Summary of policy changes April 2018

A. Introduction to Policies, Revision date 4/2/2018

Change Summary: added clarification about which rules apply, review of meeting space when evaluating resources, and updating of policy
Rationale for change: Final Rule, new AAHRPP requirement when evaluating resources, no longer under TBR

Change Specifics

1. Section V, added “When the revised Common Rule goes into effect, ETSU IRB policies will be updated to revise definition of "private identifiable information" and "identifiable biospecimen" at least every four years, or when updated in the Federal Register per §___.102(e)(7)
2. Section V, deleted reference to TBR
3. Section V, deleted “and procedures”
4. Added “including meeting space” to resource review section
5. Added Section VII
   “ETSU applies the same policies used to comply with DHHS regulations to all (non-FDA) research. When applicable, such as when required in state or local laws, tribal laws, and foreign laws, additional protections beyond those in DHHS regulations are applied (see applicable IRB policies).”

B. Policy 1, Revision date 4/2/18

Change Summary: added reference to administrative check of GCP training
Rationale for change: Final Rule

Change Specifics:

1. Section 9, GCP, added, “When the revised Common Rule goes into effect, for studies that no longer undergo continuing review, IRB Coordinators will monitor the status of GCP training for study staff administratively.”
2. Updated links in reference section

C. Policy 2, Revision date 4/2/18

Change Summary: updating of roles (Secretary to IRT), revised statement regarding alternate to reflect practice, revised statement of written requirements for credentialing to reflect practice, deleted reference to TBR, evaluations now happen around April

Rationale: no longer under TBR, updating to reflect practice, Final Rule

Change Specifics:

1. Section IIA, added, “The requirements for the composition of the IRB under the revised Common Rule vary slightly from the 1991 Common Rule. The composition of the ETSU and ETSU/VA IRB complies with both rules.”
2. Section IIA, moved the sentences prohibiting business development/ ORSPA staff from serving as members
3. Section II A, added phrase, “Under the 1991 Common Rule”
4. Section IIA, added,

   “When the revised Common Rule goes into effect, the following requirements apply to the composition of the IRB:
   Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB is required to be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB will include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.”
5. Section IID, revision of “Secretary” to “Information Research Technician”
6. Section IIE, deletion of “with concurrence of the regular membership” from alternate discussion
7. Section IIG, deletion of “of availability” from credentialing section
8. Section IIJ, revised “The campus IRB will meet every other month during the academic year, with one meeting during the summer, with additional meetings scheduled if issues or studies that require full board deliberation are received.”
   To “The campus IRB will meet every month during the academic year, with additional….”
9. Section II N, added, “The requirements regarding conflict of interest under the revised Common Rule vary very slightly from the 1991 Common Rule. The policy of the ETSU and ETSU/VA IRB complies with both rules.”
10. Section IIN, added phrase, “Under the 1991 Common Rule,”

11. Section IIN, added, “When the revised Common Rule goes into effect, no IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.”
12. Section III, moved sentence about VAMC research and mentally disabled persons
13. Section III, added, “The requirements for the composition of the IRB under the revised Common Rule vary slightly from the 1991 Common Rule. The composition of the ETSU and ETSU/VA IRB complies with both rules.”
14. Section III, added phrase, “Under the 1991 Common Rule”
15. Section III, added section:
    “When the revised Common Rule goes into effect, if the IRB regularly reviews a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration will be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.”
16. Section IV, deleted references to TBR
17. Section IV, changed annual member self-evaluations to April rather than December
18. Section IV, updated references to forms for IRB staff evaluation
19. Updated reference to VA Handbook

D. Policy 3, Revision date 4/2/2018

Change Summary: updated link, added clarifying phrases regarding continuing review and external reliance, deleted reference to date stamp, other minor updates
Rationale for change: Final Rule, link no longer accurate, text no longer accurate

Change Specifics:

1. Section I.4, updated link to ethics training
2. Section I.5, added phrase, “unless reliance on an external IRB has been established in accordance with IRB Policy 21” as qualifier to PI responsibility to ensure that ETSU or ETSU/VA IRB review is obtained; also added “as required” to mention of continuing review
3. added “For studies that require continuing review” in Section I.7 as qualifier for continuing review PI responsibility
4. Section I.20, deleted, “The audit report must bear a stamped date indicating the receipt of the report at the local site” as date received is a field on an xform 109.
5. Section I. 23, deleted reference to form 107 and instead stated “per policy” (left reference to notifying IRB of closed study)

6. Section I, 24, added “Retain records for six years from the end of the calendar year in which the study is closed
7. Section III, added “or other” to header (VPR does review for MSHA or other investigators not employed by ETSU/VA)
8. Section III, 9, added “as required” to reference to continuing review
9. Section IV, 10, deleted references to form 107 and added “per policy”, also changed “if a completed Form 107 closing the study is not submitted prior to graduation” to “if study is not closed prior to graduation”
10. Section IV.11, added phrase, “For studies that require continuing review” and deleted “unless the study has been determined to be exempt”
11. Section IV,12, added “when required” (about continuing review)
12. Section VII, corrected typo
13. Section VIII, updated “Secretary” to “Information Research Technician”
14. Section VIII 1, changed “protocol submission” to “issuance of study approvals”
15. Section VIII 8, added “as required in” instead of “refer additionally to” (policy 34)
16. Section VIII 16, added reference to webinars and changed “PRIMR/ARENA” to “PRIMR/AAHRPP”
17. Section VIII 8, deleted reference to “the President of ETSU”

E. Policy 4, Revision date 4/2/2018

Change Summary: added reference to limited review, added revised approval criteria
Rationale for change: Final Rule

Change Specifics:

1. Section II, added, “The IRB will review and has authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy”
2. Section II, added qualifier to current approval criteria; For research reviewed subject to the 1991 Common Rule and FDA research
3. Added section header and following text: For non-FDA research subject to the revised Common Rule when it goes into effect:

   “The IRB will review and has authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. When the revised Common Rule goes into effect, this will include exempt research activities under § __.104 for which limited IRB review is a condition of exemption (under § __.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) 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 IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

(5) Informed consent will be appropriately documented, or appropriately waived in accordance with § __.117.

(6) When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*When research is more than minimal risk and involves an intervention

At the time of this policy revision, ETSU is not allowing exemption under exempt categories 7 and 8. However, the information regarding limited review is included below.

(8) For purposes of conducting the limited IRB review required by § __.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and will make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § __.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § __.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) when some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects."

F. Policy 5, Revision date 4/2/2018

Change Summary: updated definitions
Rationale for change: Final Rule, revised AAHRPP Instrument for Evaluation

Change Specifics:

1. Section I.A, updated definition of research per FDA (from AAHRPP standards)

Research is defined in the FDA federal regulations as any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505 (i) or 520 (g) of the Federal Food, Drug, and Cosmetic Act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations.

2. Section I.B, added qualifying phrase to current definition of human subject, “defined under the 1991 Common Rule”, and added updated definition of human subject - “When the revised Common Rule goes into effect, ….; (changes “data” to “information or biospecimens”, adds “uses, studies, or analyzes..”)

   “When the revised Common Rule goes into effect, a human subject is defined as “a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens”

3. Section I.B, updated definition of human subject under FDA, per new AAHRPP standard:

   Human subject is “an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject might be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.”

4. Section I.C, definition of intervention, clarified that current definition is for 1991 Common Rule, and adds definition for when revised Common Rule goes into effect. (changes "data" to "information or biospecimens")

   "When the revised Common Rule goes into effect, intervention is defined as including both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes."

5. Section I.F, definition of private information, clarified current definition is for 1991 Common Rule, and adds definition when the revised Common Rule goes into effect: (only changes "which" to "that")

   When the revised Common Rule goes into effect, private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).

6. Section I. G,H, J and K, added definitions:

   - **Identifiable private information,** when the revised Common Rule goes into effect, is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
   - **An identifiable biospecimen,** when the revised Common Rule goes into effect, is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
   - **Clinical trial,** when the revised Common Rule goes into effect, means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
   - "**Public health authority**", when the revised Common Rule goes into effect, means an agency or authority that is responsible for public health matters as part of its official mandate.

7. Section III, added header to current language: “Under the 1991 Common Rule”
8. Section III, added other categories that are not research under revised Common Rule

“When the revised Common Rule goes into effect,
The Final Rule deems the following activities to be not research: certain scholarly and journalistic activities, public health surveillance activities, criminal justice activities, and authorized operational activities in support of national security missions. The IRB has the sole authority to make a final determination of whether a proposed activity is human research according to DHHS or FDA regulatory definitions. Unless you are familiar enough with these regulations to be certain that the activity does not represent human research, the activity should be brought forward to the IRB for a determination.

a. Certain scholarly and journalistic activities:

Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected, are not human subject research under DHHS regulations. This is limited to certain activities in various fields that focus directly on the specific individuals about whom information are collected. The focus is on the specific activities that collect and use information about specific individuals themselves, and not generalizing to other individuals. Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, and the findings apply to the studied community or group, and not just the individuals from whom the information was obtained, fall within the scope of the definition of research.

b. Operation activities in support of national security missions:

Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions, are not included in the DHHS definition of research. .

c. Public health surveillance activities:

The following activities are not considered research: Public health surveillance activities conducted by a public health authority, limited to those

necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
• Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
• Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
• Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

The DHHS definition of research does not include a category of activities that solely involve public health surveillance, including collecting and testing information or biospecimens in activities that are conducted, supported, requested, ordered, required, or authorized by a public health authority and that are limited to those necessary to allow the public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance. Such surveillance activities can include collecting information about trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products. Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). Public health surveillance refers to collecting, analyzing, and using data to target public health and disease prevention. Surveillance uses data from a variety of sources, including mandatory reporting of certain conditions, routine monitoring, vital records, medical billing records, and public health investigations.

The line between public health surveillance and epidemiological research can be difficult to draw, as the same epidemiological techniques may be used in both. Generally, the difference between the activities is the purpose or context in which the investigation is being conducted and the role of the public health authority.

Examples of “Not Research” under this category
The following are examples of public health surveillance activities being codified as outside of the definition of research in the DHHS regulations:
• Safety and injury surveillance activities designed to enable a public health authority to identify, monitor, assess, and investigate potential safety signals for a specific product or class of products (for example, the surveillance activities of the FDA’s Adverse Event Reporting System, the Vaccine Adverse Event Reporting System, Manufacturer and User Facility Device Experience

database, the Medical Product Safety Network, and the Sentinel Initiative);
• Surveillance activities designed to enable a public health authority to identify unexpected changes in the incidence or prevalence of a certain disease in a defined geographic region where specific public health concerns have been raised (e.g., the U.S. influenza surveillance system, which allows CDC to find out when and where influenza activity is occurring, track influenza related illness, determine what strains of influenza virus are circulating, detect changes in influenza viruses, and measure the impact influenza is having on hospitalizations and deaths in the United States);
• Surveillance activities designed to enable a public health authority to identify the prevalence of known risk factors associated with a health problem in the context of a domestic or international public health emergency;
• Surveillance activities designed to enable a public health authority to locate the range and source of a disease outbreak or to identify cases of a disease outbreak;
• Surveillance activities designed to enable a public health authority to detect the onset of disease outbreaks or provide timely situational awareness during the course of an event or crisis that threatens the public health, such as a natural or man-made disaster; and,
• Surveillance activities designed to enable a public health authority to identify the prevalence of a condition of public health importance, known risk factors associated with a condition of public health importance, or behaviors or medical practices related to prevalence of a known condition of public health importance (e.g., surveillance of the prevalence of: tobacco use, exposure to secondhand smoke, lung cancer, or use of smoking cessation treatments).

Examples of “Research” under this category:

The following would be research (even if conducted by a federal agency with a public health mandate):
• subsequent research using information collected during a public health surveillance activity, for instance, genetic analysis of biospecimens, would not be removed from the definition
• exploratory studies designed to better understand risk factors for chronic diseases, including genetic predisposition, for chronic diseases;
• exploratory studies designed to elucidate the relationships between biomarkers of exposure and biomarkers of disease;
• exploratory studies of potential relationships between behavioral factors (e.g., diet) and indicators of environmental exposures.
• Research evaluations of public health surveillance activities

d. Criminal Justice:

The collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes is not research under the DHHS regulations.

The scope of these activities is collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. The activities are necessary for the operation and implementation of the criminal justice system.

This category is also not intended to include social and behavioral studies of the causes of criminal behavior. Such studies would be considered research under the DHHS rules.

e. Secondary research involving non-identifiable newborn screening blood spots is not considered research involving human participants."

G. Policy 7, Revision date 4/2/18

Change Summary: added new exempt categories, and limited IRB review section
Rationale for Change: Final Rule

Change Specifics:

1. Section II, current wording allows VPR to make exempt determination. As only IRB members can do the limited review, deleted these references, so it now reads, "If the research is submitted by the IRB Chair, the Vice Chair will review this determination." "The exemption status must be approved by the IRB Chair or Vice-Chair or an experienced IRB member designated by the Chair."
2. Section II, added, "In addition, when the revised Common Rule goes into effect, the IRB will conduct a limited review of the research as required."
3. Top of Categories III, added "Under the 1991 Common Rule" before current exempt categories
4. Added all new exempt categories, under heading, "When the revised Common Rule goes into effect, for studies subject to the Common Rule:"

Only research activities in which the only involvement of human subjects will be in one or more of the six specific categories of exempt activities as delineated by HHS Regulations 45 CFR 46 (104) (d) are eligible to be given exempt status. ETSU has determined to not allow exemptions under category 7 or 8.

Categories 1-5 and 7-8 do not apply to FDA-regulated research.

Subpart B (pregnant women, fetuses and neonates): Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

Subpart C (prisoners): The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Subpart D (children): The exemptions at paragraphs (d)(1), (4), (5), (6), (7- not allowed at ETSU), and (8- not allowed at ETSU) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

Transnational: Laws and regulations in some countries do not allow exemptions. If the research is not eligible for an exemption under the laws of that country, even though the research may be covered by DHHS regulations, ETSU will not allow an exemption for research.

<u>The six categories are</u>**<u>:</u>**

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

The exemption at Category 1 may be applied may be applied to research with children (research subject to subpart D) if the conditions of the exemption are met.

2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § (insert reference)__.111(a)(7)

Children (research subject to Part D):
Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § (insert reference)_.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Benign behavioral interventions are:
• Brief in duration.
• Harmless
• Painless
• Not physically invasive
• Not likely to have a significant adverse lasting impact on the participants.
• The researcher has no reason to think the subjects will find the interventions offensive or embarrassing

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(6) 45 CFR 46 and 21 CFR 56.104(d): Taste and food quality evaluation and consumer acceptance studies,

a. if wholesome foods without additives are consumed or
b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture.

5. Added new section IV, Limited IRB Review

When the revised Common Rule goes into effect: Limited IRB review is a new requirement created under the revised DHHS regulations, and is unique to DHHS regulations. Limited IRB review will not be conducted by staff, but by a member of the IRB (IRB Chair or Vice-Chair or an experienced IRB member designated by the IRB Chair).

Research that requires limited review is as follows:

Category 2

• Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) where:

• The information obtained is recorded by the researcher in such a manner that the identity of human participants can be readily ascertained, directly or through identifiers linked to the participants and any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

The IRB must determine there are adequate provisions to protect the privacy interests of research participants and the confidentiality of identifiable date.

Category 3

• Research involving benign behavioral interventions in conjunction with the collection of information from adult participants through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and where:

• The information obtained is recorded by the researcher in such a manner that the identity of human participants can be readily ascertained, directly or through identifiers linked to the participants. (§___.104(3)(i)(C)) and any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation

The IRB must determine there are adequate provisions to protect the privacy interests of research participants and the confidentiality of identifiable data.

ETSU does not exempt research under categories 7 and 8.

a. Eligible research for limited review must be deemed to be no more than minimal risk.

If an IRB or EC member reviewing the research finds that research is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB or EC.

b. A complete new protocol submission xform with all relevant attachments (including but not limited to the proposed consent and all recruitment

materials) must be submitted for an exempt determination, to include limited review as indicated.

c. IRB members conducting limited IRB review may not disapprove research.
d. When conducting limited IRB review, the IRB reviewer is responsible for making this determination: for exemption Categories 2 and 3, that there are adequate protections for privacy interests of participants and the confidentiality of identifiable data. If this criteria is not met, the study may not be issued an exempt determination/approval.
e. Exempt research under limited IRB review must still meet ETSU's ethical standards (see following section)
f. Continuing review is not required for studies that qualify for a limited review.
g. ETSU retains the authority to suspend or terminate IRB approval of research approved with a limited review.

H. Policy 8, Revision date 4/2/18

Change Summary: added revised approval criteria, etc.
Rationale for Change: Final Rule

Change Specifics:

1. Section II, added "and professional competence" to requirement for expedited reviewer. Now reads, "An experienced IRB member means a voting member or alternate voting member who has served on an IRB for at least six months, and possesses the scientific expertise and professional competence needed to review the proposed research."
2. Section VII, added "For studies subject to 1991 Common Rule, VA studies, and FDA studies" above section on continuing review
3. Section V, added phrase, "For studies subject to the 1991 Common Rule"
4. Section V, added:

When the revised Common Rule goes into effect, for studies subject to the revised Common Rule:

HHS Regulations at 45CFR.46.110(b)(1) limit the use of expedited review procedures to specific research categories published in the Federal Register. The following categories of research may be reviewed by the IRB through an expedited review procedure:

b)(1) An IRB may use the expedited review procedure to review the following:

(i) Some or all of the research appearing on the list described below, unless the reviewer determines that the study involves more than minimal risk;

(ii) Minor changes in previously approved research during the period for which approval is authorized; or

(iii) Research for which limited IRB review is a condition of exemption under § __.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

Only those research activities that

(1) present no more than minimal risk to human subjects

AND

(2) involve only procedures listed in one or more of the following categories

may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.

For research subject to the revised Final Rule, research appearing on the list of expedited review categories is deemed to be no more than minimal risk. Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk. [§ .110(b)(1)(i)] If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB.

If a reviewer finds that research appearing on the expedited review list is greater than minimal risk, the reviewer must document the rationale for this determination and the rationale for review by the convened IRB or EC.

Expedited review **MAY NOT** be used if:

X research is minimal risk but does not appear in one of the listed categories

X research has been determined by reviewer to involve more than minimal risk.

X research where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

X research is classified and involves human subjects.

Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories in this list apply regardless of the age of subjects, except as noted.

The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures [§ .110(a)].

(then relists same categories)

5. Section VII, added phrase to current approval criteria: "For studies subject to the 1991 Common Rule and FDA studies"
6. Section VII, added new section on revised Common Rule approval criteria:

When the revised Common Rule goes into effect, for studies subject to the revised Common Rule,

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized by: (a) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) 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 IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § __.116

(5) Informed consent will be appropriately documented or appropriately waived in accordance with § __.117.

(6) When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*When research is more than minimal risk and involves an intervention; not applicable for expedited studies

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

4. Section VII, added: When the revised Common Rule goes into effect, and ETSU allows exemption categories 7 and 8,

8) For purposes of conducting the limited IRB review required by § __.104(d)(7)), the IRB need not make the determinations at paragraphs (a)(1) through (7) of this section, and shall make the following determinations:

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of § __.116(a)(1)-(4), (a)(6), and (d);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with § __.117; and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

7. Section VII, added “for all” phrase before section on VA studies and flagging
8. Section VII, added phrase before continuing review discussion, “For studies subject to 1991 Common Rule and FDA studies”

9. Section VII, added:

When the revised Common Rule is in effect,
The IRB will conduct continuing review of research requiring review by the convened IRB at intervals appropriate to the degree of risk, not less than once per year, except as described in § __.109(f).

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstance: Research eligible for expedited review in accordance with § __.110, (Research meets one or more categories of research that qualify for expedited review).

If the expedited reviewer determines that continuing review of an expedited study is necessary, the reviewer must explicitly justify why continuing review would enhance protection of research subjects (§ ll.109(f)(1)(i) and § ll.115(a)(3)).

10. Section VII, added “if continuing review is required” to reference to continuing review

I. Policy 9, Revision date 4/2/2018

Change Summary: added new approval criteria
Rationale for change: Final Rule

1. Section III, I, added phase before current approval criteria, “For studies subject to the 1991 Common Rule and FDA rules”
2. Section III, I, added new approval criteria:

“When the revised Common Rule goes into effect, for studies subject to the revised Common Rule,

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized by: (a) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) 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 IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § __.116

(5) Informed consent will be appropriately documented or appropriately waived in accordance with § __.117.

(6) When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*When research is more than minimal risk and involves an intervention; not applicable for expedited studies

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects."

3. Section III.I., added "For all" before general section

I. Policy 10, revision date 4/2/18

Change summary: added section addressing mods and impact on limited IRB review
Rationale for change: Final Rule

Change Specifics:

1. Section V, added:

"When the revised Common Rule is in effect, and a modification is submitted on an exempt study that underwent limited IRB review, the IRB Chair must determine in the modification request impacts the determinations made during the limited review. If so, then the IRB Chair must determine if the modification renders the study ineligible for continuing exempt status and if so, the modification will not be approved. The investigator will be notified in writing that he may withdraw the modification request and continue the study as previously determined to qualify under exemption guidelines or submit the study for appropriate review and approval through an expedited or full board review."

J. Policy 11, revision date 4/2/18

Change summary: added sections regarding elimination of continuing review
Rationale for change: Final Rule

Change Specifics:

1. Section I, item D, section on frequency of continuing review, added "Current" and "When the revised Common Rule goes into effect, this requirement changes as discussed in later sections of this policy."
2. Section II, added header, For studies under the 1991 Common Rule and FDA studies:
3. Section II, added:

"When the revised Common Rule goes into effect, for studies subject to the revised Common Rule: Continuing review by the IRB or an expedited reviewer is not required when:

• Research meets one or more categories of research that qualify for expedited review.
• Research has progressed to the point that it involves only one or both of the following:
  - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

The IRB or EC must justify the decision to conduct continuing review of research originally reviewed using the expedited procedure. When the IRB is not required to conduct continuing review, records will provide a rationale for any decisions to conduct continuing review of research otherwise eligible for review using the expedited procedure.

Continuing review is required when:
1. Other applicable regulations require continuing review. All VA and FDA research requires continuing review as described in Policy 11.

The IRB may determine that continuing review is required when:
1. The research involves topics, procedures, or data that may be considered sensitive or controversial;
2. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
3. An investigator has minimal experience in research or the research type, topic, or procedures; and/or
4. An investigator has a history of noncompliance
5. Other considerations as determined by the IRB

For expedited and full studies that do not require continuing review when the revised Common Rule goes into effect, an administrative check-in will be required to maintain oversight of open research studies. Review of this administrative check-in will be by IRB staff. See Transition Policy for details.

Continuing review is not required for research reviewed in accordance with the limited IRB review procedure described in § ll.104(d)(2)(iii)."

4. Section III A, added header, "For studies under the 1991 Common Rule and FDA studies"
5. Section III A, added:

"When the revised Common Rule goes into effect, for studies subject to the revised Common Rule:

Continuing review of studies (initially reviewed by the full convened IRB) by the IRB or an expedited reviewer is not required when:

• Research has progressed to the point that it involves only one or both of the following:

- Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care."

6. Section III B, added header**, "**For studies under the 1991 Common Rule and FDA studies"

7. Section III B, added:

When the revised Common Rule goes into effect, for studies subject to the revised Common Rule: Continuing review by the IRB or an expedited reviewer is not required when:

• Research meets one or more categories of research that qualify for expedited review. (any projects approved through expedited review initially)

8. Section IV, added header, "For studies under the 1991 Common Rule and FDA studies:"

10. Section IV A, added:

When the revised Common Rule goes into effect, for studies that require continuing review, the criteria listed above will be used to evaluate the frequency of continuing review.

11. Section IV B, added header, "For studies under the 1991 Common Rule and FDA studies:"

12. Section V.A added header, "For studies under the 1991 Common Rule and FDA studies:"

13. Added section of new approval criteria:

When the revised Common Rule goes into effect, for studies subject to the revised Common Rule:

(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized by: (a) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and (b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) 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 IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, § __.116

(5) Informed consent will be appropriately documented or appropriately waived in accordance with § __.117.

(6) When appropriate*, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

*When research is more than minimal risk and involves an intervention; not applicable for expedited studies

(b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

14. Section VI.A, added header, “For studies under the 1991 Common Rule and FDA studies:

15. Section VI.E, added header, “For studies under the 1991 Common Rule and FDA studies”

K. Policy 13, revision date 4/2/18

Change Summary: multiple changes related to Final Rule, NIH, FDA guidance
Rationale: Final Rule, updating of consent requirements, new FDA guidance, new COC NIH requirements

1. Section I, added the header “Under the 1991 Common Rule and FDA regulations”
2. Section I, LAR, added, “When the revised Common Rule goes into effect, legally authorized representative means 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 procedure(s) involved in the research.”
3. Section I, added new definition: Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
4. Section II, deleted “and initialed by the participant”.
5. Section II, added “as applicable” to references to stamping expiration date and continuing review
6. Section IVA, added, “The consent process, including the information provided in an informed consent form must be presented in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.”
7. Section IVC, added, “The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.”
8. Section IVD, added new section: Concise Summary

   “When the revised Common Rule goes into effect, for studies subject to the revised Common Rule, the consent document must begin with a concise and focused presentation of key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This beginning portion must be organized and presented in a way that facilitates

comprehension. This requirement applies to all informed consents, except for broad consents under exempt category 7. However, for some relatively simple research studies with limited risks or benefits, the entire informed consent document may be relatively brief (less than 3-4 pages) and still satisfy this requirement. In such circumstances, ETSU may determine that virtually all of the information required by § ll.116 would also satisfy this requirement.
Content and Length:
The application of this requirement will depend on the nature of the specific study and the information presented in the consent. In general, if the information in the concise summary satisfies the consent disclosure requirements, then it does not have to be repeated later in the body of the consent. If however, the concise summary just spotlights some aspects but does not disclose all necessary information, then more detail needs to be provided in the body of the consent.
In general, ETSU's expectation is that this initial presentation of the key pieces of information will be relatively short. The length will be associated with the complexity of the study itself and the information to be disclosed. For a shorter consent, a few paragraphs is expected for this concise summary. For longer consents, i.e, 20 pages, then the summary may be 3-4 pages long.

In general, ETSU expects that to satisfy this requirement, the beginning of an informed consent would include a concise explanation of the following:
(1) the fact that consent is being sought for research and that participation is voluntary;
(2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
(3) the reasonably foreseeable risks or discomforts to the prospective subject;
(4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and
(5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

The IRB determination about the concise summary is dependent on the facts of the study, and therefore the IRB may require that additional information be included in the concise summary."

9. Section waiver of informed consent, adds
   When the revised Common Rule goes into effect, an additional criteria is added: "If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format"

10. Required elements of consent:

- (#2) updated language re risks, from “state any known risks, side effects to “state a description of any reasonably foreseeable risks or discomforts to the participant
- (#3) updated language re benefits, from “describe potential benefits which might be expected by the subject and society in general” to “A description of any benefits to the subject or to others that may reasonably be expected from the research; (may be omitted if none?)
- (#5) deleted phrase “If there are no alternatives, so state.”
- (#6) deleted phrase “two names and two different telephone numbers are required” from voluntary participation section
- (#8) added “ETSU requires that the consent include contact information for the research team for questions, concerns or complaints and contact information for someone independent of the research team for problems, concerns, questions, information or input.”

11. (#10) Adds new required element: “When the revised Common Rule goes into effect, one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: This may be omitted if the research does not involve collection of identifiable information or identifiable biospecimens. If the research involves the collection of identifiable information or identifiable biospecimens, then the consent must contain whichever is the appropriate statement below:

    - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another researcher for future research studies without additional informed consent from the participant or legally authorized representative, if this might be possibility; or
    - A statement that the participant’s information or specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.”

12. Additional elements of informed consent, added, “For FDA studies, the consent process must disclose the possibility that the Food and Drug Administration may inspect the records.”
13. Additional elements of consent, added “the amount and schedule of all payments”
14. Additional elements on consent, added:
    - ✓ “When the revised Common Rule is put into effect, the consent process must disclose a statement that biospecimens, even if identifiers are removed, may be used for commercial profit and whether the participant will or will not share in this commercial profit UNLESS the study does not involve the

collection of biospecimens

- ✓ When the revised Common Rule is put into effect, the consent process must disclose a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions UNLESS there will be no clinically relevant research results. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual research results.
- ✓ When the revised Common Rule is put into effect, the consent process must disclose a statement about whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen) UNLESS the study does not involve the collection of biospecimens OR the study will not include any whole genome sequencing"

15. Section IV.G, added qualifying phrase (Under the 1991 Common Rule and FDA regulations) to existing language, and added, "When the revised Common Rule goes into effect, for studies subject to the revised Common Rule, legally authorized representative means 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 procedure(s) involved in the research."
16. Section II.H, added "When the revised Common Rule goes into effect, for studies subject to the revised Common Rule, no informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence."
17. Section IV.U, added: Broad Consent
    "As ETSU is choosing not to use exempt categories 7 and 8, the required elements of broad consent associated with these categories is not written in this policy."

18. Section IV.V, adds section on posting of consent: "When the revised Common Rule goes into effect, for clinical trials supported by federal funding, one IRB-approved consent form used to enroll participants must be posted on a publicly available Federal website to be designated."
19. Section waiver of informed consent, deletes sentence that says "FDA has no such provisions because the types of studies that would qualify for waiver or alteration are either not regulated by FDA or are covered by the Emergency Treatment provision of FDA Regulation 21 CFR 50.23".
20. Section waiver of informed consent, deletes sentence that says "Waiver of informed consent can not be given when research is subject to FDA regulation."
21. Section waiver of informed consent, deletes "not applicable to research subject to FDA regulation" and adds,
    For FDA research, the IRB may approve a consent procedure that does not

include, or that alters, some or all of the elements of informed consent set forth in 21 CFR 50.25, or waive the requirements to obtain informed consent when the IRB finds and documents that:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k)or 56.102(i)) to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

22. Section waiver of informed consent, adds: "When the revised Common Rule goes into effect, for studies subject to the revised Common Rule, an additional criteria is added: "If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format"

23. Section IV, adds,

When the revised Common Rule goes into effect, for studies subject to the revised Common Rule, the revised Common Rule adds an "exception" to the consent requirement to determine eligibility

1. Allows for the collection of identifiable information or identifiable biospecimens for purposes of screening, recruiting, or determining eligibility of prospective subjects if...

- the investigator will obtain information through oral or written communication with prospective subject or LAR, OR

the investigator will obtain identifiable private information or biospecimens by accessing records or stored identifiable biospecimens

- The IRB will be reviewing and approving the entire research proposal, and the preparatory to research activities are a part of it.
- The IRB must determine that there are adequate privacy and confidentiality safeguards in place for the preparatory-to-research activities as part of the review and approval process.

If subjects identified during the screening process are then successfully recruited to participate, all other requirements must be met.

24. Section VI, added new WOD criteria: When the revised Common Rule goes into effect, for studies subject to the revised Common Rule, a third category is added:

OR 3. It is not the cultural norm for subjects to sign such documents, as long as… the research is no more than minimal risk and an alternative documentation mechanism is used.

The oral or written information provided to participants must include all required and appropriate elements of consent disclosure.

25. Section VII C, added new language regarding CoC:
NIH updated its policy for issuing CoCs, effective October 1, 2017. This update is a result of NIH's need to implement Section 2012 of the 21st Century Cures Act, P.L. 114-255, enacted December 31, 2016. This law requires the Secretary of HHS to issue a CoC to investigators or institutions who are engaged in federally funded biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected. CoCs are automatically granted, and the requirements of such must be complied with, whenever a NIH-funded activity falls within the scope of the policy. Investigators and institutions are responsible for determining when a NIH-funded activity falls within the scope of the policy.

The term "identifiable, sensitive information" means information that is about an individual and that is gathered or used during the course of biomedical, behavioral, clinical, or other research and—
(A) through which an individual is identified; or
(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

Examples of research automatically covered by a certificate of confidentiality include:
• Biomedical, behavioral, clinical or other research, including exempt research, except where the information obtained is recorded in such a manner that human participants cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
• The collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
• The generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained.

• Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual

Certificates may also be issued if the research is not federally funded.

Certificates of Confidentiality can be requested by applying to the NIH or other authorized Federal agencies or departments. .
http://grants.nih.gov/grants/policy/coc/index.htm

When research is covered by a certificate of confidentiality, researchers:
• May not disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
• May not disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Researchers may disclose information only when:
• Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.
• Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual; • Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
• Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

Written materials require that when research is covered by a certificate of confidentiality, researchers must inform participants (for example, in the consent document) of the protections and limitations of certificates of confidentiality.

This requirement also applies to existing studies active on after December 13, 2016 whenever the study is funded in whole or in part by the NIH and involves identifiable, sensitive information For existing studies, researchers must notify participants that the research is now covered by a certificate of confidentiality. However, because a certificate of confidentiality reduces risks, the IRB does not need to require the researcher to obtain consent again based on this information, and can simply notify participants of this change.

• Written materials require that researchers conducting NIH-supported research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other researchers or organizations, regardless of whether or not the research is federally funded, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality

26. Added reference to new FDA guidance

M. Policy 15, revision date 4/2/18

Change Summary: updated vulnerable populations language
Rationale: Final Rule

Change Specifics:

1. Section I, changed “fetuses, pregnant women, mentally disabled (cognitively impaired) persons, prisoners...” to ‘ prisoners, individuals with impaired decision making capacity”
2. Section I, added, “Studies involving pregnant women/fetuses will be reviewed as indicated in this policy.”
3. Section I, changed “pregnant women, handicapped or mentally disabled persons” to “individuals with impaired decision making capacity”
4. Section I, added, ”In addition, research with pregnant women/fetuses will be reviewed by one or more individuals who are knowledgeable about and experienced in working with these subjects.”

N. Policy 23, Revision date 4/2/2018

Change Summary: added language about new required biosafety review
Rationale for change: VPR/ETSU requirements
Change Specifics: Proposed revision to Policy 23

Biohazards
The ETSU Institutional Bio Safety and Chemical Safety Committee (IBC) is responsible for developing institutional biosafety policies and for reviewing and approving research and teaching activities that use biohazards, recombinant DNA

and ensuring that protocols conform with the proper guidelines associated with the handling of toxic/hazardous chemicals as defined by the Occupational Health and Safety Administration and/or determined by the ETSU IBC.
For ETSU studies, new protocol submission (NPS) xforms will be forwarded to the Vice Provost for Research for review if the researcher indicates that the study involves:

a. shipping specimens
b. transporting of specimens (e.g., from collection site to ETSU, in any area of public access, or in between building on campus)
c. collection of specimens in non-clinical setting
d. administration of live vaccine(s)
e. exposure of researcher(s) or participants to toxic or hazardous chemicals (as defined by ETSU Biosafety) during procedures done for research purposes
f. administration of vaccines using recombinant nucleic acid

The Vice Provost for Research (VPR) will review the NPS and confirm the presence of one or more of the above criteria. The VPR will document his determination of the presence or absence of the criteria. If the VPR determines that one or more of the criteria are present, IBC review is needed. If the VPR anticipates that the IBC review may require changes that may affect the IRB review (e.g., changes affecting the protocol or information provided on the NPS), the VPR will indicate that IBC review must be obtained prior to IRB review. Otherwise, IRB review will proceed and final IRB approval will be held until IBC approval is obtained. As part of their review, IBC is responsible for checking for biosafety training for study personnel. The VPR's office forwards the IBC approval letter for the project to the IRB Coordinator. The IRB Coordinator attaches the IBC approval letter in IRBmanager, and processes as indicated (e.g., as requested change).
If the work is performed at the VA, VA Subcommittee on Research Safety (SRS) approval is required. The IRB approval letter to the PI specifies that additional approvals (VA R &D and VA Research Bio-safety Subcommittee) must be obtained prior to study initiation.

In addition, when the study involves blood draws, the IRB requirement is that the study staff who will be drawing the blood must either be a licensed or certified health care provider where this procedure falls within the scope of their practice, or have certification or other written documentation of appropriate phlebotomy training. In addition, an initial IRB approval will not be issued unless bloodborne pathogen training has been verified for study staff who are drawing blood (by the IBC if the study requires their review or by IRB staff if IBC review is not required).

Radiation
The IRB Chair will indicate on the NPS if Radiation Safety input is needed for a study that involves radiation (this is in addition to the already required review for studies that have radionuclide administration). If input from Radiation Safety is needed

(see criteria below), the Director of Radiation Safety will review the radiation aspects of the study and provide comments to the IRB regarding the radiation amount.
All ETSU (non-VA, non-MSHA) protocols involving radiation producing equipment other than the exceptions listed below must be referred to the Director of Radiation Safety. Examples include, but are not limited to, any use of an investigational radiation device, any use of an investigational radiopharmaceutical or investigational implant/seed, any use of an investigational contrast medium with radiation, any use of imaging where the imaging itself is the subject of the investigation, and non-standard of care CT or PET scans or other radiation.
Exceptions to this process are:

a. routine standard of care xrays
b. routine, standard of care diagnostic nuclear medicine tests
c. standard of care radiation therapy for cancer

Additionally, the IRB Chair or convened IRB has the discretion to request a consult with the Director of Radiation Safety or other appropriate consultant for any study.

If the work is performed at the VA, VA Subcommittee on Research Safety (SRS) approval is required. The IRB approval letter to the PI specifies that additional approvals (VA R &D and VA Subcommittee on Research Safety (SRS)) must be obtained prior to study initiation. If input from the VA Research Biosafety Subcommittee is needed (see criteria above), the Subcommittee, or appropriate representative, will review the radiation aspects of the study and provide comments to the IRB regarding the radiation amount.

O. Policy 30, Revision date 4/2/2018

Change Summary: added language about new required documentation
Rationale for change: Final Rule

Change Specifics:

1. To reference about frequency for the next continuing review, added “if continuing review is required)”.
2. Added,

“When the revised Common Rule goes into effect:

When the IRB is not required to conduct continuing review, records will document the rationale for any decisions to conduct continuing review of research. When the IRB is not required to conduct continuing review, records will contain documentation of other oversight procedures (i.e, administrative check in). Records will also contain documentation of any limited IRB reviews for exempt studies. Additionally, IRB records will contain documentation of the rationale for a reviewer determination that research

appearing on the expedited review list is greater than minimal risk, as well as the rationale for review by the convened IRB."

"In addition, IRB records will maintain the Institutional Authorization Agreements documenting the responsibilities of each entity when ETSU serves as the IRB of record or defers review to another IRB."

3. revised "Secretary" to "IRT"

P. Policy 34, Revision date 4/2/2018

Change Summary: added qualifying phrase
Rationale for change: box unchecked on FWA

Change Specifics:

1. Corrected typo "determines" and "Research"
2. Added phrase "whenever the research is subject to OHRP regulation)" as qualifier for reporting to OHRP

Q. Policy 37, Revision date 4/2/2018

Change Summary: added waiver criteria and reference to new exempt category 3
Rationale for change: Final Rule

Change Specifics:

1. To Section II, added, "When the revised Common Rule goes into effect, deception research is allowed under exempt category 3 if specific requirements are met. Refer to Exempt Policy 7 for those requirements."
2. To Section II, added additional waiver criteria, "When the revised Common Rule goes into effect, if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format"

R. Policy 38, Revision date 4/2/2018

Change Summary: added IRT to references for who can enable access to IRBmanager
Rationale for change: previously only reflected coordinator/director, needed to include IRT