TITLE: Requests for Exemption Review and Determination

1.0 PURPOSE

The purpose of this standard operating procedure is to set forth the policies and procedures the VA Central IRB will follow in determining whether requests for exemption from IRB review meet exemption requirements as specified in federal regulations.

2.0 REVISION HISTORY

Date of Initial Approval	July 18, 2009
Prior Revision Dates	April 20, 2009 September 24, 2009 March 27, 2010

3.0 SCOPE

This standard operating procedure applies to all members of the VA Central IRB, the support staff, and to investigators submitting requests for exemption from IRB review to the VA Central IRB. At this time, the VA Central IRB will only review requests for exemption submitted by Principal Investigators/Study Chairs of multi-site projects and investigators within VHACO program offices designated for review by the VA Office of Research and Development (ORD).

4.0 POLICY

4.1 It is the policy of the VA Central IRB that it will review requests for exemption submitted by investigators on research activities that are in one or more of the categories specified in VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research. The VA Central IRB will make a determination based on regulatory and VHA criteria, and document the results of the determination in writing.

4.2 Investigators may not make the exemption determination but must request appropriate review and receive a written determination from the VA Central IRB before considering the research exempt.

4.3 Research involving prisoners and focused on pregnant women may not be eligible for determinations of exemption under 38 CFR 16.101(b). There are restrictions on the use of exemption for research involving children. FDA-regulated research may only be exempt if it meets the category as described in 21 CFR 56.104(d).

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

.0 RESPONSIBILITIES

6.1 Investigators – Investigators are responsible for completing all forms required by the VA Central IRB when requesting an exemption of research from 38 CFR 16(b) or 21 CFR 56.104(d) and for providing adequate justification based upon the requested category on which their exemption request is based. Investigators may not make their own exemption determinations.

6.2 Designated Reviewers – A designated Reviewers is a scientific voting member of the VA Central IRB designated in writing by a VA Central IRB Co-Chairs to be responsible for reviewing the request for exemption on behalf of the VA Central IRB. The designated reviewer provides a recommendation to the VA Central IRB Co-Chair regarding the exempt determination or defers the review to a convened VA Central IRB meeting and providing an explanation for such deferral.

6.3 VA Central IRB Co-Chairs – A VA Central IRB Co-Chair approves requests for exemption and signs all approval documents resulting from completed reviews upon recommendation of a designated reviewer. A VA Central IRB Co-Chair can also defer the final decision regarding the exemption determination to a convened IRB meeting for review. A VA Central IRB Co-Chairs can act as a designated reviewer.

6.4 VA Central IRB Coordinator – The VA Central IRB Coordinator organizes all documents for review by the VA Central IRB Co-Chair, and/or a reviewer designated by the Co-Chair and prepares review documents for completion. If an exemption decision is made, the VA Central IRB Coordinator forwards the decision to the investigator and maintains copies of all documentation in the project files.

6.5 VA Central IRB Administrator – The VA Central IRB Administrator reviews all documents prepared by the VA Central IRB Coordinator for accuracy and completeness prior to forwarding them to the VA Central IRB Co-Chair for signature. The VA Central IRB Administrator prepares a listing of all approved exemptions for notification of the VA Central IRB at the next regularly scheduled meeting and ensures that the listing of approved exemptions is incorporated into the VA Central IRB meeting minutes as an attachment. The VA Central IRB Administrator also ensures that the designated reviewer letter is kept up-to-date and that all VA Central IRB members receive training on any new guidance regarding exemption of research.

7.0 PROCEDURES

7.1 Investigator Requests. Investigators may submit to the VA Central IRB requests for exemption from IRB review on research activities that are in one or more of the categories listed in 38 CFR 16.101(b) or 21 CFR 56.104(d).

7.1.1 The investigator will complete VA Central IRB Form 105, Request for Exemption of Research (Attachment 1), and submit this form, along with a copy of the scientific protocol to the VA Central IRB Administrative Office.

7.1.2 The investigator cites on the VA Central IRB Form 105 the specific exemption category under which the exemption is being requested and provides adequate justification.

7.2 VA Central IRB Administrative Office Initial Processing. The VA Central IRB Administrative Office processes all VA Central IRB 105 forms received as follows:

7.2.1 The VA Central IRB Administrator logs the project and Request for Exemption into the project tracking database and assigns the project a tracking number. The VA Central IRB Administrator also reviews the request to ensure the following and takes action accordingly:

7.2.1.1 If the research involves prisoners or focused on pregnant women, the research cannot be exempted and the investigator will be instructed to submit a VA Central IRB Form 108 New Project Application.

7.2.1.2 If the Request for Exemption does not meet any of the above restricted populations the VA Central IRB Administrator loads all documents received onto the VA Central IRB shared drive and assigns the project to a VA Central IRB Coordinator for further processing.

7.2.2 The VA Central IRB Coordinator ensures all required documentation is included with the request. If the request for exemption package is not complete the VA Central IRB Coordinator contacts the investigator requesting the additional information.

7.2.3 Once the request for exemption package is complete, the VA Central IRB Coordinator forwards the package, along with a VA Central IRB Form 106, Determining Whether Human Research is Exempt from 38 CFR 16 (Attachment 2), to a VA Central IRB member who has been designated in writing by a VA Central Co-Chairs to perform such reviews, or directly to one of the Co-Chairs per discussion with the VA Central IRB Administrator.

7.3 Review Process. The designated reviewer or Co-Chair reviews the request for exemption package and makes an exemption determination based on the criteria specified on the VA Central IRB Form 106 and federal regulations.

7.3.1 In performing the review, the designated reviewer, or the convened VA Central IRB as applicable, ensures the following issues have been adequately addressed for each project reviewed:

7.3.1.1 That the research does not involve any of the restrictions detailed in paragraph 7.2.1.1. If it does, the VA Central IRB Form 106 is completed accordingly and immediately returned to the VA Central IRB Coordinator.

7.3.1.2 Does the research have a sound research design? The designated reviewer ensures that the background, objectives, description of research, and the role of participants is adequate to permit a determination regarding the request for exemption.

7.3.1.3 Are the risks to participants minimal and is the research ethical?

7.3.1.3.1 If the designated reviewer determines that the research has associated risk that is greater than minimal, even if all other criteria for exemption are met, an exemption determination will not be made by the reviewer and the project will be deferred to a convened VA Central IRB Board review.

7.3.1.3.2 If the reviewer has any doubt that the research proposed meets the ethical standards as set forth in the Belmont report, an exemption determination will not be made, even if the protocol is technically exempt, and the designated reviewer defers the project to a convened VA Central IRB Board review.

7.3.1.4 Does the research meet the requirements of the Health Insurance Portability and Accountability Act (HIPAA)? Does it require a waiver or alteration of HIPAA authorization?

7.3.1.4.1 The designated reviewer ensures data security procedures are adequate and in accordance with VA guidelines, and that the anonymity and confidentiality of subjects is protected. The reviewer determines that any data or materials gathered are to be recorded in such a manner that neither the data nor materials can be linked back to the participant. The designated reviewer may contact the VA Central IRB Privacy Officer Representative for guidance if required.

7.3.1.4.2 If the reviewer has issues about the project meeting the requirements of exemption from IRB review or issues related to HIPAA authorizations, including waiver of HIPAA authorization, the project will be deferred for review at a convened VA Central IRB meeting.

7.3.2 If any portion of the project is unclear, the designated reviewer will not make a determination. Instead, the designated reviewer documents the items requiring clarification on the VA Central IRB Form 106, and returns it to the VA Central IRB Coordinator. The designated reviewer can either request clarification from the investigator or defer the review to a convened meeting of the VA Central IRB.

7.3.2.1 If the reviewer requests clarification from the investigator, the VA Central IRB Coordinator contacts the investigator in writing and requests any clarifications. A copy of the VA Central IRB Form 106 may be forwarded to the investigator to assist in making a response.

7.3.2.2 Once a response is received, the VA Central IRB Coordinator sends a new VA Central IRB Form 106, a copy of the original form, and the investigator's clarifications or revised project to the same designated reviewer. The designated reviewer then completes the exemption determination process in accordance with paragraph 7.3.3 below if satisfied with the investigator's response. If there are still issues that need to be addressed, the process is repeated.

7.3.3 In determining that a project meets one or more exemption categories, the designated reviewer, or the convened VA Central IRB as applicable, will take the following issues into consideration depending upon the exemption category requested:

7.3.3.1 A request for exemption under Category 1 on VA Central IRB Form 106 will not be granted if a project involves evaluation of new instructional strategies or a deviation from normal practices. If an educational practice or setting is altered in any significant way for the purposes of the research, an exemption will not be granted.

7.3.3.2 An exemption under Category 2 on VA Central IRB Form 106 will not be granted if a project involves survey research that deals with sensitive and private aspects of the participants' behaviors, such as sexual preferences, substance abuse, or illegal conduct. Research involving cognitive or diagnostic testing will not be exempted if the testing is psychologically invasive in nature, such as a detailed personality inventory, and could cause the participant some discomfort or distress.

7.3.3.3 If a request for exemption under Category 3 on VA Central IRB Form 106 is received, one of the VA Central IRB Co-Chairs will serve as the designated reviewer. If the exemption criteria are not met the investigator will be instructed in writing to revise and resubmit the project addressing any outstanding issues or to revise the project and re-submit as a non-exempt protocol.

7.3.3.4. An exemption under Category 4 on VA Central IRB Form 106 will not be granted if any of the data or materials will be collected after the project is submitted for review or if there is any type of linkage, to include codes, to the participants' identifiers.

7.3.3.5 A request for exemption under category 5 on VA Central IRB Form 106 will be coordinated with the Office of Research and Development to fulfill all requirements for the Under Secretary for Health's review and signature.

7.3.3.5.1 Requests for exemption under Category 5 on VA Central IRB Form 106 are reviewed by the designated reviewer to ensure the project meets the exemption criteria but then is deferred to the convened VA Central IRB for additional review. The VA Central IRB will make a recommendation to grant or not grant the exemption. This recommendation will then be forwarded in writing with the request for exemption project package to the Chief Research and Development Officer (CRADO) for review and additional concurrence by the Office of Research Oversight and the Office of General Counsel as applicable. After the CRADO concurs, it is subject to final approval by the applicable Department or Agency Head.

7.3.3.5.2 The final exemption determination will be made by the Under Secretary of Health. The VA Central IRB will include in the package for review, a draft letter for the signature of the Under Secretary of Health to the investigator approving or disapproving the request.

7.3.3.5.3 If an exemption was granted by the Under Secretary of Health, the VA Central IRB Coordinator informs the investigator in writing and forwards all applicable documentation to the investigator, keeping a copy in the project folder. If an exemption is not granted by the Under Secretary of Health, the investigator is instructed in writing to revise and resubmit the project, addressing any outstanding issues, or to revise the project and resubmit as a non-exempt project application.

7.3.3.6 An exemption under Category 6 on VA Central IRB Form 106 will not be granted if it involves consumption by the participant of any type or volume of food that has any potential risks. Projects that involve the consumption of alcohol, vitamins, or other dietary supplements do not qualify for exemption. Category 6 in 38 CFR 16.101(b) is basically identical in wording to the only exemption category described in 21 CFR 56.104(d) for FDA-regulated research applicable to projects reviewed by the VA Central IRB.

7.3.4 After completing all applicable portions of the form relating to the applicable exemption category, the designated reviewer returns the form to the IRB Coordinator in a timely manner, but no less than **ten** working days after

receipt. If the designated reviewer determines that he/she has a conflict of interest, the reviewer will not complete the review but will complete the applicable portion of the VA Form 106 and return it to the VA Central IRB Coordinator, who will then consult with the VA Central IRB Co-Chair to re-assign the project to another designated reviewer.

7.3.5 Upon receipt of a completed VA Central IRB Form 106 from a designated reviewer in which exemption of the research is recommended and a category of exemption designated, the VA Central IRB Coordinator prepares a VA Central IRB Form 107, VA Central IRB Approval of Request for Exemption of Research from 38 CFR 16 (Attachment 3) for the signature of one of the VA Central IRB Co-Chair. If the designated reviewer deferred the review to a convened IRB meeting, the VA Central IRB Administrator adds the review to the agenda of the next regularly scheduled meeting.

7.3.6 After review of the completed VA Central IRB Form 107 by the VA Central IRB Administrator, the VA Central IRB Coordinator forwards it to one of the VA Central IRB Co-Chairs, along with a copy of the VA Central IRB Forms 105 and 106, and the rest of the project package.

7.3.6.1 If the VA Central IRB Co-Chair concurs with the exemption recommendation, the VA Central IRB Form 107 is signed and returned to the VA Central IRB Coordinator.

7.3.6.2 The VA Central Co-Chair may also elect to defer the final exemption determination to a convened VA Central IRB meeting. The VA Central Co-Chair will then return the VA Central IRB Form 107 to the VA Central IRB Coordinator with instructions to schedule the project for review at the next regularly scheduled IRB meeting.

7.3.7 For all approved exemptions, the VA Central IRB Coordinator logs the approval into the VA Central IRB project tracking system and forwards a copy of the VA Central IRB Form 107 to the PI/SC within **five** working days of the approval determination being made.

7.4 Report of Approved Exemptions. All requests for exemption that were approved are reported as an agenda item at the next regularly scheduled meeting of the VA Central IRB. The VA Central IRB Administrator lists all approved exemptions since the last convened meeting on the agenda, to include the project title, principal investigator, exemption category, and date of approval. After notification of members via the meeting agenda, the listing is incorporated as an attachment to the meeting minutes.

7.5 Documentation. Copies of all documentation generated by the VA Central IRB, to include copies of VA Central IRB Forms 106, 107, and any other correspondence between the investigators and the VA Central IRB or support

staff are kept on file in the project folder. All exemption determinations made by the VA Central IRB at a convened committee meeting are recorded in the meeting minutes.

7.6 Local Site Review. Projects that have received an exempt determination must still be reviewed and approved in accordance with VHA Handbook 1200.05 before the project can be initiated. The PI/SC is responsible for obtaining this approval and for forwarding the exemption determination made by the VA Central IRB to all participating sites as applicable.

7.7 Designated Reviewer Letter. The VA Central IRB Administrator ensures that the letter appointing qualified designated reviewers is reviewed on a yearly basis by a VA Central Co-Chair and updated as needed.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research

8.3 45 CFR 46, Department of Health and Human Services, Protection of Human Subjects

8.4 21 CFR 56, U.S. Food and Drug Administration, Institutional Review Boards

8.5 OPRR Reports, 95-02, Exempt Research and Research that May Undergo Expedited Review

3 Attachments
1. VA Central IRB Form 105, Request for Exemption of Research
2. VA Central IRB Form 106, Determining Whether Human Research is Exempt From 38 CFR 16
3. VA Central IRB Form 107, VA Central IRB Approval of Request for Exemption of Research from 38 CFR 16

I have reviewed and approved the content of this SOP.

K. Lynn Cates, MD
Director, PRIDE

Date: 4/2/2010

Request for Exemption of Research

This form is used by investigators to request an exemption from the requirements of VHA Handbook 1200.05 and further VA Central IRB review. Note: If the research involves vulnerable populations to include prisoners, children, the mentally disabled, those with impaired decision-making capacity, or the economically disadvantaged, it will not be considered for exemption by the VA Central IRB. If the research is FDA-regulated research, it is only eligible for exemption under Category 6.

I. Project and Principal Investigator/Study Chair General Information

Title of Project:

Principal Investigator/Study Chair:

VA Facility Name:

VA Facility Station Number:
(If you are unsure, check online here.)

Telephone:

VA Facility Address:
Line 1:
Line 2:
Line 3:

Email:

Fax:

EXEMPTON NUMBER CLAIMED ***(Circle Category Claimed in Section V):***

1 2 3 4 5 6

II. Checklist

The following mandatory materials are included as part of this Request for Exemption in separate attachments:

- ☐ Copy of Protocol
- ☐ Investigator CV

The following checked materials are included if used as part of the research project:

- ☐ Survey Instruments
- ☐ Recruitment Advertisements
- ☐ Questionnaires
- ☐ Interview Questions
- ☐ Cover Letters
- ☐ Administrative Letters

Other:

III. Project Objectives

Briefly describe your project objectives and the research questions to be answered.

IV. Project Population and Confidentiality of Data

Please respond to all of the below. Indicate N/A if not applicable.

1. Describe the population to be included in this project.

2. Describe recruitment procedures, if applicable.Include inclusion and exclusion criteria and attach any surveys, questionnaires, recruitment materials, or cover letters. If participants are students or employees, describe how you avoid undue influence.
   ☐ N/A

3. Describe the research risks to the participants.

4. How will the privacy and confidentiality of the participants and their data be maintained and protected? *Include how the data will be collected, analyzed, coded, stored, and transmitted to others.*

5. Will a link be maintained to identify participants? ☐ Yes ☐ No ☐ N/A
   If yes, please identify the link, justify its use, and detail who will keep and have access to the link.

6. Will participants receive any payment for participating in the study? ☐ Yes ☐ No ☐ N/A
   If yes, please describe type and amount of payment.

V. Exemption Category Justification – (Check and complete the category section(s) under which you are requesting an exemption.

☐ **Category 1**

- Research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  a. Research on regular and special education instructional strategies, or
  b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2**

- Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless:
  a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  b. Any disclosure of the 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.

☐ **Category 3**

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2, if:
  a. The subjects are elected or appointed public officials or candidates for public office, or
  b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information must be maintained throughout the course of research and thereafter.

☐ **Category 4**

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

☐ **Category 5**

- Research and demonstration project is conducted by, or subject to, the approval of department or agency heads, and that are designed to:
  a. study, evaluate, or otherwise examine public benefit or service programs,
  b. procedures for obtaining benefits or services under such programs,
  c. possible changes in or alternatives to such programs,
  d. and possible changes in methods or levels of payments for benefits or services under such programs.

NOTE: The determination of exempt status for these research and demonstration projects must be made by the Under Secretary for Health on behalf of the Secretary of the Department of Veterans Affairs, after consultation with the Office of Research and Development, the Office of Research Oversight, the Office of General Council, and other experts, as appropriate.

☐ **Category 6**

Please Note: If your project involves FDA-regulated products, Category 6 is the only category of exemption that can be submitted for a determination of exemption by the VA Central IRB.

The research involves a taste and food quality evaluation and consumer acceptance studies if one of the following is true.

☐ Wholesome foods without additives will be consumed.

☐ A food will be consumed that contains a food ingredient at or below the level to be safe and for a use found to be safe

☐ A food will be consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

1. Describe the setting where the research will take place.

2. Does the consumption of the food have any potential risks such as indigestion or vitamin deficiencies? ☐ Yes ☐ No

3. Does this research involve the consumption of alcohol, vitamins, or other types of dietary supplements? ☐ Yes ☐ No

VI Investigator Assurance and Certification

As the Principal Investigator/Study Chair for this project, I certify the following:

☐	The information provided on this Request for Exemption and all associated attachments is complete and accurate to the best of my knowledge.
☐	If the VA Central IRB determines that the submitted project is exempt, I as the Principal Investigator/Study Chair maintain responsibility for the ethical conduct of the research and for safeguarding the rights and welfare of all involved human participants.
☐	This research does not focus on pregnant women or involve prisoners.
☐	I will not modify the project without contacting the VA Central IRB to ensure the project remains exempt.
☐	I will ensure a VA-approved educational training program on Human Research Subjects Protections is completed by all project team members involved in the conduct of this human subjects research project.
☐	The research will be conducted in such a manner as to comply with all VA policies and procedures, as well as all applicable federal, state, and local laws regarding the protection of human participants, to include data security requirements.
☐	I will notify the VA Central IRB upon completion of the project.

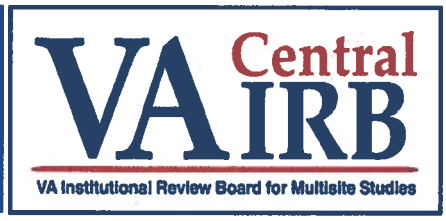
_____ _____

Signature of Principal Investigator /Study Chair Date

_____

Printed Name of Principal Investigator/Study Chair

Determining Whether Human Research is Exempt



I. *(To be completed by VA Central IRB Coordinator)*

Project Number	
Title of Project	
Principal Investigator/Study Chair	
Designated Reviewer	

II. *(To be completed by Designated Reviewer for all protocols)*

General Project Questions	**YES**	**NO**
1. Does the research focus on pregnant women or prisoners? *(If yes, the project is not eligible for an exemption.)*	☐	☐
2. Were the background, objectives, description of the research and the role of participants clear so as to make an informed decision regarding this exemption request?	☐	☐
3. Does the investigator provide adequate justification to support determination of exemption based upon the exemption category cited?	☐	☐
4. Do the risks to the participants in this project meet the regulatory definition of "minimal risk ?"	☐	☐
5. Does the research meet the requirements of the Health Insurance Portability and Accountability Act (HIPAA)?	☐	☐
6. Is the anonymity and confidentiality of the participants protected?	☐	☐
7. Are data security procedures adequate and do they meet all VA requirements?	☐	☐

If the answer to question one was "YES" and/or the answers to any of questions 2 through 7 were "NO", the protocol may not qualify for an exemption. Please provide a description of the issues in the space provided below then skip Section III, sign and date section IV. and return this form to the VA Central IRB Coordinator.

If the answer to question one was "NO" and the answers to questions 2 through 7 are yes, please answer the following additional questions regarding this study and then complete Section III.

Additional Questions if Project Meets Above Criteria	YES	NO
1. Is the selection of participants equitable?	☐	☐
2. If there are interactions with the participants, is there a need for a disclosure process for participants that describes the following:	☐	☐
a. That the activity involves research	☐	☐
b. A description of the procedures involved in the study	☐	☐
c. That participation in the study is voluntary	☐	☐
d. Name and contact information of the investigator?	☐	☐

III. *(To be completed by Designated Reviewer)*

Exemption Category – Select the exemption category(ies) that applies to the materials submitted by the PI/SC.

☐ **Category 1**

- Research is conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
  a. Research on regular and special education instructional strategies, or
  b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Category 2**

- Research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior unless:
  a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  b. Any disclosure of the 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.

☐ **Category 3**

- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior that is not exempt under Category 2, if:
  a. The subjects are elected or appointed public officials or candidates for public office, or
  b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information must be maintained throughout the course of research and thereafter.

☐ **Category 4**

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

☐ **Category 5**

- Research and demonstration project is conducted by, or subject to, the approval of department or agency heads, and that are designed to:
  a. study, evaluate, or otherwise examine public benefit or service programs,
  b. procedures for obtaining benefits or services under such programs,
  c. possible changes in or alternatives to such programs,
  d. and possible changes in methods or levels of payments for benefits or services under such programs.

NOTE: The determination of exempt status for these research and demonstration projects must be made by the Under Secretary for Health on behalf of the Secretary of the Department of Veterans Affairs, after consultation with the Office of Research and Development, the Office of Research Oversight, the Office of General Council, and other experts, as appropriate.

☐ **Category 6**

Please Note: If your project involves FDA-regulated products, Category 6 is the only category of exemption that can be submitted for a determination of exemption by the VA Central IRB.

The research involves a taste and food quality evaluation and consumer acceptance studies if one of the following is true.

☐ Wholesome foods without additives will be consumed.

☐ A food will be consumed that contains a food ingredient at or below the level to be safe and for a use found to be safe

☐ A food will be consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

IV. *(To be signed by Designated Reviewer and returned to VA Central IRB Coordinator)*

☐	This project is NOT eligible for exemption. **Please indicate reason for determination:**
☐	This project is eligible for exemption under Exemption Category(ies)
☐	This project's exempt determination status is unclear. The project is deferred for further review at a convened VA Central IRB meeting.
☐	I have a conflict of interest and am returning this form without making a determination.

_____ _____

Signed Date

Correspondence

VA Central IRB
VA Institutional Review Board for Multisite Studies

From: VA Central IRB **Date:**

TO:

(Principal Investigator/Study Chair)

(Facility Address)

SUBJECT: Determination of Request for Exemption of Human Subjects Research from IRB Review and Approval

1. The VA Central IRB received your request for exemption from IRB review and approval for the following project:

   Title of Project:

2. We are pleased to notify you that your request has been determined to be exempt on (insert date) under the below indicated exemption number.

   Exemption Category Number: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

3. Please note the following requirements applicable to this exemption determination by the VA Central IRB:

   - The research cannot start until approved in accordance VHA Handbook 1200.01.
   - You must notify the VA Central IRB when you have received final approval to begin the research.
   - If an amendment or modification to the project may change the exempt status, it must be submitted to the VA Central IRB for determination of whether the project remains exempt.
   - Upon completion of the research, notify the VA Central IRB that you have completed the exempt project.
   - As the Principal Investigator, you still have ultimate responsibility for the ethical conduct of the research and for the protection of the rights and welfare of all human subjects involved in the research.
   - Submission of a yearly status report to the VA Central IRB that no changes have been made in the project that would cause a change in the exempt status of the project will be required. You will receive and reminder notification when this requirement is due.

4. Any questions concerning the protection of the rights and welfare of the subjects under this project or for any other administrative issue pertaining to this project and the functions and responsibilities of the VA Central IRB can be addressed to the VA Central IRB Administrator at (Phone) or e-mail (address).

Signature Block of VA Central IRB Co-Chair Date

SAMPLE