NEIRB
New England Institutional Review Board

Request for Review of Claim of Exemption

Research activities involving human subjects that are exempt from IRB review are identified in 45CFR 46.101(b)(1)-(6). Those persons who have authority to make a determination of what research is exempt are expected to be well-acquainted with interpretation of the regulations and the exemptions. The federal government advises that investigators should not have the authority to make an independent determination that research involving human subjects is exempt and should check with the IRB or other designated authorities concerning the status of proposed research or changes in ongoing research. (OPRR Report dated May 5, 1995).

If you wish to have NEIRB make a determination on the possible exempt nature of your research, please complete this form and send to New England IRB, 85 Wells Avenue, Suite 107, Newton, MA 02459 or fax to New England IRB at 617-969-1310. Contact New England IRB at 617-243-3924 with any questions.

If you are seeking review for a project which commenced prior to July 27, 1981, please contact New England IRB at 617-243-3924.

Instructions: All submissions must have Sections 1, 2, 9 and 10 completed and most require that Section 3 is completed. For Sections 4-8, complete only the Section(s) applicable to your project. All submissions must also include:

- Rationale for Exempt Category Claimed/Description of Project
- CVs for Principal Investigator and all Sub-Investigators
- Medical Licenses for Principal Investigator and Sub-Investigators (if applicable)

Section 1: General Project Information

1. ProjectTitle:	Medicaid Emergency Psychiatric (Services) Demonstration (MEPD) Evaluation
2. Funding Source:	U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services

Principal Investigator Information

1. Name:	Crystal Blyler
2. Telephone Number:	(202) 250-3502
3. Fax Number:	(202) 863-1763
4. Email:	cblyler@mathematica-mpr.com

Sub-investigator Information

1. List Names:	Bonnie O'Day Melissa Azur ☐ **None**

Location of Research
Company/Site Name: Mathematica Policy Research
Street Address: 1100 1st Street, NE, 12th Floor
City: Washington State: DC Zip Code: 20002

X☐*Check here to have invoices sent to this location*

Will the PI be conducting and/or supervising study related activity at any sites not under the jurisdiction of this IRB? If yes, please provide name and address for each location AND documentation of approval to conduct research at these sites. *Note: Additional IRB approval may be required from these sites if an individual at this site is obligated to use another IRB.*

X☐No
☐ Yes

IRB Contact Information (if different from PI)

1. Name:	Brenda Natzke
2. Company Name:	Mathematica Policy Research
3. Telephone Number:	(202) 484-3287
4. Fax Number:	(202) 863-1763
5. Email:	bnatzke@mathematica-mpr.com
☐*Check here to have invoices sent to this location*	

Regulatory Information

Answer each question below:	**Yes**	**No**
A. Is the activity funded or support by HHS?	X	
B. Is the activity subject to an OHRP assurance?		X
C. Is the data supporting a FDA regulated clinical trial or being used to support a marketing application to FDA?		X
D. Does your research involve pregnant women, fetuses, prisoners including individuals on probation, or individuals with impaired decision-making capacity?	X	
E. Does the activity meet the definition of minimal risk: (the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).	X	

Section 2: Is the Activity Research Involving Human Subjects?

Answer each question below:	**Yes**	**No**
A. Is the activity a systematic investigation designed to contribute to generalizable knowledge?	X	
B. Does the activity involve obtaining information about living human subjects?	X	
C. Does the activity involve intervention or interaction with individually identifiable human subjects?	X	
If all questions are answered "No" the project may not meet the definition of research. Skip to Section 9. ***If any questions are answered "Yes" go to Section 3.***		

Section 3: Is the Research Involving Human Subjects Eligible for Exemption?

If the only involvement of human subjects will be in one or more of the following categories, check each category below as applies. If the research involves activities beyond the activities listed below, please contact NEIRB at 617 243 3924.	**Applicable?**	**If Applicable, Go To:**
A. Research conducted in established or commonly accepted educational settings, involving normal educational practices.		Section 4
B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) for which subjects cannot be identified, or release of the information would not be harmful to the subject.		Section 5
C. Research involving the use of survey procedures or interview procedures or observation of public behavior for which subjects cannot be identified, OR release of the information would not be harmful to the subject.		Section 5
D. Survey or interview of public or elected officials. Testing of public officials.		Section 5
E. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available OR if the information is recorded by the Investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.		Section 6
F. Research and demonstration projects that are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study or evaluate public benefits or services or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.	**X**	Section 7
G. Taste and food quality evaluation and consumer acceptance studies.		Section 8
H. Unidentifiable human body parts, sections or samples obtained from a morgue.		Section 9

Section 4: Exemption for Educational Settings

Answer each question below:	Yes	No
A. Is the research only conducted in established or commonly accepted educational settings, involving normal educational practices?		
B. Does the research involve only normal education practices?		
C. Does the research involve children/minor subjects?		

Section 5: Exemption for Tests, Surveys, Interviews, Public Behavior

Answer each question below:	Yes	No	N/A
A. Does the research involve only the use of educational tests, survey procedures, interview procedures, or observation of public behavior?			
B. Does the research involve the use of survey procedures, interview procedures, or observation of public behavior where the investigator participates in the activities being observed?			
C. Is the information recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects?			
D. Are the human subjects elected or appointed high level public officials or candidates for public office?			
E. If data are to be recorded by audiotape is there potential harm to subjects if the information is revealed or disclosed?			
F. Will subjects be videotaped?			
G. If the subjects may be identifiable in the research project records either by name, picture or through demographic data, is there potential harm to participants if the information is revealed? *That is: will data collection include sensitive information (e.g. illegal activities, or sensitive themes such as sexual orientation, sexual behavior, undesirable work behavior, or other data that may be painful or very embarrassing to reveal, such as death of a family member, memories of physical abuse, or finally will such sensitive information be requested about other individuals known to or related to the participant?*			
H. Will children/minor subjects be enrolled?			
I. Does any federal statute require that the confidentiality of any personally identifiable information will be maintained throughout the research and thereafter?			

Section 6: Exemption for Existing Data Documents and Specimens

Answer each question below:	Yes	No
A. Does the research involve only the collection or study of data, documents, record or specimens which existed prior to the submission of this application?		
B. Is the information being studied or collected publicly available?		
C. Will the information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers? *(i.e., the Investigator will not retain sufficient demographic information that might reasonably lead to the identification of individual subjects – name, phone number, address* ***or*** *any code number that can be used to link the Investigator's data to the source record – medical record number, social*		

security number, student record number, club membership number or employee number etc.).		

Section 7: Exemption for Public Benefit or Service Programs

Answer each question below:	Yes	No
A. Is the research conducted or approved by the Department or Agency head?	X	
B. Does the research involve only the study, evaluation or examination of public benefit or service programs?	X	
C. Does the research involve only the study, evaluation or examination of procedures for obtaining benefits or services under public benefit or service programs?	X	
D. Does the research involve only the study, evaluation or examination of possible changes to or alternatives to public benefit or service programs?	X	

Section 8: Exemption for Food Taste and Acceptance Studies

Answer each question below:	Yes	No	N/A
A. Does the research involve only a taste and food quality evaluation or a food consumer acceptance study?			
B. Are wholesome foods without additives consumed?			
C. If the test product includes a food ingredient, agricultural chemical or environmental contaminant, is it at or below a level determined to be safe by the FDA, EPA or Dept of Agriculture?			
D. Will children/minor subjects be enrolled?			

Section 9. Rationale for Exempt Category Claimed

Attach or write a brief specific description of the procedure(s) involving the human subjects in sufficient detail to demonstrate to the IRB reviewer that the research protocol meets the requirements for each category of exemption claimed in this human subjects research protocol. The text should be approximately 300 words or less on separate sheets in sufficient detail to allow the reviewer to judge exemption criteria. The description should include the following:

- The objective of the research project and background of study.
- The rationale for the use of the selected subject population & plans for recruitment & consent.
- The procedures that will be performed to generate research data & risks, if any, to subjects.
- Steps to be taken to protect the privacy and/or confidentiality of subjects.
- Include copy of questionnaires, surveys or brief outline of questions to be asked.

- If there will be direct interaction with subjects, a description of the consent process.

Section 10: Principal Investigator's Assurance

I certify that the information provided in this claim of exemption is complete and correct. I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects and the ethical conduct of this research protocol, including the protection of subjects' privacy. I agree to comply with all New England IRB policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

- The project will be performed by qualified personnel according to the research protocol,
- Maintaining a copy of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human subjects for at least three years following termination of the project,*
- Necessary review by New England IRB will be sought if changes made in the research protocol may result in the research no longer meeting the criteria for exemption.

By signing this form, I agree that I have read, understand and agree to the above policy concerning IRB exempt protocols. I am not obligated to use another IRB for this project.

Crystal R. Blyler — Principal Investigator

11/6/13 — Date

*Note: We plan to destroy the data at the end of the project.