control group, which consists of Stock Holdings of Delaware, LLC; Joan A. Schweizer, Fort Walton Beach, Florida; Karnise D. Schweizer, Fort Walton Beach, Florida, in her capacities as sole member and manager of Stock Holdings of Delaware, LLC, executrix of the estate of Arthur F. Schweizer, and trustee under the Last Will and Testament of Arthur F. Schweizer; Jarrod L. Schweizer, Boston, Massachusetts; Jason L. Schweizer, Fort Walton Beach, Florida; W. Todd Schweizer, Fort Walton Beach, Florida, individually and in his capacity as the sole member and manager of Schweizer Brothers Investments L.L.C., Fort Walton Beach, Florida; and Schweizer Brothers Investments L.L.C.; to acquire voting shares of Beach Community Bancshares, Inc., and thereby indirectly acquire voting shares of Beach Community Bank, both in Fort Walton Beach, Florida.

C. Federal Reserve Bank of Dallas (E. Ann Worthy, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *Michael Thomas Cope; Julio Cesar Ramon, Sr.; Beatrice Cortez Ramon, all of Mason, Texas; and Kenneth Charles Burow,* Comfort, Texas; collectively as a group acting in concert, to acquire voting shares of Commercial Company, Inc., and thereby indirectly acquire voting shares of Commercial Bank, both in Mason, Texas.

Board of Governors of the Federal Reserve System, October 21, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–25333 Filed 10–23–14; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 17, 2014.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Wintrust Financial Corporation,* Rosemont, Illinois, to merge with Delavan Bancshares, Inc., Delavan, Wisconsin, and thereby indirectly acquire Community Bank CBD, Delavan, Wisconsin.

B. Federal Reserve Bank of St. Louis (Yvonne Sparks, Community Development Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *Financial Services Holding Corporation,* Henderson, Kentucky; to acquire 100 percent of the voting shares of Ohio Valley Bancorp, Inc., and thereby indirectly acquire voting shares of Ohio Valley Financial Group, both in Henderson, Kentucky.

Board of Governors of the Federal Reserve System, October 20, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–25265 Filed 10–23–14; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Home Owners' Loan Act (12 U.S.C. 1461 *et seq.*) (HOLA), Regulation LL (12 CFR part 238), and Regulation MM (12 CFR part 239), and all other applicable statutes and regulations to become a savings and loan holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a savings association and nonbanking companies owned by the savings and loan holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the HOLA (12 U.S.C. 1467a(e)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 10(c)(4)(B) of the HOLA (12 U.S.C. 1467a(c)(4)(B)). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 20, 2014.

A. Federal Reserve Bank of Atlanta (Chapelle Davis, Assistant Vice President) 1000 Peachtree Street NE., Atlanta, Georgia 30309:

1. *Seminole Bancorp, Inc.,* Hollywood, Florida; to become a savings and loan holding company by acquiring 100 percent of the voting shares of Mackinac Savings Bank, F.S.B., Boynton Beach, Florida.

Board of Governors of the Federal Reserve System, October 21, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–25332 Filed 10–23–14; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Draft Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Office for Human Research Protections, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS), through the Office for Human Research Protections (OHRP) is announcing the availability of a draft guidance for the research community entitled ''Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care.'' OHRP is specifically addressing what risks to subjects are presented by research evaluating or comparing risks

associated with standards of care, and which of these risks are reasonably foreseeable and should be disclosed to prospective research subjects as part of their informed consent. OHRP is soliciting written comments from all interested parties, including, but not limited to IRB members, IRB staff, institutional officials, research institutions, investigators, research subject advocacy groups, ethicists, the regulated community, and the public at large. This draft guidance represents OHRP's current thinking on this topic.

Certain treatments and procedures that are commonly used in health care for a given type of disease or condition have come to be known as ''standards of care.'' Multiple ''standards of care'' involving widely differing treatments and risks may be available for the same disease or medical condition. Where multiple ''standard of care'' options are available for a given disease or condition, the use of the term does not imply that the options will produce similar benefits or incur similar risks. Furthermore, patients may not find those options equally acceptable, nor do physicians always use them interchangeably. Importantly there is not necessarily a limit on how different the risks from two versions of a standard of care might be. For example, it may already be known that one of those versions imposes a significantly higher risk of death than the other.

Adequate knowledge about the effectiveness and risks of standards of care and how these standards compare to each other is sometimes lacking. In recent years research studies designed to evaluate such treatments and procedures have become commonplace. These studies are often called ''comparative effectiveness research'' or ''standard of care research.''

As this type of research has become more common, so too have questions about how the HHS human subject protection regulations (45 CFR part 46) apply to such research. There is uncertainty in the research community about which risks of the research should be determined to be reasonably foreseeable risks of research and how they should be described to prospective subjects in the process of informed consent. OHRP's interpretation of the HHS research regulations has been that if people are being asked to undergo procedures in a research study that involve risks that they would not otherwise be exposed to, these are 'research risks' that people must be informed about. Only in that way are they able to make a truly informed decision about whether they are willing to participate. For comparative effectiveness or standard of care research, OHRP's general position is that the reasonably foreseeable risks of research include already-identified risks of the standards of care being evaluated as a purpose of the research when the risks being evaluated are different from the risks subjects would be exposed to outside of the study. This guidance addresses these issues in the form of frequently asked questions. OHRP will consider comments received before issuing the final guidance document.

DATES: Submit written comments by December 23, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled, Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–402-2071. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

You may submit comments identified by docket ID number HHS–OPHS–2014–0005 by one of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov.* Enter the above docket ID number in the Enter Keyword or ID field and click on ''Search.'' On the next page, click the ''Submit a Comment'' action and follow the instructions.

Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; phone 240–453–6900; email *Irene.Stith-Coleman@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. HHS Protection of Human Subjects Regulations

HHS, through OHRP, regulates research involving human subjects conducted or supported by HHS. The HHS human subjects protection regulations pertain to several different entities, including the institutional review board (IRB) charged with reviewing non-exempt human subjects research.

The IRB is an administrative body that takes the form of a board, committee, or group, and is responsible for conducting the initial and continuing review of research involving human subjects. The IRB must have authority to approve, require modification of (in order to secure approval), or disapprove all research activities regulated by HHS as required by 45 CFR 46.109(a). An IRB's primary purpose in reviewing research is to ensure the protection of the rights and welfare of human research subjects. In order to approve research, an IRB is required to make certain determinations, including that the following 46.111(a)(2) criterion is met:

> Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).

The HHS human subjects protections regulations further require that an investigator must obtain informed consent from research subjects prior to the subjects' participation in the research, unless this requirement is waived by the IRB. In this informed consent process, the subjects must be provided with ''a description of any reasonably foreseeable risks or discomforts to the subject'' as required by 46.111(a)(4) and 46.116(a)(2).

B. OHRP's Compliance Oversight Investigation of SUPPORT

On March 7, 2013, OHRP issued a compliance oversight determination letter regarding its investigation into ''The Surfactant, Positive Pressure, and Oxygenation Randomized Trial'' (SUPPORT) (*http://www.hhs.gov/ohrp/detrm_letrs/YR13/mar13a.pdf*). OHRP determined that certain risks related to the interventions being studied in the SUPPORT trial were required by 45 CFR part 46 to be disclosed to the research subjects, and that the subjects were not informed of these risks. OHRP's view of the SUPPORT trial, as described in this determination letter, triggered extensive public discussion regarding (1) what risks to subjects are presented by clinical trials studying interventions that are standards of care in the clinical

treatment context, such that an IRB must evaluate those risks in relation to the anticipated benefits of the research; and (2) how an IRB should assess whether those risks are reasonably foreseeable such that the risks must be described to prospective subjects as part of obtaining a person's informed consent.

The critical disagreement in the research community relates to the issue of what risks must be disclosed to prospective subjects in a research study where participants will be receiving a treatment that is different from the treatment they would have received outside the study, but still within the range of ''standard of care'' that some doctors use for clinical purposes. Multiple ''standards of care'' involving widely differing treatments and risks may be available for the same disease or medical condition. Where multiple ''standard of care'' options are available for a given disease or condition, the use of the term does not imply that the options will produce similar benefits or incur similar risks. Furthermore, patients may not find those options equally acceptable, nor do physicians always use them interchangeably. Importantly there is not necessarily a limit on how different the risks from two versions of a standard of care might be. For example, it may already be known that one of those versions imposes a significantly higher risk of death than the other.

In the SUPPORT trial, an infant had a 50% chance of being assigned to the ''lower oxygen'' arm (where the oxygen saturation percentage would be maintained between 85% and 89%) or the ''higher oxygen'' range (between 91% and 95%). The level of oxygen the infants received was chosen by randomization. This design was intended to move these infants far enough away from the center value (90%), so that the differences in the amount of oxygen the two groups received would allow detection of different health outcomes in the groups. Therefore, for the great majority of infants in the trial, it is likely that their participation altered the level of oxygen they received compared to what they would have received had they not participated. Some in the research community maintain that because the lower (85% to 89%) and higher (91% to 95%) ranges of oxygen saturation provided to the infants were within the standard of care range, there were no known risks to participants in the study from being randomized to these two oxygen saturation levels. OHRP disagrees with this perspective, and maintains that the key issue is that the treatment and possible risks infants were exposed to in the research were different from the treatment and possible risks they would have been exposed to if they had not been in the trial, not that the treatment provided in the trial was within the standard of care. OHRP's interpretation of the research regulations has been that, if a person in a research study is being asked to undergo procedures that involve reasonably foreseeable risks that they would not have otherwise been exposed to, then that person needs to be told about those risks. Only in this way can people make a truly informed decision about whether they are willing to participate.

OHRP has become aware, through the public reaction to OHRP's determination letter, of differing perspectives in the scientific, research, and ethics communities about these issues and how the relevant requirements of the HHS protection of human subjects regulations should apply to research studying standard of care interventions. This draft guidance is intended to clarify how to apply the HHS regulations at 45 CFR part 46 to studies that are designed to evaluate one or more standards of care.

C. Public Meeting

On August 28, 2013, a public meeting was held at the HHS Hubert H. Humphrey Building to provide an opportunity for broad public participation and public comments concerning how the HHS human subjects protections requirements should be applied to research studying one or more interventions which are used as standard of care treatment in the non-research context. HHS specifically requested input regarding how an IRB should assess the risks of research involving randomization to one of more standard of care interventions, and what reasonably foreseeable risks of the research should be disclosed to research subjects in the informed consent process. The public meeting and comments were intended to assist OHRP in developing guidance regarding what constitutes reasonably foreseeable risk in research involving standard of care interventions such that the risk is required to be disclosed to research subjects. There were 27 oral presentations at the public meeting and 72 written comments submitted during the open comment period of June 26, 2013 through September 9, 2013.

The meeting was conducted by HHS officials, including the Director of OHRP. The meeting was reserved for presentations of comments, recommendations, and data from presenters. The time for each presentation was 7 minutes. The allocation of time was based on the number of registered presenters. Presenters were scheduled to speak in the order in which they registered. Only HHS panel members questioned presenters during or at the conclusion of their presentation. The meeting was recorded and transcribed. The recording and transcription are accessible through the OHRP Web site, *http://www.hhs.gov/ohrp/newsroom/rfc/Public%20Meeting%20August%2028,%202013/aug28public.html.* In addition to materials submitted for discussion at the public meeting, individuals were offered the opportunity to submit other written comments after the public meeting. All submitted comments were considered by HHS during the guidance development phase. A discussion of the public comments is below.

II. Discussion of Public Comments

HHS invited comments at the public meeting regarding how an IRB should assess the risks of research involving randomization to one or more standard of care interventions, and which research risks should be disclosed to subjects in the informed consent process. HHS was specifically interested in public input on the following questions:

1. How should an IRB assess the risks of standard of care interventions provided to subjects in the research context?

a. Under what circumstances should an IRB consider those to be risks that may result from the research?

b. Under what circumstances should an IRB refrain from considering those risks as unrelated to the research?

c. What type of evidence should an IRB evaluate in identifying these risks?

Several commenters presented arguments for always disclosing standard of care risks to potential subjects of a clinical trial. Many felt that all risks, including those of the standard of care, must be disclosed in order to allow subjects and parents of subjects to make a fully informed choice to participate in research. Some expressed the view that the risks of standard of care interventions are magnified when incorporated into a clinical trial, and to mitigate the potential harms these commenters recommended mandating data safety monitoring plans to detect and identify perceived reasonable foreseeable risk. The outcome measures produced from data safety monitoring plans would identify the reasonably foreseeable risks of the research.

Opposing arguments were expressed against incorporating standard of care

risks for clinical intervention as risks of standard of care or comparative effectiveness research. Many commenters stated that it is inaccurate to describe standard of care intervention risks as research risks, and that good evidence of such risks is often lacking; they pointed out that many widely used medical practices are based on clinician judgments alone. Proponents of this view expressed the opinion that IRBs should not require standard of care risks to be disclosed as research risks, but rather, indicated that standard of care inventions should be addressed in the clinical treatment consent prior to enrolling potential subjects in the clinical trial.

Response: OHRP agrees that to the extent participation in a clinical trial does not impose risks that are different from those to which a subject would have been exposed had they not been in the trial, those risks should not be considered risks attributable to the research. The key issue is not whether an intervention provided to subjects is within a standard of care, but whether the treatment a subject receives (and thus the risks they are exposed to) is different from that which these subjects would have been exposed to outside of the research study. The risks that result from such a difference in treatment are risks derived from participation in the research study. Patients randomized to different standards of care in a comparative effectiveness trial should accordingly be made aware of the risks of the standards of care that are being compared. OHRP agrees that the distinction between receiving clinical care and participating in research must be made clear to subjects.

2. What factors should an IRB consider in determining that the research-related risks of standard of care interventions, provided to research subjects in the research context, are reasonably foreseeable and therefore required to be disclosed to subjects?

Many commenters recommended first defining the term ''standard of care'' prior to defining the term ''reasonably foreseeable risk.'' Various commenters stated that the term ''standard of care'' is used to refer to a medically recognized standard of care that has been accepted by medical experts as a proper treatment or procedure for a given disease or condition, and been widely used by healthcare professionals. These commenters pointed to the need for an evidentiary basis for a given standard of care, and felt that whether it was acquired through publication, through conduct of randomized clinical trials, or through expert opinion, the basis for assessing standard of care may vary throughout the medical community, and therefore the research and other evidence regarding the associated risks of a standard of care being evaluated may vary as well.

The varying definitions for ''reasonably foreseeable risk'' presented in the comments were representative of the lack of consensus of the interpretation of the term among the experts in the medical and clinical research community.

Several commenters identified a number of kinds of standards and quantitative measures to help define reasonably foreseeable risks. The proposed levels of evidence offered by the commenters included clinical trial evidence, peer and literature review analysis, professional prior experience, risk and benefit ratio analyses and baseline risks of the identified population. A few commenters expressed the view that reasonably foreseeable risks are those risks supported in peer reviewed medical literature that occur in 5% of the patients or that hold p-values of less than 0.10 in one or more trials.

One comment stated, ''events for which one can hypothesize a plausible risk but which have not been shown to be caused by the intervention should not be classified as reasonably foreseeable.'' Other commenters were opposed to attempting a suggested definition.

There was an overall agreement among the commenters about disclosing research risks of standard of care treatment to the prospective participants, but disagreement on where in the informed consent document this information should be disclosed.

Response: OHRP believes that all research and other evidence underlying medically recognized standards of care should be given appropriate consideration in determining whether risks are reasonably foreseeable. The draft guidance does not address specific quantitative approaches to evaluating or identifying reasonably foreseeable risk. With regard to which risks should be considered ''reasonably foreseeable,'' OHRP concluded that at a minimum, identified risks associated with a standard of care that are being evaluated as a purpose of the research, should certainly be considered ''reasonably foreseeable.'' A core purpose of the Common Rule is to allow prospective subjects to make informed decisions about whether to participate in research. If a specific risk has been identified as significant enough that it is important for the Federal government to spend taxpayer money to better understand the extent or nature of that risk, then that risk is one that prospective subjects should be made aware of so that they can decide if they want to be exposed to it. It would be seem inappropriate to have both the federal agency funding a study and the researchers conducting it aware of an identified risk, and yet not disclose that risk to the very subjects who would be exposed to it, while at the same time claiming that their ''informed'' consent to participation has been obtained in a very meaningful way.

3. How should randomization be considered in research studying one or more interventions within the standards of care? Should the randomization procedure itself be considered to present a risk to the subjects? Why or why not? If so, is the risk presented by randomization more than minimal risk? Should an IRB be allowed to waive informed consent for research involving randomization of subjects to one or more standard of care interventions? Why or why not?

Many commenters felt that randomization alone does not pose a research risk, while others disagreed. In certain instances, some commenters said that randomization can impose harms to research subjects. One commenter stated that ''if a research study involves random assignment of two different interventions that are sometimes used for treating an acute stroke, and death and neurological impairment are the primary endpoints being measured in the study, such research should be considered to present much greater than minimal risk to subjects.'' A subset of commenters expressed that such outcomes should be made clear in the informed consent process and document. One commenter stated ''research involving randomization to one or more standard of care interventions should follow the same requirements for informed consent as other research studies and should not be assumed to involve no more than minimal risk.''

Some commenters recommended that clinical trials involving randomization should not be permitted to waive informed consent for subjects involving standard of care interventions. One commenter suggested that the use of randomization with waiver of consent deprives subjects of the trust inherent in the doctor-patient relationship.

A small subset of commenters cited the loss of autonomy of the research participant by incorporating randomization in a protocol. When people are randomly assigned to one of a number of different standards of care, they forego the ability to choose which standard of care they prefer.

However, other comments indicated that consent could be waived for standard of care trials. One commenter stated, ''waivers of consent for randomization are appropriate, ethically defensible and necessary in the case of comparing two standards of care interventions in some cases'' and that ''waiving consent requires active and innovative ways to engage the community and reach patients.''

In addition to the ethical defensibility for waiver of consent, one commenter expressed that there is nothing inherent in randomization that should preclude consideration of a waiver. ''Most research involving prospective randomization seems likely to require informed consent; because it seems unlikely that the research would meet the 46.116 requirement that the IRB finds that the research couldn't feasibly be carried out without a waiver of consent. However, the IRB should be allowed to waive informed consent for any research that does meet all the waiver criteria.''

Others comments stressed that waiver of consent does not eliminate the duty to communicate with the research participant about the risks and benefits of a study. A few commenters expressed that potential research participants should be informed of randomization but that there is no reasonable evidence that randomization increases risk. However, the lack of evidence regarding the risk of randomization does not justify the use or prohibition of waiver of informed consent.

Response: The draft guidance treats randomization no differently than any other mechanism by which a research subject may be assigned to a particular treatment. The underlying question, as discussed above, is whether, in the study, a subject will be assigned to a treatment whose risks may be different from the risks they would have been exposed to outside of the trial. If that happens—whether it is by randomization or some other study design (e.g., all of the subjects could be assigned to the same treatment, with no randomization at all)—then those differences in risks are risks relating to participating in the research. Thus, in this sense, there are no ''special'' or unique risks to randomization. The thing that matters is whether participating in the study may expose a subject to risks that are different from those they would otherwise have been exposed to.

4. How, and to what extent, does uncertainty about risk within the standard of care affect the answers to these questions? What if the risk significantly varies within the standard of care?

One commenter stated that the fact that there is uncertainty about differences in the proposed primary and secondary outcomes between two or more groups receiving different interventions being tested in a clinical trial is one reason that such research involves foreseeable risks to the subjects. If there were no such uncertainty, there would be no reasonable basis for conducting the research in the first place, and it would be unethical to do so. Others felt that uncertainty alone does not affect the risks of standard of care research to a research subject because risks of the standard of care do not affect research risk, regardless of the magnitude or certainty of the risks of the standard of care.

Other comments in this area addressed models for research risk disclosure, such as a transparency model in which investigators would ''explain to potential research participants what scientists and physicians think they know, commonly believe and the basis for such knowledge and beliefs.''

Response: The draft guidance does not address the issue of uncertainty of risk associated with standard of care or comparative effectiveness research overall. However, the guidance does indicate that when one of the purposes of the research is the evaluation or comparison of risks associated with standards of care, and the risks of the standard of care received by the subjects are different from those risks the subjects would be exposed to outside of the research, then these risks should be considered to be reasonably foreseeable.

5. Under what circumstances do potential risks qualify as reasonably foreseeable risks? For example, is it sufficient that there be a documented belief in the medical community that a particular intervention within the standard of care increases the risk of harm, or is it necessary that there be published studies identifying the risk?

Comments focused on methods to evaluate and identify reasonably foreseeable risks, and recommended that the phrases ''reasonably foreseeable'' and ''all imaginable'' risks need to be clarified among the research community. To assist, one commenter recommended that a body of annotated examples, analogous to case law, needed to be created for IRBs to use as precedent to evaluate clinical trials. Another commenter recommended that IRBs need experts who can evaluate the actual risks to subjects.

Several comments recommended various criteria for identifying reasonably foreseeable risks, such as credible evidence, reported safety concerns, and ''significant documented belief'' in the medical community that a particular intervention would increases the risk of harm. Other comments added biological plausibility and clinical experience as qualifiers. All submitted comments concurred with the need to further evaluate the determination of reasonably foreseeable risk.

Response: As discussed above, the guidance concludes that if evaluating a particular risk associated with a standard of care is a purpose of the research, then in general that particular risk should be considered to be ''reasonably foreseeable.'' Reasonably foreseeable risks must be disclosed as risks in the informed consent process in accordance with the regulatory requirements of 45 CFR 46.116(a)(2).

OHRP recognizes that the available evidence regarding the risks of specific standards of care will vary, and may include evidence from one or more clinical trials, other research studies, the opinion of clinical experts, and the history of clinical practice, all of which are taken into account in the formulation of standard of practice guidelines. In any case, if a particular identified risk is considered significant enough to constitute a rationale for conducting the study, then this should in almost all cases imply the conclusion that the risk is ''reasonably foreseeable'' for the purposes of these regulations, and that it would be mistaken to claim that informed consent was obtained if prospective subjects were not made aware of that risk.

General Comments

Some commenters expressed views not directly related to the questions asked by OHRP. Specifically, several commenters made remarks directly related to the SUPPORT trial. In addition, other issues of concern focused on cluster randomization, consent waivers based on the research's potential for public health benefit, and rigorous research evaluations. Although the commenters disagreed with specific aspects of these topics, they agreed that these issues are growing concerns among the research community and should be discussed further.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/newsroom/rfc/index.html* or on the Federal

Rulemaking Portal at *http://www.regulations.gov/*.

Dated: October 21, 2014.

Wanda K. Jones,

Acting Assistant Secretary for Health.

[FR Doc. 2014–25318 Filed 10–23–14; 8:45 am]

BILLING CODE 4150–36–P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Notice of Advisory Council on Historic Preservation Quarterly Business Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of Advisory Council on Historic Preservation Quarterly Business Meeting.

SUMMARY: Notice is hereby given that the Advisory Council on Historic Preservation (ACHP) will hold its next quarterly meeting on Thursday, November 6, 2014. The meeting will be held in Room SR325 at the Russell Senate Office Building at Constitution and Delaware Avenues NE., Washington, DC, starting at 8:30 a.m. EST.

DATES: The quarterly meeting will take place on Wednesday, November 6, 2014, starting at 8:30 a.m. EST.

ADDRESSES: The meeting will be held in Room SR325 at the Russell Senate Office Building at Constitution and Delaware Avenues NE., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Cindy Bienvenue, 202–517–0202, *cbienvenue@achp.gov*.

SUPPLEMENTARY INFORMATION: The Advisory Council on Historic Preservation (ACHP) is an independent federal agency that promotes the preservation, enhancement, and sustainable use of our nation's diverse historic resources, and advises the President and the Congress on national historic preservation policy. The goal of the National Historic Preservation Act (NHPA), which established the ACHP in 1966, is to have federal agencies act as responsible stewards of our nation's resources when their actions affect historic properties. The ACHP is the only entity with the legal responsibility to encourage federal agencies to factor historic preservation into federal project requirements. For more information on the ACHP, please visit our Web site at *www.achp.gov*.

The agenda for the upcoming quarterly meeting of the ACHP is the following:

Call to Order—8:30 a.m.

I. Chairman's Welcome

II. Swearing in Ceremony

III. Presentation of Chairman's Award for Historic Preservation Achievement

IV. Chairman's Report

V. Historic Preservation Policy and Programs

A. Building a More Inclusive Preservation Program

1. Proposed Presidential Heritage Initiative

2. Congressional Black Caucus Foundation Event

3. Asian-American Pacific Islander Initiative

4. American Latino Heritage Initiative

B. Working with Indian Tribes

1. Proposed ACHP Policy for Tribal Historic Preservation Officers

2. Delegation of Authority to Approve Substitution of Tribal Procedures for Section 106 on Tribal Lands

3. ACHP Native American Affairs Committee

C. Funding for Tribal and State Historic Preservation Programs

D. 50th Anniversary of the National Historic Preservation Act

E. ACHP Legislative Agenda

VI. Section 106 Issues

A. 2015 Section 3 Report to the President

B. Alignment of Section 4f and Section 106 Reviews

C. Major Program Initiatives Update

1. Unified Federal Review for Disaster Recovery Projects

2. Model Covenant Guidance and USPS Report Implementation

VII. ACHP Management Issues

A. ACHP Strategic Plan Update

B. Member Communications

C. Alumni Foundation Report

VIII. New Business

IX. Adjourn

The meetings of the ACHP are open to the public. If you need special accommodations due to a disability, please contact Cindy Bienvenue, 202–517–0202 or *cbienvenue@achp.gov*, at least seven (7) days prior to the meeting.

Authority: 16 U.S.C. 470j.

Dated: October 20, 2014.

Javier E. Marques,

Associate General Counsel.

[FR Doc. 2014–25300 Filed 10–23–14; 8:45 am]

BILLING CODE 4310–K6–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

Privacy Act of 1974; Consolidation of Department of Homeland Security United States Citizenship and Immigration Services E-Verify Self Check System of Records

AGENCY: Privacy Office, DHS.

ACTION: Notice to consolidate one Privacy Act system of records notice.

SUMMARY: In accordance with the Privacy Act of 1974, the Department of Homeland Security is giving notice that it proposes to consolidate the following Privacy Act system of records notice, Department of Homeland Security/United States Citizenship and Immigration Services—013 E-Verify Self Check (76 FR 9034, February 16, 2011), into the existing Department of Homeland Security system of records notices titled Department of Homeland Security/ALL–037 E-Authentication Records System of Records (79 FR 46857, August 11, 2014) and Department of Homeland Security/United States Citizenship and Immigration Services—011 E-Verify Program System of Records (79 FR 46852, August 11, 2014). As a result of this consolidation, DHS is removing DHS/USCIS–013 from its inventory of systems of records.

DATES: These changes will take effect on November 24, 2014.

FOR FURTHER INFORMATION CONTACT: Karen L. Neuman (202–343–1717), Chief Privacy Officer, Department of Homeland Security, Washington, DC 20528.

SUPPLEMENTARY INFORMATION: Pursuant to the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, and as part of its ongoing integration and management efforts, the Department of Homeland Security (DHS) is consolidating the system of records notice, Department of Homeland Security/United States Citizenship and Immigration Services—013 E-Verify Self Check (76 FR 9034, February 16, 2011), into two existing system of records notices.

DHS will continue to collect and maintain records regarding E-Verify Self Check and will rely upon the following system of records notices titled DHS/ALL–037 E-Authentication Records System of Records (79 FR 46857, August 11, 2014) and DHS/USCIS–011 E-Verify Program System of Records (79 FR 46852, August 11, 2014). DHS is not requesting comment on this notice because the E-Authentication Records and E-Verify Program System of Records