AMERISPEAK SURVEY
IRB APPLICATION FORM—INITIAL REVIEW

To check off the "check boxes" in this document, double-click on a check-box, and select "Checked" under the "Default value."

This form has been designed to be completed for all survey projects that will utilize AmeriSpeak panels. Only survey/interview proposals utilizing AmeriSpeak should be described on this form. All other research proposals should be submitted on the full length Initial Submission form.

The completion of this form indicates that the proposed work meets all of the requirements for human subjects research. In addition, you attest that the proposed work does ***not*** involve registration on the Clinical Trials.gov website; COI disclosure due to funding by a U.S. Public Health Service Awarding Component* or by the National Science Foundation;

1. SUMMARY INFORMATION

1.1 Project Number (If the project does not yet have a PN but requires IRB review, submit the proposal number or the charge code for the department overhead.)

7984

1.2 Study Title

Test Predictability of Falls Screening Tools

1.3 Contact information for study personnel:

Principal Investigator/Client Contact:	Erin Parker, Elizabeth Burns
Institution:	Centers for Disease Control and Prevention (CDC)
Email Address:	Erin Parker – vig4@cdc.gov Elizabeth Burns – ync7@cdc.gov

Project Director: *(N/A if same as PI)*	Bess Welch
Institution:	NORC at the University of Chicago
Email Address:	welch-bess@norc.org

Contact Person: *(N/A if same as PD)*	N/A
Financial Analyst:	Nakia Sprouse

1.4 NORC departments responsible for this study

NORC Department:	Public Health
Other (Specify):	N/A

1.5 Specify whether this study is initiated internally by NORC or externally by an NORC client.

[ ] Internal/NORC ***If Internal/NORC, select one:***

[ ] Profile Survey
[ ] Panel Management/Engagement Survey
[ ] Marketing/Promote AmeriSpeak
[ ] Methodological Research
[ ] Other

[X] External / NORC

1.6 Who is funding the study? (If NORC is a subcontractor, include both the names of the original client/funding agency and the prime institution which has subcontracted out to NORC.)

Centers for Disease Control and Prevention (CDC)

1.7 Is NORC the awardee institution for a federal grant for this study?

☐ **Yes.** **If Yes,** you must submit a copy of the grant application or proposal to the IRB with your protocol submission
☒ **No.**

1.8 Is this research proposal being reviewed by one or more IRBs at institutions other than NORC?

☐ **Yes.** Complete 1.7.1.
☒ **No.**

1.7.1 What other IRB(s) are reviewing this research?

N/A

Attach copy of IRB approval if this study has been reviewed and approved by another IRB

1.9 Other Collaborating Institutions

If you are collaborating with other institutions to carry out the research, provide the name of each institution (including subcontractors and subrecipients) and describe the type of involvement of each institution (e.g., recruitment, enrollment/consenting, study procedures, follow-up, data analysis).

Name of Institution	Describe Involvement
None	

Note: Tabbing out of the bottom right cell will insert another row if needed.

2. TRAINING REQUIREMENTS

It is the **responsibility** of the **Principal Investigator/Project Director** to ensure that **all individuals involved in the conduct of human subjects research complete** human subjects protection **training prior to submission** of the project to the IRB for review, and when new personnel join a project after initial IRB approval. The requirement to undergo human subjects protection training applies to all persons with a **significant role in the conduct of the research**, including those individuals designated as:

- Principal Investigators and Co-investigators,
- Individuals named on a study grant or contract proposal,
- Individuals named as a contact person in the informed consent document(s) or recruitment materials for research,
- Individuals who obtain informed consent from prospective participants in research, and
- Individuals who obtain and analyze individually identifiable data

Proof of human subjects training does NOT need to be submitted for telephone and field interviewers working on a research project.

Per NORC IRB policy, **human subjects' protection training must be renewed every 5 years.** The options for renewing training are discussed on the IRB webpage on the Intranet.

2.1 Please list in the table below the names of all investigators and other key research personnel for this project (i.e., the personnel who will have a significant role in the conduct of this research project – you do NOT need to list field/phone interviewers). If investigators/key research personnel are not NORC employees or affiliated with NORC, please indicate their institutional affiliation:

Investigators and other key research personnel:	Institutional Affiliation (if not employed by/affiliated with NORC)
Bess Welch	
Melissa Atlas	
Rosie Sood	
Vicki Pineau	
Stephanie Jwo	
Rosalind Koff	
Nada Ganesh	
Erin Parker	**CDC**
Elizabeth Burns	**CDC**
Robin Lee	**CDC**
Terri Head	**CDC**

2.2 Have all NORC investigators and key research personnel engaged in this research project completed training on the conduct of human subjects research within the past 5 years?

☒ **Yes.**
☐ **No.**

NOTE: If any NORC investigators or key research personnel on this project have not previously submitted a human subjects' protection training completion certificate to the NORC IRB, that certificate must be emailed to IRB@norc.org before the investigator/personnel can engage in human subjects' research.

3. SUMMARY OF PROPOSED SURVEY/INTERVIEW

3.1 Describe the objective(s) of the proposed survey including purpose, research question, hypothesis and relevant background information, etc. Submit a copy of the survey instrument/interview guide and FAQ's.

This survey will be fielded using the approved AmeriSpeak panel owned and operated by NORC. This submission is for the survey being fielded via the AmeriSpeak mechanism only, not for the AmeriSpeak panel recruitment or operation itself. A subsample of AmeriSpeak panelists aged 65 years or older and representative of US adults will be randomly selected to participate in this survey according to the approved AmeriSpeak protocols. Panelists may participate online using a computer, laptop, tablet, or smartphone that they have available to them. If none of these internet options are viable for a panelist or if the panelist prefers to participate in telephone interviews instead of online surveys, the NORC call center will be administering the panel surveys by phone. Panelists will be sent a pre-notification letter/invitation as they are for all new studies, and those who complete the baseline will be sent a falls tracking log and calendar, accompanied by a cover letter, to help them record falls in between the monthly surveys. During the baseline survey, panelists will be asked to identify a proxy to whom the AmeriSpeak team can reach out in case the panelist is unavailable or unable to be reached for a monthly follow-up survey (see Attachment B-8 for explanation of this procedure).

The goals of this study are to: 1) test the ability of existing falls screening tools to predict falls in the subsequent year; 2) assess how well questions predict falls for specific groups (e.g., gender, race, disability status); 3) design an effective and parsimonious screening tool for health care practitioners to identify community-dwelling adults 65 and older at risk for falls; and 4) assess how responses to questions change over time. The intended use of the resulting data is to evaluate current screening tools and potentially design a new screening tool for health care practitioners to identify community-dwelling adults 65 and older at risk for falls. The analysis will consider individual questions and groupings of questions that predict fall risk for multiple subgroups (e.g., gender, race, disability status) of adults 65 and older. Selected study findings may be published in peer-reviewed journals and presented in oral and poster presentations.

3.2 How will survey be completed? *(Check all that apply.)*

☒ **Internet** (link provided within email to panel members)

☒ **Phone Interview**

☐ **Paper Survey**

3.3 Will the survey be piloted prior to a main fielding?

☐ **Yes.** Complete 3.3.1.
☒ **No.**

3.3.1 How many pilot respondents will be needed?

____

3.3 How many months do you anticipate this research study will last from the time final approval is granted?

36

4. PARTICIPANT POPULATION

4.1 Expected number of recruited and expected number of participants.

Recruited: 2925

Participants: 1900

4.2 Expected Age Range.

Check all that apply.

☐ **0-7.** Include a parental consent script.
☐ **8-17.** Include a child's assent script and a parental consent script.
☐ **18-64.**
☒ **65 and older.**

NOTE: If this study proposes to include "**Children"** (anyone less than 18 years old), also complete and submit *Appendix C–Research that Involves Children*.

4.3 Describe the segment(s) of the panel recruited for this research. (i.e. Describe the target population.)

The target population for the Test Predictability of Falls Screening Tools project is community-dwelling adults aged 65 and older, since this is the population that is likely to experience falls.

4.4 Will respondents be recruited from other sources in addition to the AmeriSpeak panel?

☐ **Yes.** Complete 4.4.1.
☒ **No.**

4.4.1 Describe the recruitment plan for additional participants who are not part of AmeriSpeak.

5. INCENTIVE PLAN

5.1 Incentive points offered for survey/interview completion. Describe any multiple payment tiers used based on respondent attributes.

For the Test Predictability of Falls Screening Tools project, point incentives worth $5, $2, and $10 will be awarded to panelists for completing the baseline survey, each monthly update survey (or a proxy survey), and the final survey, respectively. Panelists who complete all 11 monthly update surveys will receive a bonus point incentive worth $10. Therefore, the greatest total amount of incentives a panelist will be able to receive for participation will be worth $47 (which averages to $3.62 per completed survey).

6. RISKS AND BENEFITS

All survey/interview research involves the possible risks of **Annoyance** and **Loss of time.**

6.1 Does the research involve any of these <u>additional</u> possible risks or harms to subjects?

Check <u>all</u> that apply.

- ☐ **Intrusive questions or procedures that might be regarded as an invasion of privacy** (right to control access to personal information and person, including biological specimens or image)
- ☐ **Presentation of materials or behaviors regarded as socially unacceptable and might lead to embarrassment**
- ☐ **Procedures that may result in mental or emotional stress**
- ☐ **Deception** (delaying informed consent about the true nature of the study until post-study debriefing)
- ☐ **Punishment** (subjects are denied a benefit for any reason)
- ☐ **Questions about drug use** (including caffeine, nicotine, etc.)
- ☐ **Disclosure of information that could lead to severe social stigma or job loss**
- ☐ **Disclosure of information that could be legally harmful to subject** (e.g., child abuse, criminal behavior, political repression, or immigration status)

6.2 What is the level of risk to subjects in this research study?

- ☒ **Not greater than minimal risk (see the note below for definition of minimal risk).**
- ☐ **Greater than minimal risk.**

NOTE: Studies eligible for Exemption or Expedited Review must involve no more than minimal risk. **Minimal risk is defined by the federal regulations as follows:** "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."

7. CONFIDENTIALITY OF DATA

7.1 Will you be recording any direct identifiers (e.g., names, social security numbers, addresses, telephone numbers, etc.)**?**

- ☐ **Yes.** Complete 7.1.1.
- ☒ **No.**

7.1.1 Explain which direct identifiers will be recorded and why it is necessary to record findings using these identifiers. Describe the coding system you will use to protect against disclosure of these identifiers.

7.2 Will you retain a link between study code numbers and direct identifiers after the data collection is complete?

- ☒ **Yes.** Complete 7.2.1.
- ☐ **No.**

7.2.1 Explain why this is necessary and state how long you will keep this link.

Linkage between study code numbers and direct identifiers are needed to maintain complete history of panel member activities, incentives, and to support any inquiries from panel members. Such linkage will be kept for as long as a panelist is participating in the panel and after a panelist stops participating in the panel as required by law (currently operationalized as seven years). As mentioned in the Privacy Policy document (see IRB Protocol 13.05.02 Attachment D), a panelist can request a deletion of their data at any time by contacting the NORC Privacy Compliance Office. NORC will honor such request within 7 days of receipt of the request.

7.3 Will you provide the link or identifier to anyone outside the research team?

☐ **Yes.** Complete 7.3.1.
☒ **No.**

7.3.1 Explain why and to whom the link or identifier will be provided outside of the research team.

7.4 The AmeriSpeak security provisions from the original submission described to protect this data (password protection, encryption, etc.) **states:**

"Direct identifier data will be kept secure through NORC's data security policies and procedures in a separate panel and survey data databases. This data will be kept for as long as a panelist is participating in the panel and up to 7 years after a panelist stops participating in the panel. As mentioned in the Privacy Policy document, a panelist can request a deletion of their data at any time by contacting the NORC Privacy Compliance Office through US mail or emailing privacy@amerispeak.org. NORC will honor such request within 7 days of receipt of the request. The NORC Privacy Compliance Office will be staffed by Mike Boyer in the NORC contracts office."

7.4.1 Will this project require security provisions different from the above plan?

☐ **Yes.** Complete 7.4.2
☒ **No.**

7.4.2 Describe the data security provisions that will be used for this project.

7.5 Are you planning to obtain a Federal Certificate of Confidentiality for this research (or a Privacy Certificate from the National Institute of Justice)?

☐ **Yes.**
☒ **No.**

NOTE: A "**Certificate of Confidentiality"** helps researchers protect the privacy of human research participants enrolled in sensitive research. A Certificate of Confidentiality protects against

compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. The NORC IRB has issued a Guidance on Certificates of Confidentiality, which is available on the IRB intranet page at http://intranet.norc.org/resources/irb/default.aspx

For research funded by the National Institute of Justice, a Privacy Certificate is required rather than a Certificate of Confidentiality—see the NIJ website for further guidance on obtaining a Privacy Certificate.

8. INFORMED CONSENT PROCESS

AmeriSpeak panel surveys will be issued a waiver of documentation of consent.

NOTE: If research subjects are minors, it is necessary to complete *Appendix C—Research that Involves Children* to provide the IRB with more complete information about how you plan to conduct the consent and assent process.

8.1 State the research specific informed consent statement for each mode of data collection.

N/A. The AmeriSpeak surveys do not have a specialized informed consent for each survey. AmeriSpeak panelists consent to participate in AmeriSpeak surveys as part of their recruitment into the panel during the Registration Recruitment Core Adult Profile (RRCAP) survey. Please see Appendix B Waiver of Consent.

8.2 Describe other ways the elements of informed consent will be conveyed to those screened and to potential participants. Describe project specific screeners, emails, letters, and CATI scripts and submit applicable documents with this protocol.

N/A see 8.1

9. IRB SUBMISSION CHECKLIST

9.1 Check off below all the submission materials that apply to your project. Be sure to include them with your submission.

☒ **Appendix B** – Waiver or Alteration of Informed Consent (when one or more required elements of informed consent is not included in the consent process).

☐ **Appendix C** – Research that Involves Children.

☐ **Consent (and if applicable, assent) script for telephone interviews**

☒ **Surveys/interview scripts**

☐ **Approval certificates issued by any other IRBs reviewing this research**

10. INVESTIGATOR ASSURANCE

10.1 Read the investigator assurance statement below, and sign to indicate your acceptance. A signature is required from the Principal Investigator or the Project Director. The signature may be typed in if the protocol is submitted electronically from the email account of the Principal Investigator, the Project Director, or an authorized member of the project team; otherwise, please send a signed hard copy of this page to the IRB office.

The information provided in this form is correct. I have evaluated this protocol and determined that I have the resources necessary to protect participants, such as adequate funding, appropriately trained staff, and necessary facilities and equipment. I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc. I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. I will report in writing any significant new findings which develop during the course of this study which may affect the risks and benefits to participation. I will not begin my research until I have received written notification of final IRB approval. I will comply with all IRB requests to report on the status of the study. I will maintain records of this research according to IRB guidelines. The grant that I have submitted to my funding agency which is submitted with this IRB submission accurately and completely reflects what is contained in this application. If these conditions are not met, I understand that approval of this research could be suspended or terminated.

Principal Investigator: _____ **Date:** _____

Project Director: BESS WELCH **Date:** 3/29/17