ETR IRB Form 11: Outcome of Review Notice

ETR IRB Outcome of Review Notice Sent: 12/2/2020
Date

Project Name: Harm Reduction Toolkit for Non-Prescription Syringe Sales in Community Pharmacies	Principal Investigator: Regina Firpo-Triplett, MPH
ETR IRB #: 105	Approval Period: from 9/30/2020-9/30/2022
Funding Source: Centers for Disease Control and Prevention	Contract / Grant #: 000HCVJC-2020-49096

The ETR IRB has reviewed the above referenced project. ETR's Federalwide Assurance (FWA) number with the Department of Health and Human Services, Office for Human Research Protections is FWA00000283.

ETR IRB review Date: 12/2/2020

✓	Review Outcome	Explanation *(If additional space is needed note attachment in box below.)*	Date for Continuing Review
✓	Approval granted as submitted.		NA
	Conditional approval granted.		
	Not approved. Study terminated.		

Type of Review	**Full** [1]	**Expedited** [2] *(note Category 1-9 from table 1 below)*	**Exempt** [2] *(note Scenario A – F from table 2 below)*
Initial Application		Category 7	
Continuing Review			
Protocol Revision /Addendum			
Adverse Event			
Protocol Violation			
Closure			
Other, please specify			

[1] Full review is conducted by the entire IRB at a convened meeting.
[2] Expedited and Exempt reviews are conducted by the ETR IRB Chair on an as needed basis.

Tonya Matthews
Approval Signature of the ETR IRB Chair

12/2/20
Date

TABLE 1: The activities approved in the federal regulations for **Expedited** Review are:
1. Clinical studies of drugs and medical devices.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
8. Continuing review of research previously approved by the convened IRB. Where (a) the research is permanently closed to enrollment of new subjects; (ii) all subjects have completed all research-related interventions; (iii) and the research remains active only for long-term follow-up; or (b) where no subjects have been enrolled, and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Source: http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm

TABLE 2: To qualify as **Exempt**, a protocol must be no more than minimal risk **AND** must only involve human subjects as described in one or more of the following scenarios
A. Research conducted in established educational settings, involving normal educational practices, such as: i. research on education instructional strategies, or ii. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
B. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observation of public behavior UNLESS: i. information is recorded with identifiers linked to the subjects AND ii. subjects' responses could place subjects at risk (e.g., criminal or civil liability, financial standing, employability or reputation).
C. Research involving educational tests, surveys, interviews, or observation of public behavior is exempt if: i. the subjects are elected or appointed public officials or candidates for public office; or ii. federal statute requires confidentiality of identifiable information to be maintained permanently.
D. Research involving the collection or study of existing data, documents, or records. Sources must either be publicly available or information must be recorded without identifiers linked to the subjects.
E. Research conducted by or subject to the approval of Federal Department or Agency head, and designed to study or evaluate: 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 iv. changes in methods of payment for benefits under those programs.
F. Taste and food quality evaluation involving wholesome/safe foods.

Source: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.110