

DATE: June 15, 2016

TO: Steph Tatham

Office of Information and Regulatory Affairs (OIRA)

Office of Management and Budget (OMB)

FROM: Hilary Forster

Office of Planning, Research and Evaluation (OPRE) Administration for Children and Families (ACF)

SUBJECT: Request for Non-Substantive Change to Health Profession Opportunity Grants (HPOG)

Second Generation National and Tribal Evaluation (OMB Control Number 0970-0462)

This memo requests approval for revisions to an informed consent form previously approved for use by non-tribal Health Profession Opportunity Grants (HPOG) grantees under OMB Control Number 0970-0462. The form was revised and made into two distinct versions to align with the evaluation requirements of the Tribal HPOG grantees. The remainder of this memo provides background on the HPOG evaluation and the nature of the revisions made to the consent form.

### **Background on Research on HPOG**

ACF has funded a series of programs and related evaluations to examine "career pathways" approaches to providing post-secondary education and training; i.e., training that is organized as a series of manageable steps leading to successively higher credentials and employment opportunities in growing occupations. These programs and related evaluations include two rounds of program funding and associated evaluations for the Health Profession Opportunity Grants (HPOG) Program. HPOG grants provide funding to state and local government agencies, community-based organizations, post-secondary educational institutions, and tribal-affiliated organizations to provide education and training services to Temporary Assistance for Needy Families (TANF) recipients and other low-income individuals, including tribal members. In addition, ACF is funding the Pathways for Advancing Careers and Education (PACE) project, a rigorous evaluation of next-generation strategies for increasing the economic self-sufficiency of low-income individuals and families. Three HPOG grantees are also participating in PACE.

Funding for a first round of HPOG was awarded in 2010. Evaluation of the first round of HPOG grants has been underway since 2011 under OMB Control Number 0970-0397. The evaluation includes implementation, outcome, and impact studies of the non-tribal HPOG grants, and implementation and outcome studies of the tribal grants. ACF awarded a second round of grants – referred to as HPOG Second Generation, or HPOG 2.0 – in 2015. An evaluation of these programs – referred to as the Second Generation National and Tribal Evaluation (with the National Evaluation component pertaining to the non-tribal grantees and the Tribal Evaluation component pertaining to the tribal grantees) – is getting underway.



Like the first-round evaluation, the National Evaluation of the non-tribal grantees will focus on estimating the impacts of the HPOG 2.0 Program to inform future program design and improvement. Key participant outcomes to be measured and analyzed will include completion of education and training, receipt of certificates and/or degrees, earnings, and employment in a healthcare career. The evaluation will also include an implementation study and cost benefit analysis.

Under the National Evaluation, applicants who qualify for the HPOG 2.0 program will be randomly assigned to a treatment group that can receive HPOG 2.0 program services or a control group that cannot. Programs will be expected to conduct random assignment of applicants to the HPOG 2.0 program, with some exceptions. Participants in the impact study of the first round of HPOG grants who apply for HPOG 2.0 will generally be excluded from random assignment. In addition, tribal programs will not implement random assignment.

OMB previously approved baseline data collection and two versions of an informed consent form for the HPOG 2.0 evaluation under OMB Control Number 0970-0462 — one consent form for applicants who will be randomly assigned and a second version for applicants who will not be randomly assigned (see Attachment B: Approved non-tribal, adult lottery not required consent form). A non-substantive change request was submitted on January 14, 2016 that addressed comments made by the evaluation contractor's IRB (Abt Associates IRB) specific to the consent forms for the National Evaluation of the non-tribal grantees. These changes were approved on January 26, 2016.

#### **Reason for the Non-Substantive Change Request**

Via the non-substantive change approved on January 26, 2016, Abt Associates finalized the consent forms for use in the National Evaluation. It subsequently became necessary to develop additional consent forms for the Tribal Evaluation to address needs of the Tribal HPOG grantees and the Tribal Nations Research Group (TNRG) Research Review Board. Several Tribal HPOG grantees expressed concerns about collecting SSNs for tribal participants. The additional consent forms differentiate between grantees collecting SSNs and those not collecting SSNs but instead using unique identifiers. The TNRG promotes high quality research relevant to the Turtle Mountain Band of Chippewa Indians (a Tribal HPOG grantee) and research conducted on the Turtle Mountain Band of Chippewa Indian Reservation must be approved by the TNRG. The TNRG noted that they found the consent form was missing some elements. Therefore the evaluation contractor revised the previously approved consent form for applicants who will not be randomly assigned and made it into two distinct versions to be used by the Tribal HPOG grantees. The revised forms have been approved by the TNRG Research Review Board and the Tribal HPOG grantees. These changes do not increase the burden on potential study participants. The forms provide additional information about the study and use a format requested by the TNRG Research Review Board that has been found to be the most appropriate way to convey the intention of research and participants' involvement in the study when used for other research in their community.

Additionally, one version of the form states that SSNs will be collected and the other version states explicitly that SSNs will not be collected (unique identifiers will be used in these cases). As approved by



ACF and the evaluation team, some Tribal HPOG grantees will collect SSNs, some will use unique identifiers, and one grantee will collect both SSNs and unique identifiers, depending on whether the participant lives on the reservation or not.

This request seeks approval for use of the two revised versions of the informed consent form. The revised forms are attached to this memo (see Attachment B2: Tribal Evaluation Informed Consent Form A (SSNs); and Attachment B3: Tribal Evaluation Informed Consent Form B (Unique Identifier)). In addition, for each form, we include a side-by-side comparison of the language originally approved by OMB and the revised language (see Appendix 1: Section by Section Comparison of Tribal Informed Consent Form, Version for Grantees Collecting SSNs; and Appendix 2: Section by Section Comparison of Tribal Informed Consent Form, Version for Grantees Collecting Unique Identifier instead of SSNs). Supporting Statement A was revised and approved as part of the non-substantive change approved on January 26, 2016. We updated this version of Statement A to reflect the need for additional consent forms to be used for the Tribal HPOG evaluation. Additionally, a small error to the previously approved language not related to this request was found in Supporting Statement A. This error has been corrected in track changes.

# **Expected Benefits**

The requested changes address needs raised by the tribal grantees and ensure the flow and content of the form align with the format for informed consent used in tribal communities. We expect the requested changes to also make it easier for participants to understand the risks and benefits of participating in the study. The request also demonstrates ACF's commitment to conducting collaborative and culturally responsive evaluations in tribal communities and ensures that the needs of the tribal grantees are addressed throughout the evaluation process.

Appendix 1: Section by Section Comparison of Tribal Informed Consent Form, Version for Grantees Collecting SSNs

Section of Consent Form	Text as previously approved by OMB	Proposed Tribal Consent Form, Version for Grantees Collecting SSNs
Introduction	You are invited to take part in an important study of healthcare training programs. The study is funded by the U.S. Department of Health and Human Services. Several research organizations – including MEF, the Urban Institute, and Insight Policy Research and other researchers – are running the study for the U.S. Department of Health and Human Services. Your taking part in the study will help us learn more about how the HPOG program helps people improve their skills, find jobs, and advance in healthcare careers.  Over the next 10 years, researchers will use information about people in the program to do the study. This form: 1) describes the HPOG Outcome study and 2) requests your participation in the study. We need to tell you about the study and what it means to be part of it.	Statement of Research You are invited to take part in an important study of healthcare training programs. The study is funded by the U.S. Department of Health and Human Services (HHS). Several research organizations – including Abt Associates and NORC at the University of Chicago – are conducting the study for HHS. Over the next 10 years, researchers will use information about participants in the HPOG program to do the study. This form:  1) describes the Tribal HPOG study and 2) requests your participation in the study. We need to tell you about the study and what it means to participate in it.  An explanation of the purposes of the Tribal HPOG Study Taking part in the study will help us learn more about how the HPOG program helps people improve their skills, find jobs, and advance in healthcare careers.
Study Requirements	What does it mean to be part of the Outcomes study? We expect a total of 43,000 people at up to 27 HPOG programs across the country to participate in this study. Participation in the HPOG Outcome study is voluntary. You can choose not to be part of the study and still receive HPOG services.  The study team will collect data from all people who apply for HPOG and meet [NAME OF HPOG PROGRAM] eligibility requirements. This will happen when people first apply to the program and meet its eligibility rules.	The approximate number of subjects involved in the study  We expect approximately 3,000 people at up to five Tribal HPOG programs across the country to participate in this study. Participation in the Tribal HPOG study is voluntary. You can choose not to be part of the study and still receive HPOG services.  Expected duration of the subject's participation  The study will last 10 years.

Information Collection	What type of information will the study collect?  If you agree to participate in the study, researchers would like to collect the following information about you:  1) Information you provide when you first apply to the program including: current information about you, your family, your education, your income and your work history. This includes social security numbers.  2) Information you or other organizations provide to the [NAME OF HPOG PROGRAM] staff about the training and services you get while you are in the program.  3) Information from government sources so researchers can learn more about your future employment, earnings, and post-secondary education over the next few years. Abt will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse.	Description of the procedures to be followed  The study team will collect data from all people who apply for HPOG and meet [NAME OF HPOG PROGRAM] eligibility requirements. This will happen when people first apply to the program and meet its eligibility rules.  If you agree to participate in the study, researchers would like to collect the following information about you:  1) Information you provide when you first apply to the program including: current information about you, your family, your education, your income and your work history. This includes social security numbers.  2) Information you or other organizations provide to the [NAME OF HPOG PROGRAM] staff about the training and services you get while you are in the program.  3) Information from government sources so researchers can learn more about your future employment, earnings, and post-secondary education over the next few years. Abt and NORC will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse.
Risks and Benefits		Identification of any procedures which are experimental  There are no experimental procedures involved.
		A description of any reasonably foreseeable risks or discomforts to the subject

		The risk in participating in this study include the possibility of loss of privacy. The research organizations conducting this study will have access to the data being collected about you. These organizations are committed to keeping your personal information private.  A description of any benefits to the subject or to others which may reasonably be expected from the research  While there are benefits for individuals to take part in the HPOG program, there is no direct benefit to individuals for participating in the evaluation. The evaluation is being conducted to see if and how HPOG makes a difference in people's lives by helping them complete training and get healthcare jobs. Agreeing to participate in the HPOG evaluation will yield a societal benefit by providing information to improve workforce development programs. The findings of the HPOG evaluation overall will expand the career pathways evidence base and help build on what has been learned to date about how to design and implement successful career pathways programs and improve the outcomes of individuals who
		participate in these programs.
Privacy	Will my information be kept private?  The research organizations conducting this study will have access to the data being collected about you. These organizations are committed to keeping your personal information private. Any researchers using information to study the program must follow strict data security procedures and sign a privacy agreement. However, there is a small risk of a loss of privacy. We will take strong precautions to make sure this does not happen. Any piece of paper that includes your name or other identifying information will be kept in a locked storage area and will be destroyed after the study ends. Any computer files with	Statement describing the extent, if any, to which privacy of records identifying the subject will be maintained  The research organizations conducting this study will have access to the data being collected about you. These organizations are committed to keeping your personal information private. Any researchers using information to study the program must follow strict data security procedures and sign a privacy agreement. However, there is a small risk of a loss of privacy. We will take strong precautions to make sure this does not happen. Any piece of paper that includes your name or other identifying information will be kept in a locked

your name or other identifying information will be protected by a password and will be stored on a secure network. Your personal information will be protected to the extent allowable by law. Our reports will combine your responses with responses from others. People who read the reports will not be able to identify responses you give. Any data sets that are developed for sharing with other researchers will be stripped of information that would make it easy to identify you.

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Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

Should the Department of Health and Human Services terminate this study, your participation will end.

## Requesting Permission

# **Requesting Permission**

Participation in this study is voluntary. If you participate, we will ask you to disclose your social security number. Abt will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse. This collection is part of research activities authorized by the Patient Protection and Affordable Care Act of 2010 (H.R. 3590, Title V, Subtitle F, Sec. 5507, sec. 2008, (a)(3)(B)).

This agreement is effective from the date you sign it (shown below) until the end of HHS's research on HPOG grants, or when you choose to withdraw permission. You may choose to withdraw your participation in the study at any time. If you do withdraw, researchers will continue to use

# Voluntary Involvement

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# Research, Rights or Injury

If you participate, we will ask you to disclose your social security number. Abt and NORC will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse. This collection is part of research activities authorized by the Patient Protection and Affordable Care Act of 2010 (H.R. 3590, Title V, Subtitle F, Sec. 5507, sec. 2008, (a) (3)(B)).

This agreement is effective from the date you sign it (shown

	information collected during the time you consented. To withdraw from the study, please call toll-free at 844-717-4691 (the Abt help line).  You will receive a copy of this form for your records. An agency may not conduct and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number.  For questions or concerns about the research, call Abt Associates toll-free at 844-717-4691  For questions or concerns about your rights as a research participant, call Teresa Doksum at the Abt Associates Institutional Review Board at toll-free 877-520-6835.	below) until the end of HHS's research on HPOG grants, or when you choose to withdraw permission. You may choose to withdraw your participation in the study at any time. If you do withdraw, researchers will continue to use information collected during the time you consented. To withdraw from the study, please contact Michael Meit at NORC at the University of Chicago at 301-634-9324. You will receive a copy of this form for your records. An agency may not conduct and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number.  For questions or concerns about the research, call NORC at 301-634-9324. For questions or concerns about your rights as a research participant, call Katie Speanburg at the Abt Associates Institutional Review Board at toll-free 877-520-6835.
Statement	Statement  "I have read this form and I know that my participation in the study is voluntary and I still may receive HPOG services if I choose not to participate.    I AGREE TO BE IN THE RESEARCH STUDY   I DO NOT AGREE TO BE IN THE RESEARCH STUDY  PRINT YOUR NAME ABOVE  D A T E	Statement  "I have read this form and I know that my participation in the study is voluntary and I still may receive HPOG services if I choose not to participate.    I AGREE TO BE IN THE RESEARCH STUDY   I DO NOT AGREE TO BE IN THE RESEARCH STUDY  PRINT YOUR NAME ABOVE  D A T E

Parent or Guardian Permission Box: For HPOG applicants under the age of 18, your parent or legal guardian also must sign below:  By signing this participation agreement, I confirm that I have read and understood the description of the HPOG Study.  I AGREE TO LET MY CHILD  BE IN THE RESEARCH STUDY  CHILD NAME  I DO NOT AGREE TO LET MY CHILD  BE IN THE RESEARCH STUDY  CHILD NAME  CHILD NAME	Parent or Guardian Permission Box: For HPOG applicants under the age of 18, your parent or legal guardian also must sign below:  By signing this participation agreement, I confirm that I have read and understood the description of the Tribal HPOG Study.  I AGREE TO LET MY CHILD BE IN THE RESEARCH STUDY CHILD NAME I DO NOT AGREE TO LET MY CHILD BE IN THE RESEARCH STUDY CHILD NAME  PRINT NAME OF PARENT/GUARDIAN  PARENT/GUARDIAN SIGNATURE
PRINT NAME OF PARENT/GUARDIAN	DATE
PARENT/GUARDIAN SIGNATURE DATE	

Appendix 2: Section by Section Comparison of Tribal Informed Consent Form, Version for Grantees Collecting Unique Identifier instead of SSNs

Section of Consent Form	Text as previously approved by OMB	Proposed Tribal Consent Form, Version for Grantees Collecting Unique Identifier instead of SSNs
Introduction	You are invited to take part in an important study of healthcare training programs. The study is funded by the U.S. Department of Health and Human Services. Several research organizations – including MEF, the Urban Institute, and Insight Policy Research and other researchers – are running the study for the U.S. Department of Health and Human Services. Your taking part in the study will help us learn more about how the HPOG program helps people improve their skills, find jobs, and advance in healthcare careers.  Over the next 10 years, researchers will use information about people in the program to do the study. This form: 1) describes the HPOG Outcome study and 2) requests your participation in the study. We need to tell you about the study and what it means to be part of it.	Statement of Research You are invited to take part in an important study of healthcare training programs. The study is funded by the U.S. Department of Health and Human Services (HHS). Several research organizations – including Abt Associates and NORC at the University of Chicago – are conducting the study for HHS. Over the next 6 years, researchers will use information about participants in the HPOG program to do the study. This form:  1) describes the Tribal HPOG study and 2) requests your participation in the study. We need to tell you about the study and what it means to participate in it.  An explanation of the purposes of the Tribal HPOG Study Taking part in the study will help us learn more about how the HPOG program helps people improve their skills, find jobs, and advance in healthcare careers.
Study Requirements	What does it mean to be part of the Outcomes study? We expect a total of 43,000 people at up to 27 HPOG programs across the country to participate in this study. Participation in the HPOG Outcome study is voluntary. You can choose not to be part of the study and still receive HPOG services. The study team will collect data from all people who apply	The approximate number of subjects involved in the study  We expect approximately 3,000 people at up to five Tribal HPOG programs across the country to participate in this study. Participation in the Tribal HPOG study is voluntary. You can

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Information Collection	<ul> <li>What type of information will the study collect?</li> <li>If you agree to participate in the study, researchers would like to collect the following information about you:</li> <li>4) Information you provide when you first apply to the program including: current information about you, your family, your education, your income and your work history. This includes social security numbers.</li> <li>5) Information you or other organizations provide to the [NAME OF HPOG PROGRAM] staff about the training and services you get while you are in the program.</li> <li>6) Information from government sources so researchers can learn more about your future employment, earnings, and post-secondary education over the next few years. Abt will use your name and social security number to get some of these data from the National Directory of New Hires and the National Student Clearinghouse.</li> </ul>	If you agree to participate in the study, researchers would like to collect the following information about you:  1) Information you provide when you first apply to the program including: current information about you, your family, your education, your income and your work history. Social security numbers will <b>not</b> be collected.  2) Information you or other organizations provide to the [NAME OF HPOG PROGRAM] staff about the training and services you get while you are in the program.
Risks and Benefits		Identification of any procedures which are experimental

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Privacy	Will my information be kept private?  The research organizations conducting this study will have access to the data being collected about you. These	Statement describing the extent, if any, to which privacy of records identifying the subject will be maintained
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