PennState

HRP-591 - Protocol for
Human Subject Research

Protocol Title:

Provide the full title of the study as listed in item 1 on the "Basic Information" page in CATS IRB (http://irb.psu.edu).

Choosing an Effective Healthcare Spokesperson: An Interactive Intervention

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Version Date:

Provide the date of this submission. This date must be updated each time the submission is provided to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

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Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable. See "HRP-103- Investigator Manual, When do I have to register my project at ClinicalTrials.gov?" for more information.

NCT04599166

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1.0 Objectives

1.1 Study Objectives

Advance care planning (**ACP**) is the process of thinking through and articulating in advance one's preferences for future medical care. It has long been promoted as a way for people to receive medical treatment consistent with their values, goals, and preferences. While ACP typically involves decision-making about specific life sustaining treatments, choosing *who* will make medical decisions when the patient cannot is considered by many to be the single most important ACP action a person can take. When patients fail to designate a healthcare spokesperson (henceforth **spokesperson**), it leads to uncertainty about who will make medical decisions, what treatments are to be accepted or declined, and on what basis[4]–which can lead to familial conflict, unwanted and costly medical care, and avoidable patient suffering. So, too, when patients choose the "wrong" person to represent them, their wishes are less likely to be known or respected. Our own research suggests that when patients prefer fewer aggressive medical treatments, there is significantly lower concordance between spokespersons' decisions and patients' wishes.

Patients, families, and ACP experts have identified several qualities as being especially important for spokespersons to have. Ideally, they should know the patient's values, be available when needed, be trustworthy and caring, have good judgment, and be able to stand up under pressure. That said, many individuals (and state laws) assign spokespersons on the basis of relationship (spouse, parent, etc.) rather than personal qualities. Surprisingly, no interventions (to our knowledge) are explicitly designed to help people consider the *actual* qualities of the person they choose, much less *engage* this individual to confirm they can fully represent the patient's wishes should the need arise.

To address these gaps, we have developed a novel intervention that includes a "serious game" to help people consider the qualities they want in their spokesperson, then engage the person they choose for this role. Combining a serious topic with an enjoyable activity ("gamification"[11]) has been effective at changing health related behaviors in multiple settings with our target population ("sandwich generation" and older adults). The game element of our intervention, *"Who Would You Choose: Serious Fun"* (**WWYC**), prompts players (using scenarios and metaphors) to choose a spokesperson whose qualities are best suited to the role. At the end of the game, players identify a real-life spokesperson based on the qualities considered during gameplay. Then, using an online interface, WWYC will spark communication between the player and their chosen spokesperson. The long-term goal of this project is to help people make more thoughtful and informed choices when selecting a spokesperson, and to help these spokespersons be better prepared for their role as surrogate decision-makers. The current mixed methods study proposed here is designed to learn whether and how WWYC helps individuals select an appropriate spokesperson for healthcare decisions, as assessed via three **Specific Aims**:

Aim 1 (QUALITATIVE): To explore how playing a novel game affects people's choice of a spokesperson. Qualitative focus groups will be used to examine the group experience playing WWYC. One-on-one interviews will be used to explore how the game affected individual players' thought process for choosing a spokesperson, and whether that choice changed as a result of game-play.

Aim 2 (QUANTITATIVE): To establish that WWYC is a feasible way to help individuals choose and engage a spokesperson. We will judge WWYC as feasible if:

- We can efficiently recruit 100 individuals to play the game;
- $\geq$75% of game players report that playing the game is helpful for choosing a spokesperson;
- $\geq$75% of game players endorse the game, as measured by the Net Promoter Score;
- $\geq$75% of spokespersons engage with WWYC (using its online interface) following player request

Aim 3 (CONVERGENT MIXED METHODS): To integrate qualitative and quantitative data via a joint display to explain how the experience of playing WWYC relates to their spokesperson's willingness to

engage. We hypothesize that positive player experience with WWYC will be associated with successful engagement with their spokesperson.

If successful, this study will establish the feasibility of a serious game for helping people choose a spokesperson for medical decision-making, and result in the creation a fully functional prototype (including its online interface). We will then be positioned to conduct a randomized controlled trial evaluating the efficacy of WWYC (compared to standard methods) for improving concordance between patients' wishes and spokespersons' decisions on their behalf.

1.2 Primary Study Endpoints

Successful completion of data collection of 800 participants (400 players and 400 spokespersons) who play the "Who Would You Choose" game.

1.3 Secondary Study Endpoints

Establish feasibility of game intervention

2.0 Background

2.1 Scientific Background and Gaps

The value of advance care planning (**ACP**, which includes the key task of choosing a spokesperson) has a strong **scientific premise** grounded in decades of randomized controlled trials and public health research. Engaging in ACP: 1) reduces unwanted end-of-life medical interventions: 2) decreases stress; and 3) reduces end-of-life costs by up to 36%. Despite the importance of choosing a healthcare spokesperson, there are surprisingly little data on how to optimize that choice. To our knowledge, no studies examine how best to get people to designate a spokesperson, or how to choose a spokesperson who can/will accurately represents one's wishes. Our own research demonstrates that (for a given clinical scenario) spokespersons do a poorer job representing patients' wishes when patients desire less aggressive care (see *Preliminary Studies*). Moreover, in many states, unless next of kin are formally designated as spokesperson, they (by law) cannot decline life-sustaining treatment unless the patient is permanently unconscious or has an "end-stage condition."[31] Accordingly, to help respect patient autonomy and prevent unwanted end-of-life treatment, interventions are needed that prompt people to designate a spokesperson who can/will accurately represent their wishes when decisions need to be made. Though there is strong professional consensus about the qualities that make for a good spokesperson (is available, has good judgment, knows patient's values, etc.), little is known about which qualities the public considers most important, their rationales for choosing a spokesperson, or the best way to increase concordance between patients' wishes and spokespersons' decisions. A recent systematic review showed that the widely used intervention, Respecting Choices,[32,33] does increase advance directive completion rates and improve patient–spokesperson concordance, but the model is labor intensive, expensive to implement, and population specific. Less intensive ACP initiatives demonstrate much smaller effect sizes (10% increase in advance directive completion); difficulty getting people to make time for ACP); over-emphasis on static advance directive documents; and problems with implementation. Surprisingly, there is little research on how to help patients choose good spokespersons or prepare them for making treatment decisions. This is important because spokespersons often are unprepared to represent patients' wishes.[44]

What is needed are low-cost, high yield interventions that help people not only designate a spokesperson, but choose the *right* spokesperson. To succeed, such interventions must be appealing and readily scalable. This project will use the novel serious game, *Who Would You Choose: Serious Fun* (**WWYC**), to deepen our understanding of how people choose a spokesperson, and move us closer towards a scalable intervention for helping people optimize that choice.

2.2 Previous Data

Describe any relevant preliminary data.

We conducted feasibility and pilot testing of a revised WWYC game at 9 different venues with 93 participants (77% female, 25% minorities, see Table 3). Using a 10-point scale, we found that the majority of participants enjoyed playing the game (7.6 +/- 1.6), found it engaging (8.3 +/- 1.6), and would recommend it to others (7.3 +/- 2.3). More importantly, 84% (78/93) of participants reported that playing the game helped them "to think more deeply about the characteristics a healthcare spokesperson should have," and 75% (70/93) said it prompted them "to think more deeply about who should be their own healthcare spokesperson."

We refined the game by holding multiple informal game sessions to elicit feedback on game mechanics. Following modifications, we held formal game events using beta-versions of WWYC at 4 different venues (n=39 participants) with games facilitated by research staff to ensure rigor and fidelity. In post-game focus groups, players reported that playing WWYC was thought-provoking and enjoyable, and that it changed their views about choosing a spokesperson.

Table 3	**GAME (Stage 1A)**	**GAME (Stage 1B)**
Participants (n)	39	93
Female	9 (24%)	72 (77%)
Caucasian	18 (46%)	93 (75%)
Events (n)	4	9
Games (n)	8	18

2.3 Study Rationale

The serious game WWYC departs from standard ACP practice by transforming the task of "choosing a spokesperson" into a fun, engaging social activity that: 1) is self-contained; 2) does not require extensive training, resource investment, or infrastructure; 3) is readily scalable; and 4) leverages mobile technology (ie, smart-phones) to operationalize one's choice of a spokesperson and (eventually) assess whether that spokesperson knows one's wishes for healthcare. WWYC is innovative in that its purpose is not just to get people to choose a spokesperson, but to *improve* that choice –which no other initiative has explicitly attempted.
WWYC is different from typical efforts to designate spokespersons in that it is experiential, not didactic. It employs imaginative and metaphorical questions to help players consider key qualities of ideal spokespersons, to help them realize who in their own life embodies these qualities. This use of playful and thought-provoking questions represents a paradigm-shift for helping people engage in ACP. While other ACP-related games exist, WWYC is unique in its focus on the behavior of choosing a spokesperson, as opposed to prompting general conversations about values, goals, and beliefs.

While most ACP interventions emphasize the somewhat daunting assignment of creating detailed instructions for future medical care, WWYC focuses on a single task: identifying a spokesperson. WWYC will also provide opportunities and structure for meaningful engagement between individuals and their spokespersons. After completing game-play, the WWYC App will prompt players to 1) state which medical treatments they would want in various clinical scenarios, and then 2) send their spokesperson a request (and web link) to predict which medical treatments *they* (the spokesperson) think the player would want in those scenarios. As described in *Future Directions*, the WWYC App will eventually provide notifications to the player/spokesperson dyad about how their answers match up, and send tailored text messages that prompt discussions to help spokespersons be better prepared for their role.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

Participants must be:

- ≥18 years old
- able to read, write, and speak English
- have a working smart phone
- able and willing to forward post-activity survey to potential spokesperson

Spokesperson must be:

- ≥18 years old
- able to read, write, and speak English
- have a working smart phone

3.2 Exclusion Criteria

Participants will be excluded, if they are:

- <18 years old
- unable to read, write, and speak English
- not have a working smart phone
- unable or unwilling to forward post-activity survey to potential spokesperson

Spokesperson will be excluded, if they are:

- <18 years old
- unable to read, write, and speak English
- not have a working smart phone

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

n/a

3.3.2 Follow-up for withdrawn subjects

n/a

4.0 Recruitment Methods

4.1 Identification of subjects

To recruit participants, we will advertise via Study Finder, newspaper, radio, fliers posted in local community centers, places of worship, Penn State patient care areas, patient support groups, and word-of mouth of personal contacts, which may also include social media.

4.2 Recruitment process

4.2.1 How potential subjects will be recruited.

To recruit participants, we will advertise via Study Finder, newspaper, radio, fliers posted in local community centers, places of worship, Penn State patient care areas, patient support groups, and word-of mouth of personal contacts, which may also include social media.

4.2.2 Where potential subjects will be recruited.

Participants will be recruited throughout Pennsylvania and New Jersey regions.

4.2.3 When potential subjects will be recruited.

August 2021 to June 2023

4.2.4 Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their

eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB.

Interested participants will be informed about the study and screened for eligibility during that initial conversation (in person, via telephone, email or Zoom). Names, phone numbers, or emails will only be used for screening or scheduling purposes and will not be linked to Participant ID or data.

5.0 Consent Process and Documentation

5.1 Consent Process:

Check all applicable boxes below:

☐ **Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]***

☒ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

☐ **Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:

☐ **<u>Exempt Research at all Locations Except Penn State Health and the College of Medicine</u>: If you believe that the research activities outlined meet one or more of the criteria outlined in "HRP-312- Worksheet- Exemption Determination." Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in "HRP-590- Consent Guidance for Exempt Research"):**

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

If the research includes the use of student educational records include the following language in this section (otherwise delete): The parent or eligible student will provide a signed and dated written consent that discloses: the records that may be disclosed; the purpose of the disclosure; the party or class of parties to whom the disclosure may be made; if a parent or adult student requests, the school will provide him or her with a copy of the records disclosed; if the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.

Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator's assessment is inaccurate, an IRB Analyst will request revision to the protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB Review (see "HRP-312- Worksheet- Exemption Determination") is required or where otherwise requested by the IRB, informed consent forms for research activities

determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.

5.2 Obtaining Informed Consent

5.2.1 Timing and Location of Consent

Players:
Consent will be obtained at the time of the single study visit which will take place at Penn State Hershey Medical Center and public locations within the community.

Spokespersons:
Consent will be obtained within REDCap ahead of survey questions.

5.2.2 Coercion or Undue Influence during Consent

- Subjects will be notified in writing (see Summary Explanation of Research) that participation in this research is strictly voluntary.
- If the subject does not agree to participate, they will not be included in the study activities.
- Participants will be given as much time as needed to ask and have questions answered about the study and their decision whether to participate.

5.3 Waiver of Written Documentation of Consent

5.3.1 Indicate which of the following conditions applies to this research:

☐ The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

Describe the alternative mechanism for documenting that informed consent was obtained:

5.3.2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)

Players:
A Summary Explanation of Research will be provided prior to the start of study activities.

Spokespersons:
A Summary Explanation of Research will be provided within REDCap prior to the start of survey questions.

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

5.4.1 Indicate the elements of informed consent to be omitted or altered

Not applicable.

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

Not applicable.

5.4.3 Describe why the research involves no more than minimal risk to subjects.

Not applicable.

5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

Not applicable.

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

Not applicable.

5.4.6 Debriefing

Not applicable.

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

Not applicable.

5.5.2 Describe why the research involves no more than minimal risk to subjects.

Not applicable.

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

Not applicable.

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

Not applicable.

5.5.5 Additional pertinent information after participation

Not applicable.

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Not applicable.

5.6.2 Cognitively Impaired Adults

5.6.2.1 Capability of Providing Consent

Not applicable.

5.6.2.2 Adults Unable to Consent

Not applicable.

5.6.2.3 Assent of Adults Unable to Consent

Not applicable.

5.6.3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

Not applicable.

5.6.3.2 Assent of subjects who are not yet adults

Not applicable.

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

Not applicable.

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Not applicable.

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Not applicable.

6.3 Waiver or alteration of authorization statements of agreement

Not applicable.

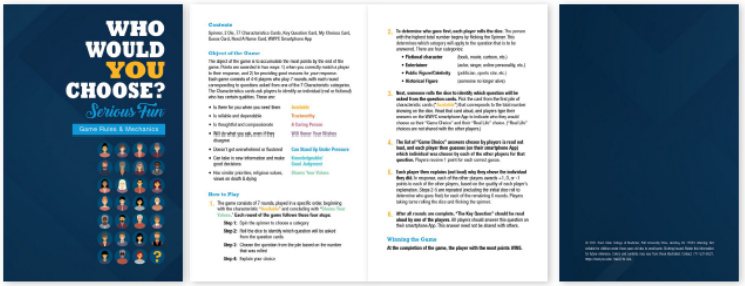
7.0 Study Design and Procedures

7.1 Study Design

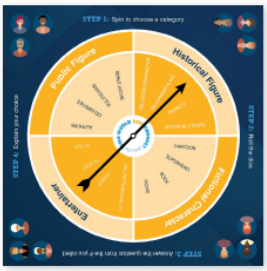
This study will use a convergent mixed methods design to: 1) explore how playing the serious game, "Who Would You Choose" (WWYC), affects individuals' choice of a spokesperson; 2) establish the feasibility of using WWYC for helping people designate an appropriate spokesperson for healthcare decisions and 3) receive a positive response from the spokesperson which will be confirmed with a completed REDCap survey. In each game event (lasting ~2 hours), research staff will help facilitate game-play for groups of 4 players, who will also 1) complete baseline questionnaires, 2) complete post-game questionnaires, and 3) participate in post-game focus group discussions. Then, players will use text messages initiated by the associated WWYC smartphone App to engage their chosen spokespersons by sending a text message inviting them to complete a brief REDCap survey asking what medical preferences they think the player would want in various clinical scenarios. If this spokesperson does not respond or complete the survey within one week, the player may forward the same test message with REDCap survey link to an alternate spokesperson. If the alternate spokesperson does not respond ro complete the survey, no additional spokespersons will be contacted. Approximately 2 weeks after the game event, players will be contacted by phone for a one-on-one interview.

Game piece examples:

Box Cover – 9" x 9"

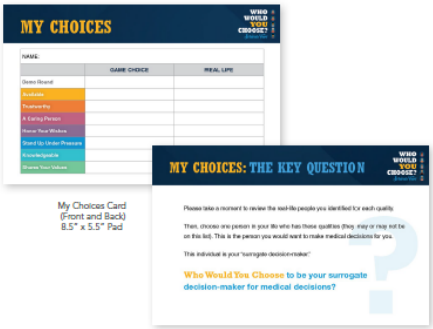


Instructions Booklet – 5.5" x 8.5" 4 page



Game Spinner – 8" x 8"

Key Question Card
(Front and Back)
8.5" x 5.5"



My Choices Card
(Front and Back)
8.5" x 5.5" Pad

Characteristics Cards
(2 decked)
3.5" x 2.5" (x11 each)


1 Min Timer

Need A Name Card – 8.5" x 5.5"

Guess Card – 8.5" x 5.5" Pad

7.2 Study Procedures

Prior to Game Play:

- After eliciting informed consent, participants will be asked to complete the following :

- Demographics (i.e. age, race/ethnicity, religiosity, education, gender, experience with surrogate medical decision-making, experience playing games, attitudes about ACP)
- Stage of Readiness to engage in ACP
- Choosing a Spokesperson (pre-activity)
- Install WYYC game app onto their personal smart phone

Game Play:
WWYC is played with 4 - 6 individuals via a smart phone app with card game components. Players 1) enter answers to game questions, 2) guess which player entered each answer (with points awarded for correct guesses), and 3) explain why they answered the way they did. The other players then decide whether a given player's explanation is good (merits an extra point), OK (no extra point), or poor (merits taking away a point). In addition to the "game choice," players also enter a "real-life choice" for each question –which is not shared, but will help them with the game's final question.

Across the 7 rounds, the game questions are intentionally unrelated to medical care so as to create a playful environment that still encourages players to reflect on spokesperson qualities. Game-play concludes after 7 rounds are completed (<1 hour), and a "winner" is identified by having the highest number of points earned. Then, one player reads instructions allowed to direct each player to choose a spokesperson (see Box 2).

> Box 2. Now that you have played "Who Would You Choose," there is one final question to answer. This question is just for you, and you don't need to share your answer with the other players.
> Please reflect on the choices you made, and what this says about your priorities and values when it comes to making medical decisions. Now, imagine being in a situation where you were unable to make medical decisions for yourself, and someone else needed to make them for you. What kind of person would you want to take on that role as your surrogate decision-maker (also known as a spokesperson)? To start, it should be someone who knows you well. But experts agree that this person should have other characteristics as well –specifically, those described on the question cards. So, ideally, this person would be available when needed, and would be someone you trust, is caring, would honor your wishes, can stand up under pressure, has good judgment, and shares your values. Please review the list of characteristics and your responses. When you are ready, write down the name of the person in your life who best embodies these qualities and who you would want to make medical decisions for you should the need arise. This individual is called your "surrogate decision-maker" and acts as your spokesperson.

There are 7 rounds to the game, corresponding to 7 qualities that a good spokesperson (or surrogate medical decision maker) should possess. These qualities were identified from a review of the literature and our pilot work (see Preliminary Data). For each round/quality, there are 11 question cards, and a roll of the dice determines which question is to be answered for that round. The player who rolled the dice also flicks a spinner to narrow game-choices to 1 of 4 general categories (Public figure, Fictional character, Entertainer, or Historical figure). After the question is read aloud each player enters a game-choice (which gets shared), as well as a "real-life choice" (which does not get shared). If players need help coming up with a game-choice, they may choose from the "Need-a-Name" options. In this version of WWYC, both answers and guesses will be recorded using a smart-phone App, but in our test version (see Preliminary Data) players wrote responses manually.

The WWYC smart-phone App will supplement the cards, dice, and spinner to provide a secure dynamic database for up to 6 players at a time. Once the game question for a given round has been selected, and each player has typed a response using their smart-phone, the App will display all responses, and allow players to guess which player gave which response. The App will keep track of players' scores (reflecting the number of correct guesses), as well as point totals. Because the App is also intended to promote engagement with spokespersons, the App will allow players to invite their spokesperson to participate. Through the App, participants will share a link with their spokesperson via text message.

Research staff coordinating the game event will visually confirm participants have forwarded this survey to their potential spokesperson. By clicking the link, the spokesperson will view the Summary Explanation of Research, confirm willingness to participate, and provide basic demographic information through REDCap. Should this spokesperson not respond after seven days, the player may forward the survey invitation link to an alternative spokesperson. Should the alternate not respond, no additional invitations will be sent. Upon leaving the event, participants will be given a formal healthcare power of attorney form to complete. Additionally, ~2 weeks after the event, the research team will contact participants by phone to conduct follow-up interviews.

Post-Game Outcomes Measured:

- Experience/process of game-play (i.e., one-on-one interviews, focus groups)
- Net Promoter Score
- Stage of Readiness to Choose a Spokesperson
- Choosing a Spokesperson
- Spokespersons' Engagement with Online Interface
- Player Evaluation

7.2 Duration of Participation

Players:

- Up to 2 hours. Anticipated time allotment is as follows:
- 5-10 minutes Informed Consent
- 5-10 minutes Explanation of game
- 45-60 minutes Game
- 30-40 minutes Feedback from participants
- 20-30 minute follow-up phone interview

Spokespersons (Surrogates):

- 15-20 minutes to read and complete online survey

8 Subject Numbers and Statistical Plan

8.2 Number of Subjects

Up to 800 participants (400 players and 400 spokespersons, with each game consisting of 4 players each)

8.3 Sample size determination

Using purposive sampling, aim to recruit 50% female and >25% ethnic/racial minority participants. As a feasibility study, the main objective is to establish viability of the intervention rather than efficacy. Thus a power analysis is not necessary. The sample size reflects the number of participants we expect to be able to recruit in this time period to obtain the information necessary to answer study questions.

8.4 Statistical methods

Quantitative data will be analyzed by first summarizing all variables with frequencies and percentages, or means, standard deviations, medians, and quartiles. The primary outcome variables will then be defined based on criteria stated above and summarized with frequencies and percentages to determine

if they reach the needed feasibility levels. As a feasibility study, we are not performing statistical testing or seeking significance as a primary goal. All analyses will be performed using SAS version 9.4

Qualitative data will undergo conventional content analysis to identify emergent themes–with focus groups and 1:1 interviews analyzed separately. All inter-disciplinary team members will review 20% of transcripts independently to create broad categories. Categories and subcategories will then be organized into a preliminary codebook, and exemplars selected to further define the codes –which will then be used to code an additional 20% of transcripts using the constant comparison method. **Biological variables** including age and gender will be assigned as attributes to examine effects on participant experiences. Inter-rater reliability will be judged using a kappa >0.7; discrepancies will be managed by group discussion to arrive at consensus codebook for coding the entire dataset (2 coders per transcript). Experienced qualitative researchers (Van Scoy, Badzek) will oversee analyses; coders will be trained by experienced members of the Penn State Qualitative Mixed Methods Core. Published criteria for **methodological rigor of qualitative research** will be used to attend to the truth-value, applicability, consistency, and neutrality of findings. To evaluate credibility (i.e., truth-value) of findings, a sub-set of participants will be asked to review a summary of data to ensure accuracy (member checking). To bolster applicability of findings to other contexts, rich/thick descriptions from interviews will be obtained to assess and compare experiences. Consistency and dependability of data will be maintained by inter-rater reliability analyses using intra-class correlation coefficients. Researchers will bracket biases and create an audit trail of coding decisions to maximize data neutrality.

9 Data and Safety Monitoring Plan

9.2 Periodic evaluation of data

All game events will be monitored for the possibility of adverse reactions to the game experience (the only study intervention).

9.3 Data that are reviewed

Adverse reactions (e.g. emotional distress) experienced by player participants.

9.4 Method of collection of safety information

Direct observation

9.5 Frequency of data collection

Every game event

9.6 Individuals reviewing the data

PIs and data safety monitor (Dr. Volpe)

9.7 Frequency of review of cumulative data

Quarterly

9.8 Statistical tests

Not applicable.

9.9 Suspension of research

In the unlikely event that the game intervention routinely provokes emotional distress, the game will be stopped pending reassessment by the study PIs and data safety monitor (Dr. Volpe).

10 Risks

This is a minimal risk study. It is possible that some individuals may experience emotional distress, however we suspect that individuals with a negative predisposition toward difficult conversations about surrogate decision-making will self-select to not participate in this research.

11 Potential Benefits to Subjects and Others

11.2 Potential Benefits to Subjects

Participation in this study has the potential to give people new insights into the process of surrogate decision making.

11.3 Potential Benefits to Others

Data from this research will help our research team improve the game, "Who Would You Choose: Serious Fun (WWYC)," and thereby provide a stronger foundation for subsequent research on the game's efficacy for helping people choose better surrogate decisions-makers (spokespersons) for medical care.

12 Sharing Results with Subjects

Not applicable.

13 Subject Payment and/or Travel Reimbursements

Player participants will be offered a $50 gift card in appreciation of their participation. Spokesperson participants will not be offered any reimbursement due to the very limited nature of their participation. The Controller's office has provided this study an exemption from using the Greenphire system. (Exemption letter can be found in Local Site Documents.)

14 Economic Burden to Subjects

14.2 Costs

Not applicable.

14.3 Compensation for research-related injury

Not applicable.

15 Resources Available

15.2 Facilities and locations

Study activities will take place at Penn State Milton S. Hershey Medical Center and at public locations in the community.

15.3 Feasibility of recruiting the required number of subjects

To maximize recruitment, study inclusion criteria are broad, and study activities will require minimal burden. We anticipate being able to recruit enough participants to meet project needs.

15.4 PI Time devoted to conducting the research

The PI (BH Levi) and Co-PI (MJ Green) will oversee all aspects of the study –including design, implementation, and analysis.

15.5 Availability of medical or psychological resources

In the event that a participant experiences psychological distress from study activities, study team personnel will work with the participant to address the distress. If further assistance is needed, we will contact David Simmons, director of pastoral services to assist.

15.6 Process for informing Study Team

The research team will meet weekly throughout the study period to ensure protocols are followed.

16 Other Approvals

16.2 Other Approvals from External Entities

Not applicable.

16.3 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – **Penn State** Health **only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of "HRP-902 - Human Tissue For Research Form" in CATS IRB.

☐ Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – **Penn State Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use. Upload a copy of "HRP-901 - Human Body Fluids for Research Form" in CATS IRB.

☐ Clinical Research Center (CRC) Advisory Committee – **All campuses** – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – **Penn State Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of "HRP-903 - Radiation Review Form" in CATS IRB.

☐ IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

17 Multi-Site Study

If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and the Penn State PI is the lead investigator, describe the processes to ensure communication among sites in the sections below.

[Do not type here]

17.2 Other sites

Not applicable.

17.3 Communication Plans

Not applicable.

17.4 Data Submission and Security Plan

Not applicable.

17.5 Subject Enrollment

Not applicable.

17.6 Reporting of Adverse Events and New Information

Not applicable.

17.7 Audit and Monitoring Plans

Not applicable.

18 Adverse Event Reporting

18.2 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

19 Study Monitoring, Auditing and Inspecting

19.2 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

20 Future Undetermined Research: Data and Specimen Banking

20.2 Data and/or specimens being stored

Not applicable.

20.3 Location of storage

Not applicable.

20.4 Duration of storage

Not applicable.

20.5 Access to data and/or specimens

Not applicable.

20.6 Procedures to release data or specimens

Not applicable.

20.7 Process for returning results

Not applicable.

21 References

Not applicable.

22 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598 Research Data Plan Review Form." In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

See HRP-598 Research Data Plan Review Form.