NU IRB Brown Bag Series

January 28, 2015
Room 750 Rubloff
12 noon-1pm

Dennis P. West PhD, Professor in Dermatology and Pediatrics
Chair for Administrative Review, Northwestern University IRB

Director Dermatology Translational Core
Director Dermatology Clinical Trials Unit
Director Dermatopharmacology Program

Regulatory and Compliance Talking Points

Exempt vs Expedited vs Not Human Research

Biorepositories

Existing Data and specimens

EDW and Data-Mining

IL Law research restrictions

Psychiatric

Genomic

Illegal Drug Use

HIV

Research Registries

QA/QI Projects and IRB Purview
PROTOCOL TITLE:

HUMAN RESEARCH DETERMINATION FORM

INSTRUCTIONS:

• Prior to initiation, investigators are required to submit and the IRB is required to review Human Research for which Northwestern University is engaged.
• The term “Human Research” is defined below for you to consider in Section 1.0.
• Section 2.0 contains examples of activities that are generally considered not to be Human Research.
• If, after reading through Sections 1.0 and 2.0, you are not certain whether your activity is Human Research or you would like for the IRB Office to determine that for you and provide documentation of that determination, complete the information on page 2 and in Section 3.0. The IRB Office uses “WORKSHEET: Human Research Determination” (HRP-310) to make its Human Research determinations. Please consult that worksheet as a guide for the information you provide in Section 3.0.
• After completing Section 3.0, create a new study in IRB 7 and upload the entire document in lieu of an Investigator’s Protocol and submit the study for IRB Office review.
• If, while reviewing this determination form, you discover that an activity is Human Research, consult the “Investigator Manual” (HRP-103) for further instructions.
• If you need assistance, contact one of the offices below:

<table>
<thead>
<tr>
<th>Social and Behavioral Research</th>
<th>Biomedical Research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chambers Hall, 2nd Floor</td>
<td>Arthur Rubloff Building, 7th Floor</td>
</tr>
<tr>
<td>600 Foster St.</td>
<td>750 N. Lake Shore Dr.</td>
</tr>
<tr>
<td>Evanston, IL 60208</td>
<td>Chicago, IL 60611</td>
</tr>
<tr>
<td>Phone: (847) 467-1723</td>
<td>Phone: (312) 503-9338</td>
</tr>
<tr>
<td><a href="mailto:irb@northwestern.edu">irb@northwestern.edu</a></td>
<td><a href="mailto:irb@northwestern.edu">irb@northwestern.edu</a></td>
</tr>
</tbody>
</table>
PROTOCOL TITLE:

ACTIVITY TITLE:

Include the full protocol title as listed in the [IRB System] (include link).

PRINCIPAL INVESTIGATOR:

Name
Department
Telephone Number
Email Address

VERSION DATE:

Include the date of submission.

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1.0 Definitions for Human Research

Review the following definitions to determine whether your activity is Human Research. Note that publication is not a determining factor for whether an activity is Human Research requiring review and approval by the IRB.

1.1 “Human Research” (according to DHHS)

The definition includes two components:

- “Research”: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

- “Human Subject”: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

If your activity does not meet both of these components, then it is not Human Research according to DHHS. Please see below for the FDA definition.

1.2 “Human Research” (according to FDA)

The definition includes two components:

- “Research”: Any experiment that involves a test article and one or more Human Subjects, and that meets any one of the following:
  
  - Must meet the requirements for prior submission to the US Food and Drug Administration under section 505(i) of the Federal Food, Drug, and Cosmetic Act meaning any use of a drug other than the use of an approved drug in the course of medical practice;
  
  - Must meet the requirements for prior submission to the US Food and Drug Administration under section 520(g) of the Federal Food, Drug, and Cosmetic Act meaning any activity that evaluates the safety or effectiveness of a device; OR
  
  - Any activity the results of which are intended to be later submitted to, or held for inspection by, the US Food and Drug Administration as part of an application for a research or marketing permit.

- “Human Subject”: An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. A human subject includes an individual on whose specimen a medical device is used.

If your activity is not research or is research that does not involve human subjects, then it is not Human Research according to FDA.
1.3 If your activity does not meet either DHHS or FDA definitions for “Human Research”, then you do not need to submit anything to the IRB Office for review. Consult “WORKSHEET: Human Research Determination (HRP-310)” for further clarification if needed.

2.0 Examples of activities that are generally considered not to be Human Research

The following are examples of activities that are generally considered not to be Human Research according to the definitions in Section 1.0. If your activity is limited to one of the examples below, then it is likely not Human Research which would need to be reviewed by the IRB. Note that publication is not a determining factor for whether an activity is Human Research.

2.1 Program Evaluation/Quality Assurance Review/Quality Improvement Project: The activity is limited to program evaluation, quality assurance, or quality improvement activities designed specifically to evaluate, assure, or improve performance within a department, classroom, or hospital setting.

Note that an evaluation, assurance review, or improvement project designed specifically for a particular setting may yield useful information for similar entities, but may still not meet one of the definitions for Human Research in Section 1.0.

2.2 Case Report: The project consists of a case report or series which describes an interesting treatment, presentation, or outcome. A critical component is that nothing was done to the patient(s) with prior “research” intent.

Note that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance.

2.3 Course-Related Activity: The project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments and otherwise do not meet either of the definitions of Human Research in Section 1.0.

Note that some course-related activities, even those conducted by students, may yield information suggesting additional investigation or analysis. If an additional activity entails Human Research, then it must be submitted to the IRB Office for review.

2.4 Journalistic or Documentary Activity (including Oral History): The activity is limited to investigations or interviews (structured or
open-ended) that focus on specific events (current or historical), views, etc. Such investigations or interviews may be reported or published in any medium, e.g, print newspaper, documentary video, online magazine.

2.5 Research Using Public or Non-Identifiable Private Information about Living Individuals: The activity is limited to analyzing data about living individuals (1) where the data have been retrieved by the investigator from public, non-restricted data sets or (2) where the private data have been provided to the investigator without any accompanying information by which the investigator could identify the individuals.

Note that “de-identified data” according to HIPAA may be identifiable according to the DHHS definition of “Human Subjects” above. Please consult “WORKSHEET: Human Research Determination (HRP-310)” for clarification and contact the IRB Office with any questions regarding research with data.

2.6 Research Using Health Information from Deceased Individuals: This activity is limited to analyzing data (identifiable or not) about deceased individuals.

Note that deceased individuals cannot be Human Subjects according to DHHS, but they may be Human Subjects according to FDA. Please review the definitions above for clarification. Note also that HIPAA or other state or local laws may still apply to this activity. Please consult the entity from which you received or accessed the information contained in the report for further guidance.
PROTOCOL TITLE:

3.0 Description of Activity

If, after reviewing the information above, (1) you are unclear as to whether your activity is Human Research and would like for the IRB Office to make a determination for you or (2) you believe that your activity is not Human Research but would like for the IRB Office to provide documentation that it agrees with your assessment, then please complete the information below. **Delete the italicized instructions below when providing your information.**

3.1 Purpose

*Briefly describe the purpose, specific aims, or objectives of the study.*

3.2 Procedures

*Briefly describe the procedures used to obtain information from the individuals with whom you will interact or intervene for this activity, including communication or interpersonal contact with individuals and physical procedures, if any.*

3.3 Data and/or specimens

*Describe the data and/or specimens that you will gather about individuals, including names of datasets you will access and links to data sources.*

- **Data and/or Specimen Collection and Analysis**
  *Describe the data and/or specimens you will collect and how they will be analyzed.*

- **Data and/or Specimen Collection Method**
  *Describe how you will obtain the data or specimens. (Are you obtaining them from another researcher? Are you pulling data from directly from a medical record? Are you pulling leftover samples from a lab?)*

- **Identifiability of Data or Specimens**
  *Indicate whether the data or specimens you collect for this activity can be directly linked to individuals, (e.g., the dataset includes names), indirectly linked through a code (e.g., the dataset includes a code and you have the key to the code), or not linked at all to individuals (e.g., the dataset includes a code, but no one but the person giving you the data or specimens has the key to the code).*
The purpose of this worksheet is to provide support for individuals in determining whether an activity is Human Research or how it is regulated. This worksheet is to be used. It does not need to be completed or retained.

### 1 Research as Defined by DHHS Regulations

- **(Check if “Yes”.)** Is the activity an investigation? (Investigation: A searching inquiry for facts; detailed or careful examination.)
- **(Check if “Yes”.)** Is the investigation systematic? (Systematic: Having or involving a system, method, or plan.)
- **(Check if “Yes”.)** Is the systematic investigation designed to develop or contribute to knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truths, facts, information.)
- **(Check if “Yes”.)** Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: Universally or widely applicable.)

### 2 Human Subject Under DHHS Regulations

- **(Check if “Yes”.)** Is the investigator conducting the Research gathering data about living individuals?

### 3 Human Subject Under DHHS Regulations

- **(Check if “Yes”.)** Will the investigator gather that data through either of the following mechanisms (specify which mechanism(s) apply):
  - Physical procedures or manipulations of those individuals or their environment for research purposes (“intervention”).
  - Communication or interpersonal contact with the individuals. (“interaction”).

### 4 Human Subject Under DHHS Regulations

- **(Check if “Yes”).** Will the investigator gather data that is either? Specify which category(s) apply if yes:
  - The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. “Private information”).
  - Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e. “Private information”).
  - Can the individuals’ identities be readily ascertained by the investigator or associated with the information (i.e. “Identifiable information”)?

If all items are checked under 1, 2, and 3 or 1, 2, and 4, the activity is Human Research under DHHS regulations.

### 5 Human Research Under USFDA Regulations

- **(Check if “Yes”)** Does the activity involve any of the following? (Check all that apply)
  - In the United States: The use of a drug³ in one or more persons other than use of an approved drug in the course of medical practice³.
  - In the United States: The use of a device⁴ in one or more persons that evaluates the safety or effectiveness of that device.
  - Data regarding subjects or control subjects submitted to or held for inspection by USFDA⁵.
  - Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by USFDA⁵.

If “Yes”, the activity is Human Research under USFDA regulations.

If the activity is Human Research under DHHS regulations or under USFDA regulations, it is Human Research under institutional policy.

### 6 Engagement

**Complete if the activity is Human Research.**

- **(Check if “Yes”)** The institution is engaged in Human Research. Use WORKSHEET: Engagement (HRP-311)
Comments:

1 The following activities conducted or supported by the US Department of Defense (USDOD) are NOT research involving human subjects:
Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the US Department of Defense Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01.

2 The term “drug” means:
   (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
   (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
   (C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
   (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

3 “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

4 The term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
   (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
   (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
   (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

5 This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to USFDA meet this requirement.

6 This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to USFDA meet this requirement.
The purpose of this worksheet is to provide support for Designated Reviewers granting exemption determinations. This worksheet is to be used. It does not need to be completed or retained.

<table>
<thead>
<tr>
<th>1</th>
<th>GENERAL EXCLUSIONS FROM EXEMPTIONS (Check if “Yes”. If either is checked, the research is not exempt.)</th>
</tr>
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<tbody>
<tr>
<td>☐</td>
<td>The research is USFDA-regulated.¹</td>
</tr>
<tr>
<td>☐</td>
<td>The research involves Prisoners and is conducted or funded by DHHS, Dept. of Defense (USDOD), or Veterans Administration (VA).</td>
</tr>
<tr>
<td>☐</td>
<td>The research involves interactions with Prisoners.</td>
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<tr>
<th>2</th>
<th>The research falls into one or more of the following categories (One or more categories must be checked)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. (Both the procedures involve normal educational practices and the objectives of the research involve normal educational practices.)</td>
</tr>
<tr>
<td>☐</td>
<td>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. In addition:</td>
</tr>
<tr>
<td>☐</td>
<td>If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (USDOD), Dept. of Education (USED), Environmental Protection Agency (USEPA), or Veterans Administration (VA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. (“N/A” if the research does not involve children or is not conducted, funded, or otherwise subject to by these agencies.)</td>
</tr>
<tr>
<td>☐</td>
<td>3. Research involving the use of educational tests¹, 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.</td>
</tr>
<tr>
<td>☐</td>
<td>4.¹ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens 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. (For research conducted, funded, or otherwise subject to regulation by any federal agency &quot;existing&quot; means &quot;existing at the time the research is proposed.&quot; Otherwise, it means &quot;existing at the time the research is proposed or will exist in the future for non-research purposes.&quot; )</td>
</tr>
<tr>
<td>☐</td>
<td>5. Research and demonstration projects which are conducted by or subject to the approval of Dept. 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. In addition: (Check if “Yes”. All must be checked)</td>
</tr>
<tr>
<td>☐</td>
<td>The program under study delivers a public benefit¹ or service¹.</td>
</tr>
<tr>
<td>☐</td>
<td>The research or demonstration project is conducted pursuant to specific federal statutory authority.</td>
</tr>
<tr>
<td>☐</td>
<td>There is no statutory requirement that the project be reviewed by an IRB.</td>
</tr>
<tr>
<td>☐</td>
<td>The project does not involve significant physical invasions or intrusions upon the privacy of subjects.</td>
</tr>
<tr>
<td>☐</td>
<td>The funding agency concurs with the exemption.</td>
</tr>
<tr>
<td>☐</td>
<td>6.¹ 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 of the food 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 US Food and Drug Administration or approved by the US Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>3</th>
<th>Criteria for approval of exempt research (Check if “Yes”)</th>
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</thead>
<tbody>
<tr>
<td>☐</td>
<td>The research involves no more than Minimal Risk to subjects. (Must be checked.)</td>
</tr>
<tr>
<td>☐</td>
<td>Selection of subjects is equitable. (That is, the research is appropriate for the population being studied.) (Must be checked.)</td>
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<tr>
<td>☐</td>
<td>If there is recording of identifiable information: (If checked the following must be checked.)</td>
</tr>
<tr>
<td>☐</td>
<td>There are adequate provisions to maintain the confidentiality of the data.</td>
</tr>
<tr>
<td>☐</td>
<td>There are interactions with subjects: (If checked the following must be checked.)</td>
</tr>
<tr>
<td>☐</td>
<td>There will be a consent process.</td>
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<tr>
<td>☐</td>
<td>The consent process will disclose that the activities involve research.</td>
</tr>
<tr>
<td>☐</td>
<td>The consent process will disclose the procedures to be performed.</td>
</tr>
<tr>
<td>☐</td>
<td>The consent process will disclose that participation is voluntary.</td>
</tr>
<tr>
<td>☐</td>
<td>The consent process will disclose the name and contact information for the investigator.</td>
</tr>
<tr>
<td>☐</td>
<td>There are adequate provisions to maintain the privacy interests of subjects.</td>
</tr>
<tr>
<td>NUMBER</td>
<td>DATE</td>
</tr>
<tr>
<td>--------</td>
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</tr>
<tr>
<td>HRP-312</td>
<td>11/10/2014</td>
</tr>
</tbody>
</table>

1 The institution’s policy is to not grant exemptions to USFDA-regulated research in category (6).
2 Includes cognitive, diagnostic, aptitude, and achievement tests
3 “If these sources are publicly available” was removed because public data cannot be private, and if there is no collection of private identifiable data, there can be no Human Subjects.
4 For example, financial or medical benefits as provided under the Social Security Act
5 For example, social, supportive, or nutrition services as provided under the Older Americans Act
6 Note that for USFDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from USFDA requirements for consent in 21 CFR §50. If an institution’s policy is to grant exemptions to USFDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR §50.27 or waived in accordance with 21 CFR §56.109(c)(1).
### WORKSHEET: Expedited Review

<table>
<thead>
<tr>
<th>NUMBER</th>
<th>DATE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HRP-313</td>
<td>11/10/2014</td>
<td>1 of 2</td>
</tr>
</tbody>
</table>

The purpose of this worksheet is to provide support for designated reviewers conducting reviews using the expedited procedure. This worksheet is to be used. It does not need to be completed or retained.

**☐ Continuing review of non-research Humanitarian Use Device (HUD) using the expedited procedure**

1. **Additional Criteria for Research Involving Prisoners** (Check if “Yes” or “N/A”. Must be checked)
   - The research is minimal risk and the prison representative concurs with this determination. (“N/A” if no prisoners as subjects.)

Initial or continuing review must meet criteria set 3. Modifications can meet either criteria set 2 or 3.

2. **Minor Modifications** (Check if “Yes” or “N/A”. All must be checked)
   - The modifications do not affect the design of the research.
   - The modifications add no more than Minimal Risk to subjects:
   - All added procedures fall into categories (1)-(7) below. (“N/A” if no added procedures)

3. **Initial Review, Continuing Review, or Modifications** (Check if “Yes” or “N/A”. All must be checked)
   - The research activities (or remaining research activities) present no more than Minimal Risk to Human Subjects. (“N/A” if research falls into category (8)(b))
   - Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will NOT reasonably place them at risk of criminal or civil liability or be damaging to the their 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 Risk. (“N/A” if the research falls into category (8)(b))

☐ The research is NOT classified:

☐ The research (or remaining research) falls into one or more of the following categories: (Check all that apply)
   - (1)(a) Clinical studies of drugs when an IND is not required.
   - (1)(b) Clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
   - (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh >110 pounds where the amount drawn is <550 ml/8 week period and collection occurs at most 2 times/week.
   - (2)(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and height of the subjects, the collection procedure, the amount of blood to be collected (at most 50 ml or 3 ml/kg/8 week period), and the frequency with which it will be collected (at most 2 times/week).*
   - (3) Prospective collection of biological specimens for research purposes by noninvasive means.
   - (4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.
   - (5) Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes.
   - (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
   - (7) Research on individual or group characteristics or behavior, or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
   - (8)(a) Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)
   - (8)(b) Continuing review of research previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.
   - (8)(c) Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)
   - (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than Minimal Risk and no additional risks have been identified.

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1 Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and US Food and Drug Administration Staff Humanitarian Device Exemption (HDE) Regulation: Questions and Answers Document issued on: July 8, 2010 states “46. What types of review functions are IRBs responsible for with respect to HUDs? IRBs are responsible for initial as well as continuing review of the HUD. For initial review of a HUD,
IRBs are required to perform their review at a convened meeting (21 CFR 56.108). For continuing review, IRBs may use the expedited review procedures (21 CFR 56.110).”

ii Classified information is sensitive information to which access is restricted by law or regulation to particular groups of persons. A formal security clearance is required to handle classified documents or access classified data. In the United States classified research involving human subjects is where the protocol, information required by the IRB for review and oversight, or information provided by the research subjects includes classified information, as defined in Executive Order 13526, “Classified National Security Information,” December 29, 2009

iii Withdrawal of blood from an indwelling venous line is a “venipuncture.”

iv Multiple withdrawals of blood from an indwelling venous line are more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure.

v Withdrawal of blood from an indwelling venous line is a “venipuncture.”

vi Multiple withdrawals of blood from an indwelling venous line are more than one collection. Therefore, a research study involving withdrawal of more than two blood samples from an indwelling venous line in a week is not eligible for review using the expedited procedure.

vii Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares.

viii Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncanulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

ix Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares.

x Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

xi Examples: Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

xii Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.
The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval (HRP-314) when research involves waiver or alteration of the consent process. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to “Submit Non-Committee Review” activity. The IRB Office uploads this checklist in the “Submit Designated Review” activity and retains this checklist in the protocol file.

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file.

The research must meet one of the following four sets of criteria

### 1 Waiver or Alteration of Consent Process

- The research is **NOT** USFDA-regulated.
- The research does **NOT** involve non-viable neonates.
- The research involves no more than **Minimal Risk** to the subjects.
  
  *Provide protocol specific findings justifying this determination:*
  
- The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects.
  
  *Provide protocol specific findings justifying this determination:*
  
- The research could **NOT** practicably be carried out without the waiver or alteration
  
  *Provide protocol specific findings justifying this determination:*
  
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
  
  *Provide protocol specific findings justifying this determination:*

### 2 Waiver or Alteration of Consent Process

- The research is **NOT** USFDA-regulated.
- The research does **NOT** involve non-viable neonates.
- The research or demonstration project is to be conducted by or subject to the approval of state or local government officials.
  
  *Provide protocol specific findings justifying this determination:*
  
- The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check all boxes that are true. One must be checked)**
  
  - Public benefit or service programs.
  - Procedures for obtaining benefits or services under those programs.
  - Possible changes in or alternatives to those programs or procedures.
  - Possible changes in methods or levels of payment for benefits or services under those programs.
  
  *Provide protocol specific findings justifying this determination:*

- The research could **NOT** practicably be carried out without the waiver or alteration.
  
  *Provide protocol specific findings justifying this determination:*

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1 45 CFR §46.116(d)  
2 45 CFR §46.116(c)
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### Waiver of the Consent Process for USFDA-Regulated Research Involving Anonymous Tissue Specimens

3. (Check if “Yes”. All must be checked)

- The research does not involve Human Subjects as Defined by DHHS.
- The study involves an in vitro diagnostic device investigation.
- The testing is noninvasive.
- The testing does not require an invasive sampling procedure that presents significant risk.
- The testing does not by design or intention introduce energy into a subject.
- The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.
- For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: “For Research Use Only. Not for use in diagnostic procedures.”
- For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: “For Investigational Use Only. The performance characteristics of this product have not been established.”
- The study uses one of more of the following: (Check all boxes that are true. One must be checked)
  - Specimens collected for routine clinical care or analysis that would have been discarded.
  - Specimens obtained from specimen repositories.
  - Leftover specimens that were previously collected for other research purposes.
- The identity of the subject is not known to the investigator or any other individuals associated with the investigation, including the sponsor meaning neither the investigator nor any other individuals associated with the investigation, including the sponsor can readily ascertain the identity of the subject.
- One of the following is true: (Check all boxes that are true. One must be checked)
  - Specimens are not coded where “Coded” means that 1) a number, letter, symbol, or combination thereof (i.e., the code) has replaced identifying information (such as name or social security number) that would enable the investigator or any other individuals associated with the investigation, including the sponsor to readily ascertain the identity of the individual to whom the specimen pertains; and 2) a key to decipher the code exists, enabling linkage of the identifying information to the specimen.
  - Neither the investigator(s) nor any other individuals associated with the investigation or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems.
- One of the following is true: (Check all boxes that are true. One must be checked)
  - The specimens are not accompanied by clinical information.
  - Clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor.
  - The individuals caring for the patients are different from those conducting the investigation and do not share information about the patient with those conducting the investigation.
  - The individuals caring for the patients do not share information about the patient with those conducting the investigation.
  - The specimens are provided to the investigator(s) without identifiers.
  - The supplier of the specimens has established policies and procedures to prevent the release of personal information.

### Waiver of Informed Consent for Planned Emergency Research

4. (Check the criteria in "CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)."

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3 Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable – April 25, 2006

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following the WORKSHEET: Criteria for Approval (HRP-314) when research involves the waiver of written documentation of consent. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to “Submit Non-Committee Review” activity. The IRB Office uploads this checklist in the “Submit Designated Review” activity retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the “Submit Committee Review” activity and retains this checklist in the protocol file.

The research must meet one of the following two sets of criteria

1. **Waiver of Written Documentation of Consent**
   - (Check if “Yes”. All must be checked)
     - The written script of the information to be provided orally (if consent is obtained in person or over the telephone) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in Section 7: ELEMENTS OF CONSENT DISCLOSURE in the WORKSHEET: Criteria for Approval (HRP-314).
     - The research presents no more than Minimal Risk of harm to subjects.
     - The research involves no procedures for which written consent is normally required outside of the research context.
   - Select one of the following: (One must be checked)
     - Written information describing the research is to be provided to the subject or the subject’s legally authorized representative.
     - Written information describing the research does not need to be provided to the subject or the subject’s legally authorized representative.

2. **Waiver of Written Documentation of Consent**
   - (Check if “Yes”. All must be checked)
     - The research is not USFDA-regulated.
     - The written script of the information to be provided orally (if consent is obtained in person or over the telephone) and all written information to be provided or electronically displayed include all required and appropriate additional elements of consent disclosure in Section 7: ELEMENTS OF CONSENT DISCLOSURE in the WORKSHEET: Criteria for Approval (HRP-314).
     - The only record linking the subject and the research would be the consent document.
     - The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.
     - Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern.
   - Select one of the following: (One must be checked)
     - Written information describing the research is to be provided to the subject or the subject’s legally authorized representative.
     - Written information describing the research does not need to be provided to the subject or the subject’s legally authorized representative.

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1. 21 CFR §56.109(c)(1) and 45 CFR §46.117(c)(2)
2. 45 CFR §46.117(c)(1)
The purpose of this checklist is to provide support for the IRB Members or the Designated Reviewer when research involves waiver or alteration of HIPAA authorization. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure).

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the HIPAA regulations. The Designated Reviewer signs, dates, and scans this checklist. The Designated Reviewer uploads the signed, dated, and scanned checklist to the "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the convened IRB completes this checklist to document determinations required by the HIPAA regulations. The IRB Chair signs and dates this checklist. The IRB Office scans and uploads this checklist to the "Submit Committee Review" activity. The IRB Office retains this checklist in the protocol file.

1 DOCUMENTATION OF WAIVER APPROVAL (Check if “Yes”. All must be checked.)

☐ The description of the PHI for which use or access is included in the protocol summary and is necessary for the research.

☐ The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: (Check if “Yes”. All must be checked)
  ☐ An adequate plan to protect the identifiers from improper use and disclosure.
  ☐ An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
  ☐ Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

☐ The research could NOT practicably be conducted without the waiver or alteration.

☐ The research could NOT practicably be conducted without access to and use of the protected health information.

Using the expedited review procedure the designated privacy board member signing below has determined that the above requirements are met, access to the protected health information described in the protocol is necessary, and waived or altered the requirement for authorization.

Reviewer Signature: ________________________ Date: ________________________