Study Title: Comparative Tests of Flu Vaccination Phone Messages
Summary of Research Protocol
October 30, 2017

This project is an unfunded research collaboration between Emmi Solutions, Inc., and a team of academic research investigators led by Brian J. Zikmund-Fisher, Ph.D. of the University of Michigan.

Emmi Solutions provides services that educate, support, remind, and ultimately prompt people to take actions toward better health on behalf of various clients, which include individual physicians or medical practices, hospital systems, and health insurance companies. As part of their service to their clients, Emmi deploys outbound, automated, Interactive Voice Response phone calls with the outlined variations to patients identified by Emmi's clients as eligible for the flu vaccine.

This study will begin by gaining consent from specific clients of Emmi Solutions to share de-identified data collected on their patient populations with the investigators for the purpose of investigating the effectiveness of different telephone scripts at promoting behavioral intentions related to vaccination.

Calls will be made at times and at a rate specified by Emmi's clients using Emmi's in-house automatic deployment system. Pre-recorded messages that adjust to patient responses will follow interaction outlines, or "scripts" developed by Emmi for the purpose of encouraging uptake of seasonal influenza vaccination. Contact information and basic demographic information about each patient is provided by the client based on their own processes and is confidentially maintained by Emmi as part of their services.

Within each client's list of patients, Emmi will randomly assign patients to receive different versions of the flu call script. Patients of larger clients will be randomized among the full set of experimental arms, while patients of smaller clients may be randomized among a smaller subset of arms to ensure statistical power for comparisons within each client's patient set, with the decision to be based on the size of the provided patient list.

As part of Emmi's standard process, each call includes one or more questions that recipients can answer during the call (e.g., by saying "yes" to the question). For the calls included in this study, at least one question will measure patients' behavioral intentions to receive an influenza vaccine.

Emmi's database records each patient's responses over the course of the call and generates one report of all patients' responses for Emmi's clients to review. This report includes Protected Health Information, such as patient names and phone numbers.

As part of this research, however, Emmi will then de-identify the reports to meet the standards of the Health Insurance Portability and Accountability Act and then send the de-identified response reports, as well as linked demographic information and call timing data, and send them to the investigators via Secure File Transfer Protocol, the preferred trusted protocol used between Emmi and their clients. Each patient record will not include any Protected Health Information and will be identified only by a unique identification number. Only Emmi will maintain and have access to the mapping algorithm that could enable matching of individual records to contact information or other protected health information.

Certain clients of Emmi also have access to other information about their patients, such as data that may indicate whether a patient actually obtains an influenza vaccination during the 2017-2018 influenza season. If clients share these data with Emmi, Emmi will in turn share with investigators (again, only using the unique patient id number and secure file transfer) for inclusion of these variables in analyses.

The research investigators (led by Dr. Zikmund-Fisher) will then conduct statistical analyses to determine if the rates of behavioral intentions to vaccinate (and actual vaccination status, when available) differed among the study arms. After preliminary bivariate analyses (e.g., chi-squared analyses), logistic regression analyses will control for variation among clients (both because client populations vary in unmeasured ways and because call timing will be different for different clients) and include available demographic information when possible.