Biomedical and Scientific Research Ethics Committee (BSREC):

Application Form for Research Ethical Approval

Date: 28-Aug-2020	**Version:** 1.1

SECTION 1. APPLICANT DETAILS

1.1 APPLICANT

Applicant's Title (optional): Dr
Applicant's Forename: Kelly
Applicant's Surname: Schmidtke
School or Department: Medical School
Warwick e-mail address: Kelly.A.Schmidtke@warwick.ac.uk
Contact telephone number: 07758933026

Applicant's Status:

STUDENT:		STAFF:	
Undergraduate Student	☐	**Professor**	☐
Taught Postgraduate Student	☐	**Associate Professor**	☐
Postgraduate Research Student	☐	**Assistant Professor**	☒
		Research Fellow	☐
Name of course/qualification:		**Teaching Fellow**	☐
		Other	☐
		Please specify:	

1.2 SUPERVISOR (COMPLETE FOR ALL STUDENT PROJECTS)

Supervisor's Title:
Supervisor's Forename:
Supervisor's Surname:
Supervisor's Post:
Supervisor's Faculty/School and Department:
Supervisor's Warwick e-mail address:
Clinical Supervisors must provide a Warwick email address
Supervisor's contact telephone number:

1.3 OTHER INVESTIGATORS/COLLABORATORS (INTERNAL & EXTERNAL)

Please list all other known collaborators, internal and external to Warwick, including the name of the company/organisation or Investigator's Warwick department/school and their role in the project:
Laura Kudrna - Research Fellow - University of Birmingham. Conceptualization and write up.

1.4 REFERRALS

Has the Project been referred to BSREC from another REC or delegated process?	Yes ☐ No ☒
If yes, please provide the reason:	☐

Referred by HSSREC as project involves the NHS	☐
Referred by department as not within the remit for delegated approval	☐
Other Please provide details:	

SECTION 2. PROJECT DETAILS	
2.1 Project Title:	Influenza 2020/2021
2.2 Estimated start date:	15/09/2020
2.3 Estimated completion date of project:	01/09/2021
2.4 Does the project involve the NHS or social care:	Yes: ☐ No: ☒
2.5 Type of Project: https://warwick.ac.uk/services/ris/research_integrity/researchethicscommittees/biomed/study_design/ Research ☒ NHS Service evaluation or Development ☐ NHS Clinical Audit ☐ Other- please specify:	
2.6 Research Sponsor: If **not** research in the NHS, please state N/A	N/A
2.7 Funder: If unfunded, please state N/A	N/A
2.8 IDEATE/Funder reference (if applicable) If your study is funded, please provide a reference	N/A
2.9 Links with other BSREC applications Is the project linked to any other BSREC application? **If yes:** Project title: Chief Investigator: BSREC Reference (if known): Nature of linkage:	Yes: ☐ No: ☒

SECTION 3: BACKGROUND/LAY SUMMARY

Please provide a lay summary of the project:

The summary should be easily understood by someone who is not an expert in the area. Definitions and explanation of terms should be provided (avoid technical language).

To include:

- *context for the proposed study*
- *a brief literature review supported by appropriate references*
- *a description of the proposed study and population to be studied building on review of previous studies/evidence*
- *the scientific benefit of the proposed study*

As part of the fight against COVID-19, the UK government has announced its most comprehensive flu campaign to date (https://www.gov.uk/government/news/most-comprehensive-flu-programme-in-uk-history-will-be-rolled-out-this-winter). This should not be surpising, as every year NHS hospitals experience an overwhelming number of influenza cases, and COVID-19 increases this concern. As in previous years, the flu vaccine is free at the point of care for people 65 and over. New this year is that later in the season the vaccine will be made available free at the point of care for people 50 and over. However, if people refuse to take the vaccine this comprehensive program cannot benefit public health.

While access to vaccines remains a barrier to eradicating vaccine preventable disease in lower income countries, in higher income countries like the UK vaccine hesitancy stands in the way. In 2019, the World Health Organisation (WHO) listed increasing vaccine hesitancy as one of the ten biggest threats to global health. Recent outbreaks of vaccine preventable diseases, like measles and pertussis, are alarming. (Hotez, 2019). Over half of UK residents express vaccine hesitant attitudes (Luyten J, 2019), and a substantial proportion, 16%, already say they would refuse a COVID-19 vaccine. (https://www.theguardian.com/media/2020/jul/07/almost-one-in-six-britons-say-would-refuse-covid-19-vaccine; also see this report where only 53% of people are certain or very certain they would take up a COVID-19 vaccination when one becomes available: https://www.kcl.ac.uk/news/whos-most-likely-to-refuse-a-covid-19-vaccine).

The degree to which hesitancy is expressed varies across characteristics of the vaccine considered and the time and place it is offered, and across characteristics of the person including their perceptions of complacency, convenience, confidence, calculations, and communal responsibility, i.e. the “5Cs” (Betsch et al 2018). Information campaigns can be used to influence all the 5Cs, and public facing information is often a necessary component of public health campaigns that may also include structural components, i.e. complex interventions (Craig et al 2008). Largely, information campaigns can be viewed as a type of educational intervention.

Educational interventions typically assume that information drives attitudes and behaviour change. Therefore introducing new information (facts and figures) about vaccines effectiveness should alter people’s willingness to take them up. However, it is unlikely that vaccine hesitant people will stumble upon pro-vaccine educational information themselves, as people seek information that will largely confirm their already deep-seated beliefs: intuitions come first, strategic reasoning comes second (Haidt, 2012; Meppelink et al. 2019). Where external agents deliver educational interventions directly to people (e.g. doctors during a consultations), education remains largely ineffective. For example, one study found that providing parents with information negating the existence of risk posed by vaccinations increased their risk perceptions (Betsch et al 2013).

At least in part, educational interventions fall short of what is needed to alter people’s intentions because they focus on people’s system 1 rational thinking processes and neglect their system 2 automatic thinking processes, as described by dual process theories (Stanovich et al 2000). To become more effective, public health messages must be tailored to align with the “beliefs, attitudes, and motivations” of the very people they intend to influence (Dredze et al 2013).

Rossen et al (2016) point out that fact-led educational interventions to increase parents' intentions to vaccinate their children are particularly ineffective where more subtle content opposes the recipient's deep-seated values (also see Amin et al 2017 and Hornsey et al 2018). In a different context, recycling behaviour, Kidwell et al (2013) demonstrated that messages aligned with people's deep-seated values (i.e. the moral foundations that underlie political ideologies) are more likely to promote desired behavioural intentions than unaligned messages.

The present research also expands the scope of previous research in two ways. First, rather than investigating parental attitudes towards vaccination, we will look at people's intentions to self-vaccinate. Second, using Kidwell's et al (2013) methods (an anonymous online survey, study 1) as a guide, we will explore the effectiveness of messages aligned (or unaligned) with the moral foundations that underlie individual's political ideologies on their intentions to be vaccinated.

We intend for this project to act as a small pilot study for a larger study that may be rolled out in 2021-2022 season. However, note that our intended sample size (200 people) exceeds that used in Kidwell's study (82 in Study 1), because some people may have already vaccinated by the time this study is approved to conduct. If we find encouraging results in this pilot study, in our future study our sample size will be informed by the effect size we find in this study, and those participants will be stratified to match the most recent UK census, e.g. for gender, region and socio-economic status.

References:

Amin AB, Bednarczyk RA, Ray CE, et al. Association of moral values with vaccine hesitancy. Nat Hum Behav. 2017;1(12):873-880.

Betsch C, Schmid P, Heinemeier D, Korn L, Holtmann C, Böhm R. Beyond confidence: Development of a measure assessing the 5C psychological antecedents of vaccination. PLoS One. 2018 doi: 10.1371/journal.pone.0208601

Betsch C, Sachse K. Debunking vaccination myths: Strong risk negations can increase perceived vaccination risks. Health Psychology. 2013;32:146-55.

Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M; Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.

Dredze M, Broniatowski DA, Smith MC, Hilyard KM. Understanding Vaccine Refusal: Why We Need Social Media Now. Am J Prev Med. 2016;50(4):550-2.

Haidt, J. (2012). The righteous mind: Why good people are divided by politics and religion. New York: Pantheon Books.

Hornsey MJ, Harris EA, Fielding KS. The psychological roots of anti-vaccination attitudes: A 24-nation investigation. Health Psychol. 2018;37(4):307-15.

Hotez, P. America and Europe's new normal: the return of vaccine-preventable diseases. Pediatr Res 85, 912-4 (2019).

Kidwell B, Farmer A, Hardesty DM. Getting liberals and conservatives to go green: political ideology and congruent appeals. Journal of Consumer Research, 2013;40(2):350-67.

Luyten J, Bruyneel L, van Hoek AJ. Assessing vaccine hesitancy in the UK population using a generalized vaccine hesitancy survey instrument. Vaccine. 2019;37(18):2494-501.

Meppelink CS, Smit EG, Fransen ML, Diviani N. I was right about vaccination: confirmation bias and health literacy in online health information seeking. J Health Commun. 2019;24(2):129-40.

Rossen IL, Hurlstone MH, Lawrence CM. Going with the grain of cognition: applying insights from psychology to build support for childhood vaccination Front. Psychol. 2016; 7:1483

Stanovich KE, West RF. Individual difference in reasoning: implications for the rationality debate? Behavioral and Brain Sciences. 2000;23(5):645-726.

SECTION 4 RISK ASSESSMENT AND ETHICAL CONSIDERATIONS CHECKLIST

Complete the checklist ticking '<u>Yes</u>' or '<u>No</u>' to all questions.

Where you have ticked '<u>Yes</u>' to a question below, you will need to specifically address the ethical issues raised by that point and detail what safeguards will be put in place to minimise the potential risks/harm in the relevant section of the application form or in the space provided.

		Yes	No
A	**Does the study involve participants who are <u>particularly vulnerable</u> or <u>unable to give informed consent</u> or in a <u>dependent position</u> (e.g. children, your own students, over-researched groups, people with learning difficulties, people with <u>mental health problems</u>, <u>young offenders</u>, people in <u>care facilities</u>, <u>prisoners</u>)?** ***(If yes, please provide details in section 7 – Informed Consent)***	☐	☒

B	**Will participants be taking part in the study without their consent or knowledge at the time, or will deception of any sort be involved (e.g. covert observation of people in non-public places)?** ***(If yes, please provide details in section 7 – Informed Consent)***	☐	☒
C	**Is there a risk that the highly sensitive nature of the subject might lead to disclosures from the participant concerning their involvement in illegal activities or other activities that represent a threat to themselves or others (e.g. sexual activity, drug use, or professional misconduct)?** If yes, please provide details:	☐	☒
D	Could the study induce **psychological distress or anxiety**, or produce **humiliation**, or **cause harm**, or lead to **negative consequences** beyond the risks encountered in normal life? • *Applicable to studies involving sensitive topics, vulnerable participants as well as studies involving driving experiments, simulators, computational or physiological experiments. For the latter, please detail potential risks associated with any equipment and how these will be monitored and addressed in the space below.* • *Please also consider the risk to individuals if any personally identifiable data collected as part of the study is accidently disclosed. Please see guidance note for more information.* If yes, please provide details: The survey contains statements about political positions that participants may disagree with and experience strong feelings from considering. Including these statements is important to capture participants' political orientations the day they take the survey. In addition, the survey also contains statements about intentions to practice different health behaviours: receiving an influenza vaccination, receiving a future COVID-19 vaccination and wearing a mask. For each statement participants are explicitly asked to express how much they agree or disagree on a 7-point scale. We want participants to (1) be able to freely choose whether to engage with the questions, (2) know that these questions are being asked for the purpose of research and that we are not advertising a particular view, and (3) feel comfortable expressing agreements and disagreements. In the information sheet we now state the survey topics precisely to facilitate a more informed choice about whether to take part: "If you choose to take part, the survey may take 8 minutes to complete. In it, you will be asked to answer questions about your health behaviours (taking up vaccines and wearing a mask) and background characteristics (including your political views, age and gender). You will be given some information about being vaccinated for influenza. We plan to recruit 200 participants. There are no major foreseen personal risks or benefits, although some questions on politics or health may inspire strong feelings." We also emphasise that these are research questions that they can disagree with: "The views expressed in the survey are not the views of the researchers or the University, but are here to allow participants like you to express their own views. You may not agree with some of the statements and are free to express disagreements." If participants to not want to answer questions about politics, they can withdraw from the survey by closing their browser window with no consequence. This is also stated in the information sheet: "Can I withdraw? While taking the survey, you can withdraw at any time, and for	☒	☐

	any reason, simply by closing your browser." Lastly, to take part in the survey participants will have to respond "YES" to a consent item that reads: "I recognise that the views expressed in the survey are not the views of the researchers or the University, but are here to allow participants to express their own views, and that I am free to express disagreements." This additional step helps to ensure that participants are actively engaging with this information.		
E	Does the study involve **substantial physical exertion**? If yes, please provide details:	☐	☒
F	Does the study involve the **administration** of any substance? If yes, please provide details:	☐	☒
G	Does the study involve **physically intrusive procedures**, use of **bodily materials** or **human tissue**, or **DNA/RNA analysis**? • *Approval from the University's GMBSC (Genetic Modification and Biosafety Committee) is required before collection or use of any of these materials within the United Kingdom.* • *For studies overseas, please consult the GMBSC to confirm that the require risk assessments are completed.* If yes, please provide details: Click here to enter text.	☐	☒
H	Is any **reward**, apart from travelling and other expenses, to be given to participants? If yes, please provide details and justification for this, to ensure this is appropriate, and **not** seen as a bribe or to coerce participants into taking part:	☐	☒
I	Could the proposal give rise to researchers having any **conflicts of interest**? ***https://warwick.ac.uk/services/finance/resources/regulations/fp1*** • *Consider relationships/previous personal interactions with participating organisations, participants etc.* If yes, please provide details including how this will be managed:	☐	☒
J	Will any part of the project be undertaken overseas? If yes, please state which Country/Countries, the locations at which the project will be undertaken, e.g. public place, school, company, hospital, University, researcher's office, including the services of an overseas cloud hosting provider for storage or a market research company etc. and the local permissions in place for this (where required): Please see University Guidance for data processing overseas: ***https://warwick.ac.uk/services/idc/dataprotection/internationaldatatransfers/***	☐	☒
K	Will the researchers go to any areas where their **safety may be compromised**? If yes, please provide details, including what measures will be put in place to minimise risks and ensure the researcher's safety. A risk assessment should be submitted with the application:	☐	☒
L	Will **pregnant women** be participants in the study? • *Please note, while you may not purposefully be recruiting pregnant women to the study, consider if any special measures would need to be put into place or if it is appropriate for these individuals to take part, e.g. safety risks* If yes, please provide details:	☐	☒
M	**Will the study involve children <u>under 5 years</u> old?**	☐	☒

	If yes, please provide details:		
N	**Is the research commissioned by the <u>military</u>?*** **If yes, please provide details:**	☐	☒
O	Is the research commissioned under an **EU security call**?* If yes, please provide details:	☐	☒
P	Does the research involve the acquisition of **security clearances?*** If yes, please provide details:	☐	☒
Q	Does the research concern **terrorist or extreme groups**?* If yes, please provide details:	☐	☒
R	Does the research involve an **intervention**? • *An "intervention" here is understood as a systematic controlled change of participant conditions, which could be psychological or physical. It can include but is not limited to changes in diet, activity, access to information, or use of certain products.* If yes, please provide details: It is an online survey in which participants will be randomly allocated to one of two groups. Each group will read a different appeal to take up the influenza vaccination.		
S	Does the study involve any additional ethical considerations or risks to participants or the researcher that are not listed above? If yes, please provide details:	☐	☒

** Please refer to the University webpages on Prevent Duty*

SECTION 5: STUDY DESIGN, METHODOLOGY & ANALYSIS

5.1 Clearly state the research aim(s) of the project:

To include:

- *a clear explanation and justification for the research question(s)/aim(s)*

To explore whether a message aligned with the moral foundations that underlie a person's political ideology increase their willingness to take up the seasonal influenza vaccination.

5.2 What are the objective(s) for the project:

- *Objectives are intermediate steps that will help you to meet your research aim(s)*

The main objective is to compare how people with different political ideologies respond to an appeal to take up the seasonal influenza vaccination, when the appeal content is aligned (or unaligned) with the moral foundations underlying those political ideologies.

We also plan to describe the characteristics of people who have and have not already taken up the vaccination (e.g. age), and their intentions to take up related health behaviours: receiving a future COVID-19 vaccination and wearing a mask.

5.3 Study design and data collection methods:

To include:

- *a clear description of the study design and data collection methods*
- *a suitable design should reflect the aim(s) of the study*
- *This may include ethnography/observations, interviews, focus groups, questionnaires, document analysis etc.*
  - ***Ethnography/Observations**- what/who will be observed, by whom, for how long? What equipment (if any) will be used for recording etc.?*
  - ***Interviews**- who is conducting the interviews, how, where and when- by telephone/in person/skype; will they be recorded- how? How long will they last? How will the interview guide be developed? etc.*
  - ***Focus groups**- who is leading, how will they be organised, when and where will they take place, how will they be recorded? How long will they last? etc.*
  - ***Questionnaires**- who has designed the questionnaire, who will distribute it, how long will it take to complete etc.*

- ***Document analysis****- what documents will be requested, where from, by whom, what permissions are in place for this etc.*
- ***Experimental*** *– what tests/lab work will be undertaken on participants, by whom, is specialist training required before undertaking?*
- ***Secondary analysis of previously collected data****- analysis of data that has been previously collected by a third party for research or other purposes, that is not publicly available e.g. healthcare, student, financial records. Please state whether the data set is identifiable or anonymised.*

This is an observational study with a randomized sub-component for participants who have not already received the seasonal influenza vaccination this season.

The study will be conducted as an online, anonymous questionnaire.

The questionnaire has been designed by the current research team using a university approved Qualtrics account.

According to Qualtrics estimates, it may take participants 8 minutes to complete. The survey is designed to be anonymous, e.g. no IP information will be collected. There are places for participants to write free-text responses, and any identifiable information entered in free-text boxes will be redacted from our data-files, as described in section 8.10. A PDF copy of the full survey (information/consent sheet and all questions) is attached as a supporting document. The anonymous link to the survey is provided here: http://warwick.co1.qualtrics.com/jfe/form/SV_cUXTQ1rMOWJFq7j. Any responses recorded before the survey is disseminated (e.g. from reviewers of this ethics application) will not be analysed and will be deleted before the planned participant recruitment commences.

Each part of the survey is described below.

**Receiving informed consent: Participants will read an information sheet and give their informed consent to take part in the study. The information sheet will include statements that "The views expressed in the survey are not the views of the researchers or the University, but are here to allow participants to express their own views. You may not agree with some of the statements and are free to express disagreements." Only participants who indicate meeting all the eligibility criteria and who consent to the survey will be allowed to advance.

**Demographics: Participants will be asked their age in years (options: 50 to 99+ and prefer not to say), resident region of England (9 ONS regions: https://www.ons.gov.uk/geography/regions), gender identity (male, female, non-binary, other, and prefer not to say) and ethnicity (5 UK groups, and prefer not to say: https://www.ethnicity-facts-figures.service.gov.uk/style-guide/ethnic-groups).

**Political ideology: Before completing a 10-item conservativism scale used in a similar study investigating the effect of messages on behaviour (Day et al 2014), participants will be reminded that "We are interested in your opinions on a variety of issues. The views expressed here are not the views of the researchers or the University, but are here to allow participants to express their own views. You are free to express agreements and disagreements. We appreciate your honest responses.". The questionnaire includes two questions related to each of the five issues: one worded in conservative terms (e.g. The economic market will naturally correct itself), while the other liberal terms (e.g. The government must regulate the economy). Participants will be asked how much they disagree or agree with each statement on a seven point scale from 'strongly disagree' to 'strongly agree'. Then they will be asked to self-report their political orientation measured using a seven point scale, from very liberal to very conservative; this question will act as a face-validity check that should highly correlate with the conservativism scale.

Day MV, Fiske ST, Downing EL, Trail TE. Shifting liberal and conservative attitudes using moral foundations theory. Personality and Social Psychology Bulletin, 2014;40:1559-73. https://doi.org/10.1177/0146167214551152.

**Vaccination against influenza in 20/21 season: Next participants will be asked whether they received an influenza vaccination in the 20/21 season already (Yes or No).

--Participants who say "yes", will then be asked approximately when they received the vaccination (DD/MM/YYYY), where they received the vaccination (GP, pharmacy, other) and if they went with anyone to get their vaccination (no, a friend, a family member, or someone else). Lastly, they will be asked to describe why they took up the vaccination this year in a free-text box.

--Participants who say "no", will then be randomly allocated to view one of two appeals to take up the influenza vaccination. As in Kidwell et al.'s (2013) study, one appeal aligns with a conservative ideology and the other aligns with a liberal ideology. After reading these appeals, participants will be asked about their agreement with several statements on a seven point scale; these statements are manipulation checks to verify that the appeals evoke the immediately intended foundations. Then participants will be asked whether they intend to take up the influenza vaccination this seasons on a seven point scale, from 'strongly disagree' to 'strongly agree', and then be asked to explain their answer in a free-text box.

Kidwell B, Farmer A, Hardesty DM. Getting liberals and conservatives to go green: political ideology and congruent appeals. Journal of Consumer Research, 2013;40(2):350-67.

**Spill-over behaviours: Next all participants (those who vaccinated already and those who did not) will be asked about their intentions to take up a future COVID-19 vaccination when one becomes available, and their intentions to wear a face mask in a store that does not require face masks using the same seven point scale, from 'strongly disagree' to 'strongly agree'.

**Closing: Participants who have not already vaccinated will see debriefing information that reminds them that the study should not be construed as medical advice, and that they should speak to a medical professional if they are uncertain if they should take up the influenza vaccine. Hyperlinks are provided for participants to learn more about the study this study is based on and to learn more about the UK's influenza vaccinations policies this year. We also provide them with the opportunity to tell us anything else they think is relevant to the survey in a free-text box, or write "I prefer not to say". We have found this free-text box to be useful in previous surveys to source alternative explanations for our findings.

5.4 Data Analysis

To include:

- *Specifically what data sets will be collected (name, date of birth, email address, ethnicity, health status, financial records, IP address etc.)*
- *whether this data will be collected directly from participants (e.g. via questionnaires/interviews) or indirectly, from a third party (previously collected data set) and how i.e. web form, online application, paper form*
- *Detail the analysis methods that will be undertaken e.g. content analysis, framework analysis, interpretative phenomenological analysis etc. and any statistical analyses.*
- *Describe how and by whom any data will be transcribed, coded, de-identified, stored, transferred, accessed, archived*
- *Any software used in the analysis should be specified and detailed how it will be used in the project*

The data will be collected directly from participant responses to the anonymous survey described above. No IP addresses will be collected. The data will be downloaded from Qualtrics into an SPSS file that is then stored in password protected files on the University of Warwick's servers.

The data will be analysed by Kelly Ann Schmidtke using SPSS. All of this software is provided by the University of Warwick.

As a reminder this is a pilot study and our analyses are designed to inform a future study, for which we will seek future ethical approval early in 2021.

The primary analysis will only include those participants who have not yet vaccinated. The primary analysis will be a multiple regression. Participants average political ideology scores to the conservatism scale will be mean-centred. Then Political ideology (continuous variable), Appeal type (nominal variable) and the interaction between Political ideology and Appeal type will be used to predict vaccination intentions (continuous variable). We anticipate finding an interaction effect (alpha < .05).

Two check analyses will be performed. The first check is a face-validity check of the conservativism scale; this analysis will look at the correlation between participants' average political ideology scores to the 10-items and their self-reported political ideology. We expect to find a significantly positive correlation. The second check of the appeals; this analysis will look at how participants responded to the manipulation check items. We expect to find that participants who viewed the conservative appeal to have higher responses to an average of the two conservative checks than participants who viewed the liberal appeal, and vice versa.

The exploratory analysis will describe the proportion of participants that have already vaccinated, and the political ideologies, age, gender, ethnicity and current resident region of England for all participants.

For the participants who have already vaccinated, we will chart how many vaccinated on each week, up to the week the survey is disseminated. We will also describe the proportion who take up the vaccination at different locations, and the proportion who did so with a friend or family member. The reasons participants give for vaccinating will be thematically analysed. Lastly, we will describe the proportion of these participants who express some intention to engage in the spill-over behaviours: taking up the COVID-19 vaccination when it becomes available and wearing a face-mask in a store that does not require it.

For the participants who have not already vaccinated, we will assess whether the participants' demographic characteristics are similar across the randomly allocated groups using t-tests (for age) and chi-square tests (for categorical variables). Then, for each group we will describe the proportion who express some intention to be vaccinated, not to be vaccinated, and who neither agree nor disagree with the intention item. The reasons participants give for their responses will be thematically analysed. Lastly, we will describe the proportion of participants who express some intention to engage in the spill-over behaviours: taking up the COVID-19 vaccination when one becomes available and wearing a face-mask in a store that does not require it.

SECTION 6: RECRUITMENT

6.1 State the total number of planned participants and the sampling strategy; provide justification for this:

To include:

- *The rationale behind the proposed size of the sample*
- *Will the sample size provide enough data to answer the research question?*
- *If sampling will be continued until saturation is reached, then this should be stated and linked to the research question*
- *Sampling strategy- is this random, snowball, purposive, convenience etc.*
- *What is the rationale for this- it should reflect the methodological framework for the study*

The proposed sample size is 200.

Rationale/Sufficient size: This is a pilot study. The sample size is informed by a previous study (Kidwell et al 2014, Study 1) where 82 participants took part. We are recruiting more participants for two reasons. First, we anticipate some (maybe up to 50%) of our participants will have already taken up the vaccine by the time this survey is approved to conduct. Therefore the number of participants available for our primary analysis described in section 5 may only be 100. Second, 100 is still more than Kidwell's study 1, and this may will allow us to detect smaller differences between groups. If the results of this pilot study support a full study, we will seek ethical approval for that full study and include in our application a sample size calculation informed by the effect size found in this study.

Rationale/Strategy: The sampling strategy is a sample of convenience of Prolific Academic UK panellists. Recruitment will be stratified using the Prolific's "Political Party Affiliation UK" pre-screening question, such that 100 opportunities to take part will be made available to panellists who identify with the Labour party and the remaining 100 opportunities to panellists who identify with the Conservative party.

To be clear, participants will not be asked what party they affiliate with in our survey, rather participants have already indicated which party they affiliate with in their Prolific Academic profile.

Prolific panellists have consented to their pre-screening responses being used in this manner. This recruitment stratification will maximize the opportunity to have a balanced set of responses across political orientations for our primary analysis described in section 5. It is important to ensure that participants represent two major political parties, because we hypothesize that differences in political orientation will affect responses to health promotion appeals. We recognize that participants' political orientation can change over time, and appreciate that the participants who choose to take part may not amount to a perfect 50:50 split. Nevertheless, we will have a balance of participants who, at one time, identified with either the Conservative or Labour party.

6.2 Where applicable, state the breakdown of participants by type and number of each type of participant, e.g. children (include age), parents, teachers, health care professionals etc.:

Type of Participant:	**Number:**
Identify as being affilitated with the Labour Party	100
Identify as being affilitated with the Conservative Party	100

6.3 Please provide clear inclusion criteria:

- Residence in England
- Age 50+ years old, inclusive

The age criteria is set at 50+ years old, because this is the age group currently being advised by Public Health England to seek the flu jab as soon as possible this season. (https://www.gov.uk/government/news/most-comprehensive-flu-programme-in-uk-history-will-be-rolled-out-this-winter).

6.4 Please provide clear exclusion criteria:

- Not a resident in England
- Age younger than 50 years old, exclusive

6.5 Please detail how participants will be recruited to the study:

To include:

- *How participants will be identified/screened and approached; by whom?*
- *Where participants will be recruited from and when?*
- *Detail the source of any personal information that may be used to identify participants. If this information will be accessed by someone outside the team who would have access to this information as part of their day to day role, the reason for this should be explained, and permissions detailed e.g. healthcare, student records etc.*
- *Will any vulnerable groups be recruited?*
- *What materials will be used to recruit participants- please provide copies of posters, leaflets, invitation emails, etc.*
- *Where will the above materials be advertised: list and provide details of locations, websites, social media etc.*
- *Will any recruitment tools be used e.g. SONA- please specify and provide details.*

How/Where/Source: The opportunity to participate in our study will be posted on Prolific Academic UK, an online survey platform commonly used to recruit participants to anonymous online surveys in the UK and that has been used by researchers at the University of Warwick already. For further information see: https://www.prolific.co/). The demographic characteristics will be set on Prolific such that the study is only available to people who have already confirmed they meet the age and resident criteria for participation.

Vulnerable Groups: No vulnerable groups will be recruited.

Advertising materials: The study description made available to participants on Prolific will read "This is a research study. If you choose to take part, you will be presented with information about influenza and asked to make choices. It may take you 8 minutes to complete. You will be compensated for your time with 1.00 GBP."

SECTION 7: INFORMED CONSENT

7.1 Please detail the process for obtaining informed consent.

*Informed consent **must** be obtained prior to the participant undergoing any research activities that are specifically for the purposes of the study. This should involve discussion with potential participants or their legally acceptable representative; the presentation of written materials e.g. participant information leaflet(s) –PIL(s) and consent form, and the opportunity to ask questions.*

To include:

- *How and when informed consent will be obtained- written, verbal etc. provide details and justification. Justification must also be provided if informed consent will **not** be sought or if consent will be assumed (please note this needs to be appropriate to the study type).*
- *Who will be taking consent? What training has been undertaken for this?*
- *When and how potential participants will be issued with the information leaflet, in what format and how long they will be given to consider taking part?*
- *Does the study involve children- if so, will consent be obtained from parents, if not provide clear justification why not.*
- *Are the informed consent materials appropriate for the target audience- consider age / language / literacy levels / cultures etc.*

As a reminder, this is an anonymous online study and an appropriate combined information / consent form has been created to contain all the recommended information. A copy of this information / consent form is available in Supporting Documents.

7.2 Please detail how participants withdraw from the study if they have requested to do so.

The process by which an individual can withdraw their participation from the study without giving a reason or experiencing any detrimental effects e.g. should they not wish to continue with their participation in an interview or focus group.

To include:

- *Consideration for any data already collected up until this point- whether it is possible for this to be removed. E.g. it may not be possible to identify data once submitted for an anonymous survey. This needs to be clear in the participant information leaflet (PIL).*
- *Researchers should specify up to what point participants can withdraw their data from a study and **how** a participant would request this- this also needs be clear in the participant information leaflet (PIL).*
- *Consideration should be given to when data will be anonymised, analysed, published etc. make sure it is possible/feasible for data to be withdrawn if this is being offered to participants. It may be appropriate to provide a time frame for withdrawal.*

While taking the survey, participants can withdraw by closing their browser window. Participants will not be able to withdraw from the study after they have submitted their data. If we enabled participants to email us to withdraw their data after the survey, even with a randomly generated code, then we would be collecting identifiable data: their email addresses. As the information gathered in this survey is not sensitive, this withdraw restriction should be acceptable. Further, participants will be made aware of this withdraw restriction in the information sheet.

SECTION 8: DATA COLLECTION, USE & STORAGE (DPA 2018 & GDPR)

For projects involving processing of personally identifiable data, please answer the questions below to map the data flow to indicate the data controllers and data processors. This can be submitted as a separate document if necessary, please see accompanying guidance note from the Information Data Compliance team.

8.1 Does the project involve the collection, analysis or storage of personally identifiable data?

Yes ☐ No ☒

'Personal data' is any information relating to an identified or identifiable natural person- a 'data subject'.

*An identifiable natural person is one who can be identified, directly **or** indirectly, in particular by reference to an identifier (such as a name, an identification number, location data, financial data, opinion, an online identifier), or to one or more factors specific to the physical, physiological, genetic, mental, socio- economic, cultural, race, religion, trade union membership, political beliefs, medical, gender or social identity of that natural person.*

If yes, please provide details of what will be collected: As described in section 8.10, the free-text spaces in our survey may allow participants to reveal unrequested idenfiiable information. If this happens, that information will be redacted from our data-files, as described in section 8.10.

8.2. Does the project involve the collection, analysis or storage of any personally identifiable, special category data or criminal offence data? Yes ☐ No ☒

Special category data includes personal data which is by its nature, particularly sensitive in relation to fundamental rights and freedoms of individuals such as: racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data (for the purpose of identifying a natural person), data concerning health or data concerning a natural person's sex life or sexual orientation. This type of data merits specific protection as the context of its processing. Failure to handle this data correctly could result in significant risks to the fundamental rights and freedoms of the individuals.

If yes, please provide details of what will be collected and for what purpose:

What measures are being implemented to reduce or eliminate the risk to these participants' data for the duration of the period that their personal data is collected and stored? Please see accompanying guidance note for more information.

8.3 Does the project involve the collection or analysis of personal data relating to children under 13 or vulnerable groups? **Yes ☐ No ☒**

UK law provides that for data protection purposes an individual aged under 13 years old is considered a child. For the purposes of the GDPR, a child is someone aged under 16 years old, although Member States are able to reduce this age. Please consider Member State law as Parental/Guardian consent will be required for a child participating in the research.

If yes, please provide details of what will be collected:

For what purpose do you need to process the children's or vulnerable person's data?

What measures are being implemented to reduce or eliminate the risk to these participants' data for the duration of the period that their personal data is collected and stored?

8.4 Who will have access to the study data?

Include individuals internal and external to the University and what level of access they have to the data e.g. anonymised, pseudonymised, identifiable etc.

Please note you will need to hold a University approved data sharing/processing agreement with each third party (external to the University) with whom data is to be shared.

Only the researcher at the University of Warwick will have access to the anonymous data for analysis purposes.

8.5 During the project, will data be hosted on any external platforms or use new technology? Yes ☒ No ☐

e.g. Apps, online survey tools (qualtrics, Bristol online surveys etc.), recruitment tools (Prolific, SONA etc.), cloud hosting tools.

If yes, please provide details of the system(s) and how they operate: Qualtrics (an online survey platform) and Prolific Academic (an online participant recruitment tool). Both these systems are already used by researchers at the University of Warwick.

Have you contacted Information Security (informationsecurity@warwick.ac.uk) **regarding whether these technologies will be required to go through the Information Assurance workbook approval process?** https://warwick.ac.uk/services/idc/informationsecurity/faqs/purchasingissues/ **Yes ☒ No ☐**

How and when will the data be deleted and who by?

The data on Qualtrics will be deleted by the Kelly Schmidtke by 1 September 2021

8.6 Will any research activities be audio or video recorded? Yes ☐ No ☒

This needs to be clear in the participant information leaflet and consent form.

If yes, please provide details of what will be recorded, how long it will be kept, how it will be stored securely and how it will be deleted:

8.7 Will data be shared with any organisation external to the University for processing? Yes ☐ No ☒

e.g. external transcription services, external statistics support, archiving etc.

If yes, please provide details of the sharing arrangements: clarify whether the data shared will be identifiable, the external organisation to which it will be sent and what contracts/arrangements are in place to safeguard the data and ensure the data processors/controllers will comply with data protection requirements:

8.8 Please detail how, where, in what format and for how long the research data will be stored securely, including on back up storage.

e.g. hard/electronic copies, locked filing cabinets in researcher's office, encrypted files, password protected devices, Warwick servers. Please also consider consent forms here. These should be stored separately to research data.

The anonymous data will be stored in Qualtrics online until the date stated in 8.5, and in a password protected file on the University of Warwick's servers for a period of at least 10 years from the date of any publication which is based upon it.

8.9 For this project, will data be processed, (to include the collation, collecting, distributing, sharing, accessing, reviewing, amending, deletion) transferred or stored in any Countries outside UK?

Yes ☐ No ☒

e.g. the use of transcribing service outside the UK , market research company, cloud hosting provider

If yes, please provide details of the country/countries and the collection/transfer/storage arrangements:

8.10 Describe compliance and proportionality measures in place to satisfy the requirements of the Data Protection Act 2018 and the GDPR.

e.g. how will you ensure: fairness and transparency to research participants, data quality, data minimisation (only collect data which is necessary for the purpose(s) of the study), purpose limitation (no further processing of the data for purposes incompatible to those for which it was collected), de-identification of the data as soon as possible, appropriate technical and organisational measures in place to avoid unauthorised access and accidental loss or damage to data etc. Please see the accompanying guidance note from the Information Data Compliance Team to help answer this question.

No personally identifiable information will be requested in the survey.

There is the potential for participants to reveal their identity in the free-text responses requesting other information (e.g. "Why do you intend to receive the influenza vaccination this season (2020/21)?"). If this occurs, any identifiable information will be redated from the retained datafiles described in 8.8 using the symbols "**********" to depict where a redaction has occurred. For example, we would redact any names, identification numbers (e.g. telephone), location data, and an online identifier (email addresses, IP addressses).

8.11 Is it anticipated that there will be any future use of the data? Yes ☒ No ☐

If yes, please provide details (if known at this stage). This should be clear in the Participant Information Leaflet and on the consent form if there is potential for future use of this data:

The findings gathered from the data may be used to inform a future study.

SECTION 9: DISSEMINATION

Please describe the dissemination arrangements for the study:

To include:

- *What will happen to the results at the end of the study?*
- *Will this study have any pathways to impact? ('Pathways to Impact' are activities designed to ensure any potential impact is realised, measured and evidenced.)*
- *How and where will the results be reported/published?*
- *Are there any plans to notify/debrief the participants of the outcome of the study, either by provision of the publication, or via a specifically designed newsletter, presentation etc.?*
- *If it is possible for the participant to specifically request results from the researcher when would this information be provided e.g. after the Final Study Report had been compiled or after the results had been published?*

We will publish the results of this study in a weblog such as the Applied Research Collaboration Newsletter and/or the London School of Economics Politics and Policy Blog. As no contact information will be taken from participants during the survey, it will not be possible to make them aware of the findings

SECTION 10: FURTHER INFORMATION (OPTIONAL)

Please provide any further details/information relevant to this application that may aid the ethical review process.

To include:

- *For complex studies with multiple work packages, collaborators or steering groups, applicants may wish to submit a protocol or supplementary documents in addition to this application form detailing the roles and responsibilities of each party.*
- *Projects that require further approvals e.g. HRA approval for research in the NHS may also wish to submit a protocol for review.*
- *Peer review*
- *Patient and public involvement*
- *Flow diagram*
- *Data management plan*

N/A

SECTION 11: SUPPORTING DOCUMENTS

BSREC will need to review **all** participant facing documents associated with this application.

There may be more than one type of each document for each study, i.e. multiple participant information leaflets if there are different participant groups, or work packages.

Please specify below, which documents have been submitted with this application (where applicable):

☒ Participant information leaflet(s)
☒ Consent form(s)
☐ Poster(s)/advertisement(s)
☐ Invitation email(s)
☒ Questionnaire(s)/Survey question(s)
☐ Interview schedule(s)/topic guide(s)
☐ Data Collection form
☐ Data flow map
☐ Data Management Plan
☐ Risk assessment
☐ Protocol (optional- needs to be consistent with the application)
☐ Other, please specify:

SECTION 12. SIGNATURES AND DECLARATIONS

12.1 RESEARCHER/APPLICANT

The information in this form together with any accompanying information is complete and correct to the best of my knowledge and belief and I take full responsibility for it.

I undertake to abide by the University of Warwick's Research Code of Practice in undertaking this study.

I understand that BSREC grants ethical approval for projects, and that the seeking and obtaining of all other necessary approvals and permissions prior to starting the project is my responsibility.

I confirm I am familiar with and will conduct my project in line with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 2018), reporting any data breaches to the University's Information and Data Director: DPO@warwick.ac.uk.

I understand that I must not begin research and related projects with human participants, their data or tissue until I have received full approval from the relevant Research Ethics Committee of the University of Warwick.

I understand that any changes that I would like to make to this study after receiving approval from BSREC, including changes to the research team or study end date must follow BSREC procedures as detailed on the BSREC web pages.

Name of Researcher: Kelly Ann Schmidtke

Signature: Kelly Ann Schmidtke
Date: 28/08/20

Send a signed copy of the form to bsrec@warwick.ac.uk, along with copies of **all** study documentation, including questionnaires, interviews schedules/topic guides, posters/leaflets, invitation emails etc.

12.2 SUPERVISOR SECTION

I confirm that I have read this application and will be acting as the student researcher's supervisor for this project.

The proposal is viable and the student has the appropriate skills to undertake the research. Participant recruitment procedures, including the Information Leaflet(s) to be provided and the process for obtaining informed consent, are appropriate, and the ethical issues arising from the project have been addressed in the protocol.

I have reviewed any questionnaires, interview schedules/topic guides where relevant, and these are appropriate for the project.

I understand that BSREC grants ethical approval for projects, and that the seeking and obtaining of all other necessary approvals and permissions prior to starting the project is the responsibility of the student.

I confirm I am familiar with and will ensure the student will conduct the project in line with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 2018) reporting any data breaches to the University's Information and Data Director: DPO@warwick.ac.uk.

I understand that research and related projects with human participants, their data or tissue must not commence without full approval from the relevant research ethics committee of the University of Warwick.

Name of Supervisor:

Signature:
Date:

NB: An e-mail from the Academic Supervisor that states the above, in lieu of a signature on this form, may be sent to: bsrec@warwick.ac.uk

If you have not already done so, you are strongly recommended to undertake the Research Integrity Online Training Course. All details relating to this course can be found here.