RESEARCH FOR WHICH REVIEW BY THE
DUKE UNIVERSITY HEALTH SYSTEM
HUMAN RESEARCH PROTECTION PROGRAM IS REQUIRED
7/27/2012

All research involving human subjects must be reviewed by the DUHS HRPP prior to initiation of the research when it:
- is sponsored by DUHS, including all of its institutional components; OR
- is conducted by or under the direction of any employee or agent of DUHS (including a student, resident or fellow*) in connection with his or her institutional responsibilities, regardless of funding source (or lack thereof), and regardless of the performance site**; OR
- is conducted by or under the direction of any employee or agent of DUHS using any DUHS property or facility; OR
- utilizes DUHS non-public information*** to identify or contact human subjects

unless:
- the research will be reviewed by an IRB designated on the DUHS Federal-wide Assurance and an IRB Authorization Agreement is in place, in which case an administrative review will occur by an IRB Chair/Vice-Chair or the Executive Director to ensure compliance with DUHS standards, such as use of the MO345 template form on which to format the consent document(s); OR
- the DUHS IRB determines that:
  - the research is not eligible for exemption from IRB review, and
  - the research meets one or more of the examples of not being engaged in human subjects research listed in OHRP guidance on “Guidance on Engagement of Institutions in Human Subjects Research”, dated 10/16/2008 and found at: [http://www.hhs.gov/ohrp/policy/engage08.pdf](http://www.hhs.gov/ohrp/policy/engage08.pdf) OR
- the Duke faculty or staff member plans to conduct research with human subjects solely at the Durham Veterans Administration Medical Center (DVAMC), no research funding comes through DUHS and the investigator provides documentation of DVAMC IRB approval of that research****; OR
- the research meets the criteria for exemption from review prior to the initiation of an emergency use of a test article.

* Duke medical students, residents or fellows who are involved in research led by others at Duke must be listed as Key Personnel on the IRB submission. Duke medical students, residents or fellows who are involved in research led by others at an unaffiliated site may satisfy their responsibilities to the IRB by meeting the requirements of the “Policy and Procedure for Duke Trainees Engaged in
Research Involving Human Subjects at a Site Other Than Within DUHS”. This policy, appropriately modified, applies to DUHS residents and fellows who do research involving human subjects while away from DUHS as a part of their training program. It also applies to DUSOM faculty members not on sabbatical or leave who do such research while away from DUHS.

** If the performance site is not a DUHS facility, the DUHS IRB will oversee the research activity upon execution of an appropriate agreement between DUHS and the collaborating investigator unless an alternate written agreement is in place that cedes authority to another IRB. Note that such oversight may occur as described above*.

*** In this case, the IRB reviewer(s) may conclude that the use of the non-public information does not lead to the user being engaged in research involving human subjects as defined by OHRP.

**** If the Duke investigator plans to conduct a portion of the research using a Duke facility, the research will be reviewed by the DUHS IRB in compliance with all applicable federal regulations/guidelines and DUHS policies.

The IRB will review and approve research conducted outside the United States by DUHS employees or students, even if the foreign research activity has no U.S. federal funding. The IRB may approve such non-U.S. funded research, provided it determines that: (a) the research conforms to proper codes of ethics (such as the Declaration of Helsinki and/or the Belmont Report), and (b) the research is approved by the foreign research site's ethical review authority. Requirements for the informed consent process will follow the laws and customs of the country in which the research is being conducted, but the DUHS IRB will ensure that protections equivalent to those afforded research subjects in the U.S. are present. If a U.S. Department or Agency funds the research, then the IRB would expect the foreign research site to have an approved Federal-wide Assurance and meet all applicable DHHS and FDA regulations and guidance.

IRB review and approval of a research project must occur before the research begins, and continuing assessment by the IRB must occur during the life of the research study through the process of periodic continuing review of the research.

The IRB, represented by its Chairs, Vice-Chairs or Executive Director, must make a series of determinations before it decides whether to consider an activity to be research involving human subjects that requires IRB approval before study initiation. The reviewer may use the “Checklist to Determine if an Activity is Subject to IRB Review” to assist him/her in this process.

For an activity to be eligible for IRB approval at the time of initial review, the IRB must determine in the following order that:

1. The activity involves research;
The activity involves research with human subjects;
(3) The activity is not eligible for exemption from IRB review;
(4) The institution and its investigators/staff will be engaged in research involving human subjects.

Research Involving Human Subjects: means any activity that either:
- Meets the DHHS definition of "research" and involves "human subjects" as defined by DHHS; or
- Meets the FDA definition of "research" and involves "human subjects" as defined by FDA.

Research (DHHS) [45 CFR 46.102(d)] - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject (DHHS) [45 CFR 46.102(f)] - a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.
- “Intervention” as defined by DHHS regulations means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
- “Interaction” as defined by DHHS regulations means communication or interpersonal contact between investigator and subject.
- “Private information” as defined by DHHS regulations means 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 which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- “Identifiable information” as defined by DHHS means information that is individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Clinical Investigation (FDA) [21 CFR 56.102(c)] - 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 act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the 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 deemed to be synonymous for purposes of this part.

- “Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act” means any use of a drug other than the use of an approved drug in the course of medical practice. [21 CFR 312.3(b)]
- “Experiments that must meet the requirements for prior submission to the Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act” means any activity that evaluates the safety or effectiveness of a device. [21 CFR 812.2(a)]
- Any activity in which results are being submitted to or held for inspection by FDA as part of an application for a research or marketing permit is considered to be FDA-regulated research. [21 CFR 50.3(c), 21 CFR 56.102(c)]

Human Subject (FDA) [21 CFR 56.102(e); 21 CFR 812.3(p)] - an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy individual or a patient. For research that evaluates the safety or effectiveness of a device, the definition includes a human on whom or on whose specimen an investigational device is used. A subject may be in normal health or may have a medical condition or disease.

Note that the Privacy Rule (HIPAA), including its research provisions, applies to both living and dead people, and the research provisions apply when the DHHS definition of research (45 CFR 46.102(d)) is met.

The IRB Chair/Vice-Chair/Executive Director reviews the proposed activity to determine and document whether the activity meets the DHHS definition of research (45 CFR 46.102(d)); and the activity meets the DHHS definition of human subject (45 CFR 46.102(f)); or the activity meets the FDA definition of clinical investigation (or research) (21 CFR 50.3(c) and 21 CFR 56.102(c)), and the activity meets the FDA definition of human subject (21 CFR 50.3(g) and 21 CFR 56.102(e)). When the FDA definitions are met, the activity is Research Involving Human Subjects that is FDA regulated. If the DHHS definitions are met, the activity is Research Involving Human Subjects that is DHHS regulated. If both sets of definitions are met, the activity is Research Involving Human Subjects and is both DHHS- and FDA-regulated.

In order for the IRB Chair/Vice-Chair/Executive Director to make these determinations, the person proposing to conduct the activity must submit via the e-IRB a description of proposed activities that is sufficient for the reviewer to assess whether or not the proposed activities meet the regulatory definitions of research involving human subjects.
When the Chair/Vice-Chair/Executive Director determines that the activity is Research Involving Human Subjects, s/he further determines whether the institution is engaged in research. The IRB Chair/Vice-Chair/Executive Director uses the OHRP guidance “Engagement of Institutions in Research” to determine whether the institution and its investigators would be engaged in research and the research subject to DUHS IRB review. At any point in this process, the IRB Chair/Vice-Chair/Executive Director may request additional information from the PI to make the determination. If still unclear, the Chair/Vice-Chair/Executive Director may contact OHRP or FDA officials for guidance.

Some activities, such as developing a case report or a limited case series (<4 cases) for publication, or quality improvement activities that do not meet the definition of research, or research involving deceased individuals (see Decedent Research under policy guidance on the Privacy Rule [HIPAA]), are not human research according to OHRP and FDA.

When the IRB Chair/Vice-Chair/Executive Director determines that the activity does not meet the definition of Research Involving Human Subjects, the Investigator is notified in writing that the activity does not meet the definition of Research Involving Human Subjects, and that the activity does not require further IRB consideration. Investigators are provided with the basis for the determination and are informed that they may not make changes to the activity without first reviewing the changes with the IRB Chair/Vice-Chair/Executive Director to determine whether the changes are consistent with the determination. If the changes would require that the activity is now subject to IRB review, the investigator must resubmit the research for initial review as described elsewhere in this policy.

When the activity is determined to be Research Involving Human Subjects, the investigator must submit the research for initial review as described elsewhere in this policy.

(3) The criteria for Exemption from IRB Review according to OHRP (45 CFR 46.101(b) (1)-(6)):

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   
   (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
   
   (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
   
   (i) the human subjects are elected or appointed public officials or candidates for public office; or
   
   (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   
   (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

   - The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
   
   - The research or demonstration project must be conducted pursuant to specific federal statutory authority.
   
   - There must be no statutory requirement that the project be reviewed by an IRB.
   
   - The project must not involve significant physical invasions or intrusions upon the privacy of participants.
   
   - The exemption must have authorization or concurrence by the funding agency.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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 U.S. Department of Agriculture.

The exemptions 45 CFR 46.101(b)(1-6) do not apply to research involving prisoners, as stated in 45 CFR 46 Subpart C. The exemptions 45 CFR 46.101(b)(1-5) cannot be applied to FDA regulated research. The exemption 45 CFR 46.101(b)(2) does not apply to research involving children, as stated in 45 CFR 46 Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed and research involving the use of educational tests.

The criteria for *Exemption from IRB Review according to FDA (21 CFR 56.104)*:

Activities involving drugs or medical devices will not be eligible for exemption from DUHS IRB review unless the activity falls within 21 CFR 56.104, or the activity involves the use of an FDA approved drug or device in the course of medical practice. Activities for which the data will be submitted to or held for inspection by the FDA for regulatory purposes are not eligible for exemption from IRB review.

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or 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 U.S. Department of Agriculture.

FDA exemption categories (a) – (c) cannot be applied to activities that meet the DHHS definition of “research” and involve “human subjects”.

*Note that 45 CFR 46.101(b)(6) and 21 CFR 56.104(d) are largely identical with the exception that 21 CFR 56.104(d) is only an exemption from 21 CFR 56 (i.e., the requirement for IRB review) and is not an exemption from 21 CFR 50 (i.e.,*
the requirement to obtain informed consent in accordance with and to the extent required by 21 CFR 50.)

The IRB Chair/Vice-Chair/Executive Director is responsible for reviewing and determining whether the research is exempt from 45 CFR 46 and/or 21 CFR 56. He/she may use the “Checklist to Determine If Research May Be Declared Exempt from IRB Review” for assistance in making this determination. If he/she finds that the information provided by the investigator is insufficient to determine whether the proposed research meets the criteria for exemption, the investigator may be asked to complete the “Exempt Research Project Summary”.

As part of this review, the IRB Chair/Vice-Chair/Executive Director may use the “Checklist to Determine If Research May Be Declared Exempt from IRB Review” to consider whether the research meets DUHS standards for informed consent, subject privacy and the confidentiality of the subject’s data even if the Chair/Vice-Chair/Executive Director concludes that the research meets the criteria for exemption from IRB review. The IRB Chair/Vice-Chair/Executive Director may use a review sheet to indicate whether or not the research is exempt from IRB review. If the IRB Chair/Vice-Chair/Executive Director determines that the research is exempt from the requirements of 45 CFR 46 and/or 21 CFR 56, periodic continuing review will not be required unless changes are made to the research, and then the Chair/Vice-Chair/Executive Director will review the PI’s changes and determine whether they affect the exemption status and thus prompt the requirement for IRB protocol submission and subsequent IRB review.

The IRB Chair/Vice-Chair/Executive Director may request additional information from the PI to make these determinations. If the research does not meet the criteria for exemption, the protocol is reviewed through an expedited procedure or by full board review at a convened meeting of the IRB, as appropriate to the research activities.

Investigators are notified in writing that the research is exempt from periodic continuing review or further IRB consideration (i.e., the notification never expires). Investigators are also notified that they may not make changes to the research activity without first submitting the changes to the IRB for the Chair/Vice-Chair/Executive Director to determine whether the changes prompt reconsideration of the activity’s exempt status. If the activity no longer meets the criteria for exemption, the investigator must resubmit the activity for review by the IRB at a convened meeting or through the use of the expedited review procedure.

In general, institutions are considered engaged in an HHS-conducted or -supported non-exempt human subjects research project (and, therefore, would need to hold or obtain OHRP-approved FWAs and certify IRB review and approval to HHS) when the involvement of their employees or agents in that project includes any of the following:
(1) Institutions that receive an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e., awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.

(2) Institutions whose employees or agents intervene for research purposes with any human subjects of the research by performing invasive or noninvasive procedures.

Examples of invasive or noninvasive procedures include drawing blood; collecting buccal mucosa cells using a cotton swab; administering individual or group counseling or psychotherapy; administering drugs or other treatments; surgically implanting medical devices; utilizing physical sensors; and utilizing other measurement procedures.

[See scenarios B.(1), B.(2), and B.(3) below for limited exceptions.]

(3) Institutions whose employees or agents intervene for research purposes with any human subject of the research by manipulating the environment.

Examples of manipulating the environment include controlling environmental light, sound, or temperature; presenting sensory stimuli; and orchestrating environmental events or social interactions.

[See scenarios B.(1) and B.(3) below for limited exceptions.]

(4) Institutions whose employees or agents interact for research purposes with any human subject of the research.

Examples of interacting include engaging in protocol-dictated communication or interpersonal contact; asking someone to provide a specimen by voiding or spitting into a specimen container; and conducting research interviews or administering questionnaires.

[See scenarios B.(1), B.(2), B.(3), and B.(4) below for limited exceptions.]

(5) Institutions whose employees or agents obtain the informed consent of human subjects for the research.

(6) Institutions whose employees or agents obtain for research purposes identifiable private information or identifiable biological specimens from any source for the research. It is important to note that, in general, institutions whose employees or agents obtain identifiable private information or identifiable specimens for non-exempt human subjects research are considered engaged in the research, even if the institution’s employees or agents do not directly interact or intervene with human subjects. In general, obtaining identifiable private information or identifiable specimens includes, but is not limited to:
(a) observing or recording private behavior;
(b) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens provided by another institution; and
(c) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens already in the possession of the investigators.

In general, OHRP considers private information or specimens to be individually identifiable as defined in 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

[See scenarios B.(1), B.(2), B.(3), B.(7), B.(8), B.(9), and B.(10) below for limited exceptions.]

B. Institutions Not Engaged in Human Subjects Research

Institutions would be considered not engaged in an HHS-conducted or -supported non-exempt human subjects research project (and, therefore, would not need to hold an OHRP-approved FWA or certify IRB review and approval to HHS) if the involvement of their employees or agents in that project is limited to one or more of the following. The following are scenarios describing the types of institutional involvement that would make an institution not engaged in human subjects research; there may be additional such scenarios:

(1) Institutions whose employees or agents perform commercial or other services for investigators provided that all of the following conditions also are met:

(a) the services performed do not merit professional recognition or publication privileges;
(b) the services performed are typically performed by those institutions for non-research purposes; and
(c) the institution’s employees or agents do not administer any study intervention being tested or evaluated under the protocol.

The following are some examples, assuming the services described would not merit professional recognition or publication privileges:

- an appropriately qualified laboratory whose employees perform routine serum chemistry analyses of blood samples for investigators as a commercial service.
- a transcription company whose employees transcribes research study interviews as a commercial service.
- a hospital whose employees obtain blood through a blood draw or collect urine and provide such specimens to investigators as a service.
• a radiology clinic whose employees perform chest x-rays and send the results to investigators as a service.

(2) Institutions (including private practices) not selected as a research site whose employees or agents provide clinical trial-related medical services that are dictated by the protocol and would typically be performed as part of routine clinical monitoring and/or follow-up of subjects enrolled at a study site by clinical trial investigators (e.g., medical history, physical examination, assessment of adverse events, blood test, chest X-ray, or CT scan) provided that all of the following conditions also are met:

(a) the institution’s employees or agents do not administer the study interventions being tested or evaluated under the protocol;
(b) the clinical trial-related medical services are typically provided by the institution for clinical purposes;
(c) the institution’s employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research; and
(d) when appropriate, investigators from an institution engaged in the research retain responsibility for:
   (i) overseeing protocol-related activities; and
   (ii) ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

Note that institutions (including private practices) not initially selected as research sites whose employees or agents administer the interventions being tested or evaluated in the study—such as administering either of two chemotherapy regimens as part of an oncology clinical trial evaluating the safety and effectiveness of the two regimens—generally would be engaged in human subjects research (see scenario B.(3) below for a limited exception). If such an institution does not have an FWA, its employees or agents may be covered by the FWA of another institution that is engaged in the research through an Individual Investigator Agreement. See http://www.hhs.gov/ohrp/policy/cdebiol.html.

(3) Institutions (including private practices) not initially selected as a research site whose employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis (e.g., an oncologist at the institution administers chemotherapy to a research subject as part of a clinical trial because the
subject unexpectedly goes out of town, or is unexpectedly hospitalized), provided that **all** of the following conditions also are met:

(a) an investigator from an institution engaged in the research determines that it would be in the subject’s best interest to receive the study interventions being tested or evaluated under the protocol;
(b) the institution’s employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;
(c) investigators from the institution engaged in the research retain responsibility for:
   (i) overseeing protocol-related activities;
   (ii) ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
   (iii) ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; and
(d) an IRB designated on the engaged institution’s FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution not selected as a research site.

(4) Institutions whose employees or agents:
(a) inform prospective subjects about the availability of the research;
(b) provide prospective subjects with information about the research (which may include a copy of the relevant informed consent document and other IRB-approved materials) but do not obtain subjects’ consent for the research or act as representatives of the investigators;
(c) provide prospective subjects with information about contacting investigators for information or enrollment; and/or
(d) seek or obtain the prospective subjects’ permission for investigators to contact them.

An example of this would be a clinician who provides patients with literature about a research study at another institution, including a copy of the informed consent document, and obtains permission from the patient to provide the patient’s name and telephone number to investigators.

(5) Institutions (e.g., schools, nursing homes, businesses) that permit use of their facilities for intervention or interaction with subjects by investigators from another institution.

Examples would be a school that permits investigators from another institution to conduct or distribute a research survey in the classroom; or a business that permits investigators from another institution to recruit research subjects or to draw a blood sample at the work site for research purposes.
(6) Institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research.

Note that in some cases the institution releasing identifiable private information or identifiable biological specimens may have institutional requirements that would need to be satisfied before the information or specimens may be released, and/or may need to comply with other applicable regulations or laws. In addition, if the identifiable private information or identifiable biological specimens to be released were collected for another research study covered by 45 CFR 46, then the institution releasing such information or specimens should:

(a) ensure that the release would not violate the informed consent provided by the subjects to whom the information or biological specimens pertain (under 45 CFR 46.116), or

(b) if informed consent was waived by the IRB, ensure that the release would be consistent with the IRB’s determinations that permitted a waiver of informed consent under 45 CFR 46.116 (c) or (d).

Examples of institutions that might release identifiable private information or identifiable biological specimens to investigators at another institution include:

(a) schools that release identifiable student test scores;
(b) an HHS agency that releases identifiable records about its beneficiaries; and
(c) medical centers that release identifiable human biological specimens.

Note that, in general, the institutions whose employees or agents obtain the identifiable private information or identifiable biological specimens from the releasing institution would be engaged in human subjects research. [See scenario A.(6) above.]

(7) Institutions whose employees or agents:

(a) obtain coded private information or human biological specimens from another institution involved in the research that retains a link to individually identifying information (such as name or social security number); and

(b) are unable to readily ascertain the identity of the subjects to whom the coded information or specimens pertain because, for example:
- the institution’s employees or agents and the holder of the key enter into an agreement prohibiting the release of the key to the those employees or agents under any circumstances;
- the releasing institution has IRB-approved written policies and operating procedures applicable to the research project that prohibit the release of the key to the institution’s employees or agents under any circumstances; or
- there are other legal requirements prohibiting the release of the key to the institution’s employees or agents.

For purposes of this document, coded means that:
(a) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, and/or combination thereof (i.e., the code); and
(b) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Although this scenario resembles some of the language in OHRP’s Guidance on Research Involving Coded Private Information or Biological Specimens, it is important to note that OHRP’s Guidance on Research Involving Coded Private Information or Biological Specimens addresses when research involving coded private information or specimens is or is not research involving human subjects, as defined in 45 CFR 46.102(f) (see http://www.hhs.gov/ohrp/policy/cdebiol.html). As stated above in Section II., this Guidance on Engagement of Institutions in Human Subjects Research should only be applied to research projects that have been determined to involve human subjects and that are not exempt under HHS regulations at 45 CFR 46.101(b).

(8) Institutions whose employees or agents access or utilize individually identifiable private information only while visiting an institution that is engaged in the research, provided their research activities are overseen by the IRB of the institution that is engaged in the research.

(9) Institutions whose employees or agents access or review identifiable private information for purposes of study auditing (e.g. a government agency or private company will have access to individually identifiable study data for auditing purposes).

(10) Institutions whose employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.
(11) Institutions whose employees or agents author a paper, journal article, or presentation describing a human subjects research study.

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