Appendix 6:

Human Subject Determination checklist

and

Other OHRP Checklists
Human Subject Regulations Decision Charts

September 24, 2004

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. OHRP welcomes comment on these decision charts. The charts address decisions on the following:

- whether an activity is research that must be reviewed by an IRB
- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?
Chart 2: Is the Human Subjects Research Eligible for Exemption?
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?
Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?
Chart 8: May the IRB Review Be Done by Expedited Procedures?
Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?
Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.) (Footnotes of 45 CFR 46.101(b) and 46.101(h) apply.)

**“Only” means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.**

- NO
  - Will the only** involvement of human subjects be in one or more of the following categories?
    - Research conducted in established or commonly accepted educational settings, involving normal education practices? YES → Exemption 45 CFR 46.101(b)(1) may apply. Go to Chart 3
    - Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior? AND/OR YES → Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply. Go to Chart 4
    - Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens? AND/OR YES → Exemption 45 CFR 46.101(b)(4) may apply. Go to Chart 5
    - Research studying, evaluating, or examining public benefit or service programs? AND/OR YES → Exemption 45 CFR 46.101(b)(5) may apply. Go to Chart 6
    - Research involving taste and food quality evaluation or consumer acceptance studies? AND/OR YES → Exemption 45 CFR 46.101(b)(6) may apply. Go to Chart 7

- YES
  - No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations. Go to Chart 8
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research only conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

- NO: Research is not exempt under 45 CFR 46.101(b)(1). Go to Chart 8
- YES: Does the research study involve only normal education practices? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)
  
- YES: Research is exempt under 45 CFR 46.101(b)(1) from all 45 CFR part 46 requirements.
- NO: Continue with the chart.

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Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

From Chart 2

Does the research involve only the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

YES

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

YES

Research is not exempt under 45 CFR 46.101(b)(2).

Research is exempt under 45 CFR 46.101(b)(2) from all 45 CFR part 46 requirements.

NO

Research is not exempt under 45 CFR 46.101(b)(2) or (b)(3).

NO

Does the research involve children to whom 45 CFR part 46, subpart D applies?

YES

Does the research involve survey procedures, interview procedures, or observation of public behavior where the investigator participates in the activities being observed? [45 CFR 46.409(a)]

YES

Research is exempt under 45 CFR 46.101(b)(3).

NO

Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

YES

Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.

NO

Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

YES

Research is exempt under 45 CFR 46.101(b)(2).

NO

Research is not exempt under 45 CFR 46.101(b)(2).

Go to Chart 8

September 24, 2004
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?

From Chart 2

Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *

('Existing' means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

YES

Are these sources publicly available?

YES

Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements.

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

Research is not exempt under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

Go to Chart 8

*Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/policy/index.htm#tissues and http://ohrp.hhs.gov/index.htm#stem, and on coded data or specimens at http://ohrp.hhs.gov/index.htm#coded for further information on these topics.

September 24, 2004
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

YES

Does the research or demonstration project involve only the study, evaluation, or examination of:

- Public benefit or service programs; → YES

NO

Procedures for obtaining benefits or services under public benefit or service programs; → YES

NO

Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs; → YES

NO

Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs?

NO

Research is not exempt under 45 CFR 46.101(b)(5).

YES

Research is exempt under 45 CFR 46.101(b)(5) from all 45 CFR part 46 requirements.*

NO

Go to Chart 8

*Note: See OHRP guidance on exemptions at http://www.hhs.gov/ohrp/policy/exemption.html for further description of requirements for this exception.

September 24, 2004
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

From Chart 2

Does the research involve only a taste and food quality evaluation or a food consumer acceptance study?

YES

Are wholesome foods without additives consumed?

YES

Research is exempt under 45 CFR 46.101(b)(6) from all 45 CFR part 46 requirements.

NO

Is food consumed that contains a food ingredient, 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?

YES

NO

Research is not exempt under 45 CFR 46.101(b)(6).

Go to Chart 8

September 24 2004
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.1107?*

- From Chart 2, 3, 4, 5, 6, or 7
  - Has the research been previously reviewed and approved by the IRB?
    - YES
      - Is the review a continuing review? [45 CFR 46.1105(a)]
    - NO
      - Does the research present no more than minimal risk to human subjects and does the research involve only procedures included in categories 1 through 7 on the list of categories of research that may be reviewed through an expedited review procedure? [45 CFR 46.1105(b)(1)]
        - YES
          - Review by convened IRB is required.
          - Are measures in place to make risks no more than minimal?
            - YES
              - Go to Chart 10
            - NO
              - Review by convened IRB is required.
        - NO
          - Does the review involve a minor change in approved research during the one year or less period of approval? [45 CFR 46.1105(b)(2)]
            - YES
              - Go to Chart 9
            - NO
              - Is the research classified? [Paragraph (D) of Categories of Research That May Be Reviewed By an IRB Through an Expedited Review Procedure.]
                - YES
                  - Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging? [Paragraph (C) of Categories.]
                    - YES
                      - Go to Chart 10
                    - NO
                      - Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution's or IRB's use of the expedited review procedure. [45 CFR 46.110(a)]
                - NO
                  - Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution's or IRB's use of the expedited review procedure. [45 CFR 46.110(a)]

* Note: See expedited review categories and ONHP guidance on the use of expedited review procedures at http://aanz.hhs.gov/index.html#expedited for further information on expedited review.

September 24, 2001
Chart 10: Can informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)**

**(Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. (See 45 CFR 46.408(a)))**

From Chart 8 or 9

Will the research or demonstration project be conducted by or subject to the approval of state or local government officials?

[45 CFR 46.116(c)(1)]

- **YES**
  - Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of 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?
  
  [45 CFR 46.116(d)(1)]

  - **YES**
    - Is it practicable to conduct the research without the waiver or alteration?
    
    [45 CFR 46.116(e)(3)]
    
    - **YES**
      - No waiver of informed consent or alteration of consent elements is allowed.*

    - **NO**
      - Go to Chart 11

  - **NO**
    - Will the research involve greater than minimal risk, as defined in Section 46.102(i)? [45 CFR 46.116(d)(1)]

- **NO**

  Will it practicable to conduct the research without the waiver or alteration?

  [45 CFR 46.116(d)(3)]

  - **YES**
    - No waiver of informed consent or alteration of consent elements is allowed.*

  - **NO**
    - Will waiving or altering the informed consent adversely affect the subjects' rights and welfare?

    [45 CFR 46.116(d)(2)]

    - **YES**
      - Go to Chart 11

    - **NO**
      - Will pertinent information be provided to subjects later, if appropriate?

      [45 CFR 46.116(d)(3)]

      - **YES**
        - Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.

      - **NO**
        - If informed consent is not waived entirely

*Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/policy/index.html#emergency for further information on emergency research informed consent waiver.

September 24, 2004
Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

From Chart 10

Would the consent document be the only record linking the subject and the research and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(c)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

AND

IRB may require investigator to provide subjects with a written statement regarding the research. [45 CFR 46.117(c)]

AND

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research. [45 CFR 46.117(c)(3)]

Subject’s wishes will govern whether informed consent is documented. [45 CFR 46.117(c)(3)]

NO

IRB may NOT waive the requirement for a signed consent form for any subjects.

September 24, 2004
Human Subject Regulations Decision Charts

September 24, 2004

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- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.

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Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?
Chart 8: May the IRB Review Be Done by Expedited Procedures?
Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?
Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here.

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.101(a)]

- **NO** Activity is not research, so 45 CFR part 46 does not apply.
- **YES** Activity is research. Does the research involve obtaining information about living individuals? [45 CFR 46.102(b)]

  - **NO** The research is not research involving human subjects, and 45 CFR part 46 does not apply.
  - **YES** Does the research involve intervention or interaction with the individuals? [45 CFR 46.102(c), (d)]

    - **NO** The research is not research involving human subjects, and 45 CFR part 46 does not apply.
    - **YES** Activity is research involving human subjects. Is it conducted or supported by HHS? [45 CFR 46.104(b)]

      - **NO** Go to Chart 2
      - **YES** Is the information individually identifiable? (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)]

        - **NO** Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) [45 CFR 46.102(f)]
        - **YES** Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A requirements apply to the research. As appropriate, subpart B, C, and D requirements also apply.

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.104(f)]
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

Has HHS prohibited exemption of the human subjects research?
(All research involving prisoners, some research involving children)
[Footnote 1 to 45 CFR 46.101(a): 45 CFR 46.101(a)(1)]

September 24, 2004

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

*From Chart 1*

**NO**

Will the only** involvement of human subjects be in one or more of the following categories?

- Research conducted in established or commonly accepted educational settings, involving normal educational practices?
  - **YES**
    - Exemption 45 CFR 46.101(b)(1) may apply.
    - Go to Chart 3
  - **NO**

- Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
  - **YES**
    - Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply.
    - Go to Chart 4
  - **NO**

- Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?
  - **YES**
    - Exemption 45 CFR 46.101(b)(4) may apply.
    - Go to Chart 5
  - **NO**

- Research studying, evaluating, or examining public benefit or service programs?
  - **YES**
    - Exemption 45 CFR 46.101(b)(5) may apply.
    - Go to Chart 6
  - **NO**

- Research involving taste and food quality evaluation or consumer acceptance studies?
  - **YES**
    - Exemption 45 CFR 46.101(b)(6) may apply.
    - Go to Chart 7
  - **NO**

*From Chart 1*

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply. Subparts B, C, and D also apply if subjects are from covered vulnerable populations.

Go to Chart 8
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research only conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

- NO → Research is not exempt under 45 CFR 46.101(b)(1).
- NO → Go to Chart 8

YES

Does the research study involve only normal education practices? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)

- YES → Research is exempt under 45 CFR 46.101(b)(1) from all 45 CFR part 46 requirements.
- NO

September 24, 2004
Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

From Chart 2

Does the research involve only the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

- YES
  - Does the research involve children to whom 45 CFR part 46, subpart D applies?
    - NO
    - NO
      - Research is not exempt under 45 CFR 46.101(b)(2) or (b)(3).
      - Go to Chart 8
    - YES
    - Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)
      - NO
      - NO
      - Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.
      - NO
      - Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?
        - YES
        - Research is exempt under 45 CFR 46.101(b)(2) exemption from 45 CFR part 46 requirements.
        - NO
        - Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?
          - YES
          - Research is not exempt under 45 CFR 46.101(b)(2).
          - NO
          - However, the 45 CFR 46.101(b)(3) exemption might apply.

- NO
  - Does the research involve survey procedures, interview procedures, or observation of public behavior where the investigator participates in the activities being observed? (45 CFR 46.103(b))
    - YES
    - Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)
      - NO
      - NO
      - Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.
      - NO
      - Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?
        - YES
        - Research is exempt under 45 CFR 46.101(b)(2) exemption from 45 CFR part 46 requirements.
        - NO
        - Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?
          - YES
          - Research is not exempt under 45 CFR 46.101(b)(2).
          - NO
          - However, the 45 CFR 46.101(b)(3) exemption might apply.

September 24, 2004
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?

From Chart 2

Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *

("Existing" means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

YES

Are those sources publicly available?

YES

Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements.

NO

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

NO

Research is not exempt under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

Go To Chart 0

* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/policy/index.htm#tissues and Asian, and on coded data or specimens at http://www.hhs.gov/ohrp/policy/index.htm#coding for further information on these topics.

September 24, 2004
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

YES

Does the research or demonstration project involve only the study, evaluation, or examination of:

Public benefit or service programs; YES → Research is exempt under 45 CFR 46.101(b)(5) from all 45 CFR Part 46 requirements. *

NO

Procedures for obtaining benefits or services under public benefit or service programs; YES →

NO

Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs; YES →

NO

Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs? YES →

NO

Research is not exempt under 45 CFR 46.101(b)(5). → Go to Chart 8

* Note: See OHRP guidance on exemptions at http://www.hhs.gov/ohrp/policy/index.html#exempt for further description of requirements for this exemption.

September 24, 2004
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

From Chart 2

Does the research involve only a taste and food quality evaluation or a food consumer acceptance study?

YES

Are wholesome foods without additives consumed?

YES → Research is exempt under 45 CFR 46.101(b)(6) from all 45 CFR part 46 requirements.

NO

Is food consumed that contains a food ingredient, 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?

YES → Research is exempt under 45 CFR 46.101(b)(6) from all 45 CFR part 46 requirements.

NO → Research is not exempt under 45 CFR 46.101(b)(6)

GO TO CHART 8

September 24 2004
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

From Chart 2

Does the research involve only a taste and food quality evaluation or a food consumer acceptance study?

YES

Are wholesome foods without additives consumed?

YES

Research is exempt under 45 CFR 46.101(b)(6) from all 45 CFR part 46 requirements.

NO

NO

Research is not exempt under 45 CFR 46.101(b)(6).

NO

Go to Chart 8

September 24 2004
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at http://www.hhs.gov/ohrp/policy/index.html. Expanded for further information on expedited review.

From Chart 2, 3, 4, 5, 6, or 7

Has the research been previously reviewed and approved by the IRB? → YES → Is the review a continuing review? (45 CFR 46.110(c)(4))

NO →

Does the research present no more than minimal risk to human subjects? and does the research involve only procedures included in categories 1 through 7 on the list of categories of research that may be reviewed through an expedited review procedure? (45 CFR 46.110(b)(1))

NO →

YES →

Review by convened IRB is required.

Are measures in place to make risks no more than minimal? 

NO →

NO →

Go to Chart 9

YES →

Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging? (Paragraph (C) of Categories.)

NO →

NO →

Go to Chart 10

YES →

YES →

Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution's or IRB's use of the expedited review procedure. (45 CFR 46.110(a))

September 24, 2004
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?

**Note:** If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. (See 45 CFR 46.404(c))

From Chart 8 or 9

1. Will the research or demonstration project be conducted by or subject to the approval of state or local government officials? (45 CFR 46.116(c)(1))
   - YES
     - Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of 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? (45 CFR 46.116(d)(3))
   - NO
     - Will the research involve greater than minimal risk, as defined in Section 46.102(f) (45 CFR 46.116(e)(1))
       - NO
       - Go to Chart 11
       - YES
         - Is it practicable to conduct the research without the waiver or alteration? (45 CFR 46.116(b)(3))
           - NO
           - NO
           - YES
           - No waiver of informed consent or alteration of consent elements is allowed.*
             - NO
             - YES
               - Will waiting or allowing the informed consent adversely affect the subjects' rights and welfare? (45 CFR 46.116(c)(2))
                 - NO
                 - NO
                 - If Informed consent is not waived entirely
                   - YES
                     - Waiver of informed consent or alteration of consent elements is allowed if IRB document these findings and approves waiver or alteration.
                   - NO
                     - Go to Chart 11

* Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/policy/index.html. Further information on emergency research informed consent waiver.

September 24, 2004
Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

From Chart 10

Would the consent document be the only record linking the subject and the research and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(c)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

AND

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research. [45 CFR 46.117(c)(1)]

NO

IRB may not waive the requirement for a signed consent form for any subjects.

YES

Subject's wishes will govern whether informed consent is documented. [45 CFR 46.117(c)(1)]

September 24, 2004
Human Subject Regulations Decision Charts

September 24, 2004

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. OHRP welcomes comment on these decision charts. The charts address decisions on the following:

- whether an activity is research that must be reviewed by an IRB
- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.

Considerations

The charts are intended to assist IRBs, Institutions, and Investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?
Chart 2: Is the Human Subjects Research Eligible for Exemption?
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?
Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimen) Apply?
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?
Chart 8: May the IRB Review Be Done by Expedited Procedures?
Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?
Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here.

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? (45 CFR 46.102(a))

YES

Activity is research. Does the research involve obtaining information about living individuals? (45 CFR 46.102(b))

YES

Does the research involve intervention or interaction with the individuals? (45 CFR 46.102(c)(1), (2))

YES

Activity is research involving human subjects. Is it conducted or supported by HHS? (45 CFR 46.101(d)(1))

YES

Is the research covered by an applicable OHRP approved assurance created under 45 CFR 46.103?

YES

Unsecured exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A requirements apply to the research. As appropriate, subpart B, C, and D requirements also apply.

NO

Is the research non-exempt and not classified as research involving minimal risk? (45 CFR 46.108)

YES

Go to Chart 2

NO

Activity is not research, so 45 CFR part 46 does not apply.

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? (45 CFR 46.102(b)(2))

YES

Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.) (45 CFR 46.102(b)(3))

NO

BUT

NO

BUT

Other Federal, State and local laws and/or regulations may apply to the activity. (45 CFR 46.101(h))

AND

4/9/2014
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

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Has HHS prohibited exemption of the human subjects research?
(All research involving prisoners, some research involving children)
[Footnotes 1 to 45 CFR 46.101(b) and 45 CFR 46.091(b)]

**NO**

Will the "only"* involvement of human subjects be in one or more of the following categories?

- Research conducted in established or commonly accepted educational settings, involving normal educational practices?
  - YES → Exemption 45 CFR 46.101(b)(1) may apply. → Go to Chart 3
  - AND/OR
  - Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
    - YES → Exemption 45 CFR 46.101(b)(2) or (b)(3) may apply. → Go to Chart 4
    - AND/OR
    - Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?
      - YES → Exemption 45 CFR 46.101(b)(4) may apply. → Go to Chart 5
      - AND/OR
      - Research studying, evaluating, or examining public benefit or service programs?
        - YES → Exemption 45 CFR 46.101(b)(5) may apply. → Go to Chart 6
        - AND/OR
        - Research involving taste and food quality evaluations or consumer acceptability studies?
          - YES → Exemption 45 CFR 46.101(b)(6) may apply. → Go to Chart 7
          - NO → No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations. → Go to Chart 8
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research only conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

- NO: Research is not exempt under 45 CFR 46.101(b)(1).
  - Go to Chart 8
- YES: Does the research study involve only normal education practices? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)
  - NO
  - YES: Research is exempt under 45 CFR 46.101(b)(1) from all 45 CFR part 46 requirements.

September 24, 2004
Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

From Chart 2

Does the research involve only the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

YES

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

NO

Does the research involve human children to whom 45 CFR part 46, subpart D applies?

YES

Research is not exempt under 45 CFR 46.101(b)(2).

However, the 45 CFR 46.101(b)(3) exemption might apply.

Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

NO

Research is not exempt under 45 CFR 46.101(b)(2) or (b)(3).

Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

NO

Go to Chart 8

September 24, 2004

YES

Research is exempt under 45 CFR 46.101(b)(3) from all 45 CFR part 46 requirements.

NO

Research is exempt under 45 CFR 46.101(b)(2) exemption from 45 CFR part 46 requirements.
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?

1. From Chart 2
2. Does the research involve only the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *
   ("Existing" means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)
3. YES
   a. Are these sources publicly available?
      - YES
         - Research is exempt under 45 CFR 46.101(b)(4) from all 45 CFR part 46 requirements.
      - NO
         - Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?
   - NO
      - Research is not exempt under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.
4. NO
   - Go to Chart 8

* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/policy/index.html#tissues and http://www.hhs.gov/ohrp/policy/index.html#stem, and on embalmed data or specimens at http://www.hhs.gov/ohrp/policy/index.html#embalmed for further information on these topics.

September 24, 2004
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

YES

Does the research or demonstration project involve only the study, evaluation, or examination of:

- Public benefit or service programs;

NO

Procedures for obtaining benefits or services under public benefit or service programs;

YES

Research is exempt under 45 CFR 46.101(b)(5) from all 45 CFR part 46 requirements.*

NO

Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs;

YES

Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs?

NO

Research is not exempt under 45 CFR 46.101(b)(5)

NO Go to Chart 8

* Note: See OHRP guidance on exemptions at http://www.hhs.gov/ipirp/index.html#exempt for further description of requirements for this exemption.

September 24, 2004
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

From Chart 2

Does the research involve only a taste and food quality evaluation or a food consumer acceptance study?

YES

Are wholesome foods without additives consumed?

YES

Research is exempt under 45 CFR 46.101(b)(6) from all 45 CFR part 46 requirements.

NO

Is food consumed that contains a food ingredient, 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?

NO

Research is not exempt under 45 CFR 46.101(b)(6).

YES

Go to Chart 8

September 24 2004
Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

- Has the research been previously reviewed and approved by the IRB using expedited procedures?
  - YES
  - NO

- Have conditions changed such that the research is no longer eligible for expedited review (e.g., protocol change or experience shows research to be of greater than minimal risk)?
  - YES
  - NO

- Research is eligible for IRB review through expedited procedures.
  - YES
  - NO

- Have any additional risks been identified since IRB review at a convened meeting?
  - YES
  - NO

- Has the IRB documented and reviewed the research at a convened meeting that the research involves no greater than minimal risk?
  - YES
  - NO

- Category 9
  - (a) For this site:
    - Is the research permanently closed to enrollment of new subjects?
    - Have all subjects completed all research-related interventions?
    - Does the research at this site remain active only for long-term follow-up of subjects?
  - NO
  - YES

- (b) Have no subjects been entered at this site?
  - NO
  - YES

- Are the remaining research activities at this site limited to data analysis?
  - NO
  - YES

- September 24, 2004
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?

**Note:** If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply (45 CFR 46.116(c)).

From Chart 8 or 9

Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of 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? (45 CFR 46.116(c)(3))

YES  NO

Will the research or demonstration project be conducted by or subject to the approval of state or local government officials? (45 CFR 46.116(c)(1))

YES  NO

Will the research involve greater than minimal risk, as defined in Section 46.102(1)? (45 CFR 46.116(b)(1))

YES  NO

Is it practicable to conduct the research without the waiver or alteration? (45 CFR 46.116(b)(3))

YES  NO

Will waiving or altering the informed consent adversely affect the subjects' rights and welfare? (45 CFR 46.116(b)(2))

YES  NO

Will pertinent information be provided to subjects later, if appropriate? (45 CFR 46.116(b)(2))

YES  NO

Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.

Go to Chart 11

If informed consent is not waived entirely

YES

If it is practicable to conduct the research without the waiver or alteration? (45 CFR 46.116(b)(3))

YES  NO

No waiver of informed consent or alteration of consent elements is allowed.

September 24, 2004

*Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/policy/index.html for further information on emergency research informed consent waiver.
Chart 11: Can Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

From Chart 10

Would the consent document be the only record linking the subject and the research, and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(a)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

AND

IRB may require investigator to provide subjects with a written statement regarding the research. [45 CFR 46.117(c)]

NO

IRB may NOT waive the requirement for a signed consent form for any subjects.

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research. [45 CFR 46.117(c)(1)]

Subject's wishes will govern whether informed consent is documented. [45 CFR 46.117(c)(1)]

September 24, 2004
## Criteria for Approval

### 1. Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

**Points to Consider:**
- Consider physical, psychological, social, legal, and economic risks.
- Has the appropriate departmental scientific review occurred?
- Are the aims and objectives clearly defined?
- Are there adequate preliminary data and is there appropriate justification for the research?
- Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?
- Are there qualified staff and resources to conduct the research?
- Is there appropriate monitoring of the subject during and after the research?
- Are medical or psychological resources available that participants might require as a consequence of the research?
- Are adequate references provided?

**Comments:**

### 2. HIPAA Requirement

**Points to Consider:**
- HIPAA is not required.
- HIPAA Authorization Confirms with University’s model language
- HIPAA is not required for all RowanSOM faculty

**Comments:**

### 3. Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

**Points to Consider:**
- Consider physical, psychological, social, legal, and economic risks.
- Are procedures that will answer the scientific question being performed anyway?
- If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm?
- Is there a clear differentiation between research and standard of care procedures?

**Comments:**

### 4. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

**Points to Consider:**
- Consider physical, psychological, social, legal, and economic risks. Are the risks and benefits adequately described?
- Does the investigator have access to a population that will allow recruitment of the necessary number of participants?
- Does the investigator have sufficient time to conduct and complete the research?
- Is the research and timeline for completion feasible?
- Does the knowledge expected to result have importance?
- Are there adequate plans to notify the subjects about the research results (clinical issues, suicidal, referrals)

**Comments:**
5. Brochures and Publications

**Points to Consider:**
- Drug/device brochure or research proposal included
- Previous publications (for studies involving drugs/device PDR info or websites) pertinent to the study submitted.

6. Advertisement

**Points to Consider:**
- Radio, video, web, e-mail or newspaper ad provided
- Advertisement says it is a research
- It is free of coercive language
- Mentions remuneration
- Responsibility for costs.

7. Enrollment Information

**Points to Consider:**
- How many subjects are to be enrolled at Rowan/RowanSOM
- Who is to be enrolled?
  - a. Healthy volunteers
  - b. Ill subjects
  - c. Minors
  - d. Pregnant women, fetuses or neonates
  - e. Prisoners (if prisoners, if you are prisoner advocate, mark yes in comments column)
  - f. Decisionally impaired subjects
  - g. Subject population is appropriate for study
  - h. Students
  - i. Equitable selection process

The process requires consideration of the extent to which a proposed subject population is already burdened by poverty, illness, poor education, or chronic disabilities in deciding whether they are the appropriate population for the proposed study. Does procedures investigator will be using ensure that everyone has an equal chance of being selected with appropriate consent, free of coercion by not being in a position to make vulnerable decision making position, providing accurate information (without deception) and the rights to privacy and confidentiality respected.

8. Selection of participants is equitable.

**Points to Consider:**
- Consider the purpose of the research.
- Are the inclusion and exclusion criteria adequately defined and equitable?
- Are there populations vulnerable to coercion and undue influence and has this been addressed?
- Are there acceptable procedures for screening subjects prior to recruitment?
- If there is exclusion of women, minorities, and other vulnerable populations are they justified?

**Comments:**

9. Inclusion Criteria:

**Points to Consider:**
- Subject’s inclusion criteria delineated and rationalized?

10. Exclusion Criteria:

**Points to Consider:**
- Are subject’s exclusion criteria correctly delineated and rationalized?
11. Recruitment procedures are acceptable

**Points to Consider:**
- Is the setting, location and timing of recruitment appropriate for the research being conducted?
- Are recruitment methods well defined and appropriate for the population?
- Are all recruitment materials non coercive, and easily understood?

**Comments:**

12. The research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants. *(Not applicable if the research involves no more than minimal risk.)*

**Points to Consider:**
- Does the protocol adequately specify:
  - Who will monitor the data?
  - What data will be monitored?
  - How frequently will data be monitored?
  - What analyses will be performed on the data?
  - What decision rules (e.g., stopping rules) will be considered?
- Is there a plan to promptly detect unexpected harms or an increase in frequency or severity of harms?
- Is there an adequate plan to stop the protocol if benefits are proven to outweigh harms or harms are proven to outweigh benefits?

**Comments:**

13. There are adequate provisions to protect the privacy of participants.

**Points to Consider:**
- Will participants have an expectation of privacy?
- Will participants think that the information sought by the investigator is appropriate?
- Will participants be comfortable in the research setting?
- Are there adequate provisions to consider and assure the privacy of the subject?

**Comments:**

14. There are adequate provisions to maintain the confidentiality of the data.

**Points to Consider:**
- Is confidentiality assured?
- Are there adequate provisions to protect the confidentiality of the data?
- Will data release cause risk of harm?
- Are appropriate techniques being used to protect confidentiality (storage, coding, use of identifiers)
- Does the protocol specify where the data and consent form will be stored?

**Comments:**

15. Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence. *(do not complete if these populations are not included)*

**Points to Consider:**
- If the research involves pregnant women, fetuses, or neonates complete Research Involving Pregnant Women, Fetuses, or Neonates checklist.
- If the research involves prisoners complete Research Involving Prisoners checklist.
- If the research involves children complete Research Involving Children checklist.
- If the research involves a surrogate consent process complete Research Involving Use of Surrogate Consent Process checklist.
16. Drugs, Biologics, Devices  □ NA

**IF THE PROTOCOL INVOLVES THE TESTING OF DRUGS & BIOLOGICS select category as appropriate:**

a. □ Drug is marketed / FDA-approved & will be used as marketed/approved.

b. □ Drug is investigational and research is conducted under IND. IND information included and investigational drug brochure is attached.

c. □ Drug is marketed but being studied in an off label indication. IND information included

d. □ Drug is marketed but being studied in an off label indication. PI claims no IND is required.

In order for no IND to be required all of the following must be true:
- The results will not be reported to the FDA as a well controlled study in support a new drug indication for use will it be reported or to support any significant change in the labeling of the drug?
- The study is not intended to be reported to the FDA in support of a new indication for use or to support any other significant change in labeling.
- The study is not intended to support a significant change in the advertisement for the product.
- The study does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks associated with the use of the product.)
- The study is conducted in compliance with the requirements for CCI review and informed consent.
- The study is conducted in compliance with the requirements for the promotion and sale of drugs.

Do you agree that all the above are true?  □ YES  □ NO

Comments:

16b. If protocol involves the testing of Devices complete and select appropriate:

a. □ Sponsor categorizes investigational device as significant risk (SR) and IDE is provided.

b. □ Sponsor categorizes investigational device as non-significant risk (NSR)

   In order for the device to be considered a NSR, all the following must true:
   
   - is not intended as an implant to remain more than 30 days in the human body and does not present a potential for serious risk to the health, safety, or welfare of a subject;
   - is not purported or represented to be for a use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject;
   - is not for a use of substantial importance in diagnosing, curing, mitigating, treating, or otherwise preventing impairment of human health and does not presents a potential for serious risk to the health, safety, or welfare of a subject
   - the device does not present a potential for serious risk to the health, safety and welfare of the subject.

Do you agree that the following are true?  □ YES  □ NO

d. □ Device is marketed / FDA-approved & will be used as marketed/approved

e. □ 510(k) is marketed / FDA-approved & will be used as marketed/approved  □ documentation attached

f. □ Humanitarian Use Device □ documentation attached

Comments:

10 C. Does the protocol describe acceptable accountability, storage, access, and control of the drug or device?  □ YES  □ NO

Comments:

17. CONSENT FORM AND DOCUMENTATION OF CONSENT

*a. Complete if there is a request Complete WAIVER OF INFORMED CONSENT (no consent obtained by any method) NA □

Do you agree that the following are true?  □ YES  □ NO

1. The research involves no more than minimal risk to the subjects
2. The waiver/alteration will not adversely affect the rights and welfare of the subjects
3. The research could not practically be carried out without the waiver or alteration, and
4. When appropriate, the subject will be provided with pertinent information after participation.
17c. Complete if Informed Consent will be appropriately documented in accordance with the regulations  NA

18. HIPAA authorization conforms with University's model authorization language?  YES  NO

19. Collaborative Research:
- Outside collaborators are directly involved  YES  NO
- Outside IRB has approved the study (if necessary)  YES  NO
- Outside collaborators have signed agreement with Rowan/RowanSOM to enroll subjects in this study  YES  NO
- Name of the institution and approval from outside institution included  YES  NO

1. Review the consent document verifying that it contains the following required elements:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>YES</th>
<th>NO</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>A statement that the study involves research.</td>
<td></td>
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<tr>
<td>An explanation of the purposes of the research.</td>
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<tr>
<td>An explanation of the expected duration of the participant’s participation.</td>
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<tr>
<td>A description of the procedures to be followed.</td>
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<tr>
<td>Identification of procedures that are experimental. (May be omitted if there are none.)</td>
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<tr>
<td>A description of any reasonably foreseeable risks or discomforts to the participant. (May be omitted if there are none.)</td>
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<tr>
<td>A description of any benefits to the participant or to others, which may reasonably be expected from the research. (May be omitted if there are none.)</td>
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<tr>
<td>A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the participant. (May be omitted if there are none.)</td>
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<tr>
<td>A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. (May be omitted if confidentiality will not be maintained.)</td>
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<tr>
<td>A statement that notes the possibility that the Food and Drug Administration may inspect the records (May be omitted for research that is not FDA-regulated.)</td>
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<tr>
<td>An explanation as to whether compensation is available if injury occurs. (May be omitted if the research involves no more than minimal risk.)</td>
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</tr>
<tr>
<td>If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. (May be omitted if the research involves no more than minimal risk.)</td>
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</tr>
<tr>
<td>An explanation as to whether any medical treatments are available if injury occurs. (May be omitted if the research involves no more than minimal risk.)</td>
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<tr>
<td>An explanation of whom to contact for answers to pertinent questions about the research.</td>
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<td></td>
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</tr>
<tr>
<td>An explanation of whom to contact for answers to pertinent questions about the research participant’s rights.</td>
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<tr>
<td>An explanation of whom to contact in the event of a research-related injury to the participant. (Note: May not be omitted just because the research involves no more than minimal risk.)</td>
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</tr>
</tbody>
</table>
Contact information for the research team for questions, concerns, or complaints. □ YES □ NO

Information for someone independent of the research team for problems, concerns, □ YES □ NO

A statement that participation is voluntary. □ YES □ NO

Statement that refusal to participate will involve no penalty or loss of benefits to which participant is otherwise entitled. □ YES □ NO

A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. □ YES □ NO

A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. (Look for when research involves investigational drugs/devices, novel procedures involving risk, or where a goal of the research is to define safety.) □ YES □ NO □ NA

A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.) □ YES □ NO □ NA

Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. (Look for when the protocol mentions this as a possibility.) □ YES □ NO □ NA

Any additional costs to the participant that may result from participation in the research. (Look for when additional costs are expected.) □ YES □ NO □ NA

The consequences of a participant's decision to withdraw from the research. (Look for when withdrawal from the research will have adverse consequence.) □ YES □ NO □ NA

Procedures for orderly termination of participation by the participant. (Look for when such procedures are part of the protocol.) □ YES □ NO □ NA

A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. (Look for on long-term clinical trials.) □ YES □ NO □ NA

The approximate number of participants involved in the study. □ YES □ NO □ NA

The amount and schedule of all payments to the participant. □ YES □ NO □ NA

Comments: 

15d. Complete if the investigator has requested use of the short form

Short Form Used? □ YES □ NO

(There is a provision in the regulations to allow verbal explanation of the research followed by the subject signing a brief statement that the research was explained. This is used most frequently when an interpreter is used for a non-English speaking subject.)

Comments: 

16. Complete if this project is federally funded and Rowan is the primary awardee

□ YES □ NO
<table>
<thead>
<tr>
<th>17. Reviewer’s Final Assessment/Opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk Level</strong></td>
</tr>
<tr>
<td>☐ Minimal Risk</td>
</tr>
<tr>
<td>☐ Greater than minimal risk</td>
</tr>
<tr>
<td><strong>Approval</strong></td>
</tr>
<tr>
<td>☐ No changes: there is an acceptable risk/benefit ratio and protocol and consent document are acceptable as submitted</td>
</tr>
<tr>
<td><strong>Conditional Approval</strong></td>
</tr>
<tr>
<td>☐ Minor changes needed in the informed consent document, protocol or other study materials</td>
</tr>
<tr>
<td>☐ Administrative review (typos, missing signatures)</td>
</tr>
<tr>
<td>☐ Review by Chair or designee</td>
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<tr>
<td>☐ Review by Subcommittee</td>
</tr>
<tr>
<td><strong>Deferral</strong></td>
</tr>
<tr>
<td>☐ (For Expedited Research) Refer to Full Board</td>
</tr>
<tr>
<td>☐ Clarifications or additional information is required regarding a specific aspect of study</td>
</tr>
<tr>
<td>☐ There is an unacceptable risk/benefit ratio, because (check all that apply):</td>
</tr>
<tr>
<td>☐ Protocol poorly written, lacking significant amounts of information regarding scientific justification, study procedures, risk reduction, etc.</td>
</tr>
<tr>
<td>☐ It is possible that a response for the investigator could alter the risk/benefit ratio</td>
</tr>
<tr>
<td>☐ There are ethical concerns that can be addressed by obtaining more information or requiring changes in study design and procedures</td>
</tr>
<tr>
<td><strong>Disapproval</strong></td>
</tr>
<tr>
<td>☐ Risks significantly outweigh the benefit or value of the knowledge to be gained</td>
</tr>
<tr>
<td>☐ There are significant ethical concerns or questions that result in the study being unacceptable</td>
</tr>
<tr>
<td>☐ YES</td>
</tr>
<tr>
<td>☐ NO</td>
</tr>
<tr>
<td>☐ YES</td>
</tr>
<tr>
<td>☐ NO</td>
</tr>
</tbody>
</table>

You may attach a marked up copy of the consent/assent forms and/or other study materials with any edits, changes, typos or suggested wording. Circle word/phrases that need to be rewritten in lay language or clarified. Please make clear which comments are suggestions and which are required.

Additional Comments/Questions you would like the Principal Investigator to address:

(Blank space for additional comments/questions)

8-13-2013