regulation and U.S. international legal obligations concerning protection of refugees and similarly displaced persons.

U.S. international legal obligations:

The United States has relevant international legal obligations under the International Covenant on Civil and Political Rights (ICCPR), 999 U.N.T.S. 171, under customary international law, see Restatement (Third) of the Foreign Relations Law of the United States sec. 702 (1986), and as a state party to the 1967 Protocol Relating to the Status of Refugees, 19 U.S.T. 6223, T.I.A.S. No. 6577, 606 U.N.T.S. 267, incorporating arts. 2-34, Convention Relating to the Status of Refugees, of July 28, 1951 (189 U.N.T.S. 150).

The Protocol obligates the United States to cooperate with the U.N. High Commissioner for Refugees in conduct of the UNHCR's mission. The UNHCR's protective mission in turn requires deference to UNHCR administrative interpretations, including the paramount principle of refugees' and asylum seekers' privacy and security of person. UNHCR cautions against behavioral research on refugees and asylum seekers. UNHCR, Operational Guidance: Mental Health & Psychological Support Programming for Refugee Operations, <http://www.refworld.org/docid/53a3ebfb4.html> (2013).

In accord with U.S. Protocol obligations and respect for privacy and dignity in an especially problematic setting, U.S. agencies should respect that.

IN SUM:

The proposed use of focus groups in this project would endanger and violate the rights of participants and would provide no actionable information for the sponsor agency. The use of focus groups here violate the Paperwork Reduction Act and concurrent applicable law and would expose these vulnerable people and others to unjustifiable risk. The focus group components of this proposal should be stricken from the project.

Thank you for your attention. Please keep us informed on the status of this project.

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Sent from:

Gerald S. Schatz, Esq.
Post Office Box 178
505 North Mill Street
Northport, Michigan 49670
geraldschatz@charter.net
231.386.5936
231.632.0328